NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

March 2-3, 2022

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

Please do not remove the book from the meeting room.

Nevada State Board of Pharmacy

985 DAMONTE RANCH PARKWAY • SUITE 206 • RENO, NEVADA 89521
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Date Posted: February 8, 2022

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday March 2, 2022, at 9:00 am. The meeting will continue, Thursday, March 3, 2022, 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 at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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 of 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 person. Public comment may also be submitted to the Board at pharmacy@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 January 12,13, 2022, 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. Bioness Inc. – Valencia, CA
   B. CPAP.com – Stafford, TX
   C. DRUGSOURCE, INC. – Elk Grove Village, IL
   D. Lantz Medical, Inc. – Indianapolis, IN

   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))

   E. American Regent, Inc. – New Albany, OH
   F. Cypress, Hawthorn and Macoven – Brentwood, TN
   G. Grove Pharmaceuticals – Miami, FL
   H. North American Rescue, LLC – Greer, SC
   I. Noven Pharmaceuticals, Inc. – Miami, FL
   J. Padagis US LLC – Minneapolis, MN
   K. RVL Pharmaceuticals, Inc. – Bridgewater, NJ
   L. Waylis Therapeutics LLC – Wixom, MI
   M. Xeris Pharmaceuticals, Inc. – Chicago, IL

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

   N. Agile Therapeutics, Inc. – Princeton, NJ

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

O. BioCareSD – Tempe, AZ
P. Health Coalition, Inc. – Doral, FL
Q. Padagis South Carolina LLC – Duncan, SC
R. UPS Supply Chain Solutions, Inc. – Fairdale, KY

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

S. AmerisourceBergen Drug Corporation – Whitestown, IN
T. Den-Mat Holdings, LLC – Lompoc, CA
U. Millstone Medical Outsourcing, LLC – Olive Branch, MS

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

V. DENTSPLY North America LLC – Lancaster, PA

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

4.2.7 Background checks completed in compliance with NRS 639.500. No Disqualifying Events.

W. Cardio Partners, Inc. – Woodruff, WI
X. DHL Supply Chain (USA) – Knoxville, TN
Y. My Medical Supply – Little Rock, AR
Z. Optum Wholesale, Inc. – Covina, CA
AA. SpecialtyCare, Inc. – Nashville, TN

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

BB. Omnia Pharmacy Inc. – Las Vegas, NV
CC. Save Mart Pharmacy #551 – Carson City, NV
DD. Save Mart Pharmacy #552 – Carson City, NV
EE. Save Mart Pharmacy #553 – Reno, NV
FF. Save Mart Pharmacy #554 – Reno, NV
GG. Save Mart Pharmacy #555 – Reno, NV
HH. Save Mart Pharmacy #556 – Reno, NV
II. Save Mart Pharmacy #559 – Reno, NV

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

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

JJ. Allergy Partners Therapeutics – Asheville, NC

KK. Apex Specialty Pharmacy – Riverside, MO
LL. Avel eCare Pharmacy – San Antonio, TX
MM. CTCA/Rx – Newnan, GA
NN. Healthcare Pharmacy LLC – Phoenix, AZ
OO. HomeCare Rx, Inc. – Fairfield, NJ
PP. InfuCare Rx of LA – Kenner, LA
QQ. InfuCare Rx of MD –Cumberland, MD
RR. IV Solutions Rx – Tampa, FL
SS. MedWiseRx – Austin, TX
TT. Optime Care Inc. – Earth City, MO
UU. Premise Health Wellness Center - Brentwood, TN
VV. Simple Meds, LLC – Indianapolis, IN

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

4.7 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Non-appearance (**FOR POSSIBLE ACTION**)

◈ REGULAR AGENDA ◈

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

A.	Kinex Medical Company, LLC	(21-039-MP-S)
B.	Darrel Foth, RPH	(21-186-RPH-N)
C.	Sircy M. Moore, DVM	(21-111-CS-S)
D.	Lesli Ann Hewitt-Spears, DVM	(21-112-CS-N)
E.	Paul H. Howse, RPH	(20-135-RPH-S
F.	Justine Stanevich	(20-135-PT-S)
G.	Order to Show Cause: Richard Washinsky, MD	(19-232-CS-S)
H.	William Bannen, MD	(21-213-CS-S)
I.	Marcia Clevesy, APRN	(21-214-CS-S)
J.	Mahendra DeFonseka, MD	(21-215-CS-S)
K.	George Dockendorf, DO	(21-216-CS-S)
L.	William Torch, MD	(21-227-CS-N)
M.	Lydia O'Connor-Sanders, DO	(21-225-CS-S)
N.	Jose Dastas, RPH	(18-130-RPH-S)
O.	Vertisis Custom Pharmacy, LLC	(18-130-PH-S)

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

A.	Sandra Bledsoe, D/B/A VIP Faces	(21-042-S)
B.	Sandra Bledsoe, D/B/A Revenge MD	(21-042-B-S/21-042-C-S)

7. Petition for Reinstatement of Controlled Substance Registration and Dispensing Practitioner Registration pursuant to NRS 639.257 – Appearance. **(FOR POSSIBLE ACTION)**

   Dhaval Shah

8. Applications for Advance Practice Registered Nurse – Prescribe Registration (NAC 639.850) – Appearance. (**FOR POSSIBLE ACTION)**

   Blake Kigerl

9. Application for Pharmacist Registration Renewal (NRS 639.127) – Appearance. (**FOR POSSIBLE ACTION)**

   Darrel Foth

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

    Brandy Baker

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

    Kurt Howe

12. Application for Veterinarian Authority to Dispense Drugs (NAC 639.7423) – Appearance **(FOR POSSIBLE ACTION)**

    Sircy Moore

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

    A. Northmark Pharmacy – Cincinnati, OH
    B. Sofie Co – Gilroy, CA

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

    A. Abbott Laboratories, Inc. – Irving, TX - Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) -
    B. Abbott Laboratories Inc. - Irving, TX - Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) -
    C. Abbott Laboratories Inc. – North Chicago, IL - Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) -

D. Abbott Laboratories Inc. – Plano, TX - Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) -
E. Abbott Laboratories Inc. – Roseville, MN - Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) -
F. Abbott Laboratories Inc. – Sylmar, CA – Background Check Not Required - Publicly Traded (NAC 639.593(7)(a)) –
G. Abbott Laboratories Inc. – Temecula, CA
H. Abbott Molecular Inc. – Elk Grove Village, IL - Background Check Not Required - Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
I. Abbott Molecular Inc. – Des Plaines, IL - Background Check Not Required - Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
J. Abbott Rapid Dx North America, LLC – Freehold, NJ – Background Check Not Required - Publicly Traded (NAC 639.593(7)(a))
K. Abbott Rapid Dx North America, LLC – San Diego, CA – Background Check Not Required - Publicly Traded (NAC 639.593(7)(a))
L. Alere San Diego Inc. – Pomona, CA – Background Check Not Required - Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
M. Allergan USA, Inc. – Madison, NJ – Background Check Not Required - Publicly Traded (NAC 639.593(7)(a))

15. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

    Greenbay Specialty Pharmacy – Las Vegas, NV – Background Check completed in compliance with NRS 639.500 - No Disqualifying Events – No Disclosures

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

    A. Eagle, Inc. – Hoover, AL
    B. Empower Pharmacy – Houston, TX

17. Application for Ambulatory Surgery Center License. – Appearance. **(FOR POSSIBLE ACTION)**

    A. Centennial Specialty Surgery Center – Las Vegas, NV
    B. Mountain West Surgical Center – Reno, NV

18. Discussion and Possible Action on Adoption of Emergency Regulation pursuant to NRS 233B.0613 to authorize pharmacists and other healthcare professionals to dispense oral medications for the treatment of COVID-19 subject to certain conditions. **(FOR POSSIBLE ACTION)**

19. 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).

20. 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

◈ PUBLIC HEARING ◈

Thursday March 3, 2022 – 9:00 am

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

A. **Amendment of Nevada Administrative Code (NAC) 639.208.** The proposed amendment to NAC 639.208 will amend the requirements necessary for an applicant to obtain a registration as a pharmacist by reciprocity. (LCB File R040-21)

B. **Amendment of Nevada Administrative Code (NAC) Chapter 639** authorizing the Board to require certain euthanasia technicians to register with the Board; increasing certain fees; revising requirements for certain applications; requiring an applicant for registration as a pharmacist, pharmaceutical technician, or pharmaceutical technician in training to undergo a criminal background check; revising requirements for an outsourcing facility engaged in the compounding of sterile drugs. (LCB File R025-21)

C. **Amendment Of Nevada Administrative Code (NAC) 639.220, 639.715, 639.718 and 639 .720**: Use of automated drug dispensing system or mechanical device to dispense prescription drugs. (LCB File R013-21)

D. **Amendment to Nevada Administrative Code (NAC 639.)** The proposed amendments will create a new section to implement the provisions of Senate Bill 325 requiring the Board to adopt regulations that establish requirements to allow a pharmacist to dispense drugs approved by the United State Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. (LCB File R039-21)

22. Date and Location of Next Scheduled Board Meeting:

April 13-14, 2022 – 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.

No Continuing Education credit will be given for attending this Board meeting.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

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MINUTES

January 12-13, 2022

BOARD MEETING

Pursuant to Governor Steve Sisolak's Emergency Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

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	Jade Jacobo	Krystal Freitas	Gener Tejero
Wayne Mitchell	Rolf Zakariassen	Richard Tomasso	

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Peter Keegan	Darlene Nases	Joe Dodge
Courtney Lee	Leo Basch	Ken Scheuber	Luis Curras
Dena McClish	Sarah Bradley	Rosalie Bordelove	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 January 12 2022, 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 December 1-2, 2021, Meeting Minutes (**FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the December 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. Americare Respiratory Services, Inc. – Irvine, CA
B. Expedite LLC – Lithia Springs, GA
C. Pumps It, Inc. – Houston, TX
D. The Home DME Company – Southfield, MI

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))

E. Alydia Health, Inc. – Menlo Park, CA
F. Aucta Pharmaceuticals, Inc. – Piscataway, NJ
G. Avet Pharmaceuticals Inc. – East Brunswick, NJ

H. Dukal, LLC – Ronkonkoma, NY
I. Dutch Ophthalmic, USA, Inc. – Exeter, NH
J. Greenstone LLC – Peapack, NJ
K. Next Science – Jacksonville, FL
L. PharmaEssentia USA Corporation – Burlington, MA
M. University of Iowa Pharmaceuticals – Iowa City, IA
N. USAntibiotics, LLC - TN

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

O. Haemonetics Corporation – Clinton, PA

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

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

P. LifeScience Logistics, LLC – Brownsburg, IN
Q. LifeScience Logistics, LLC – Whitestown, IN

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

R. Adagio Therapeutics, Inc. – Waltham, MA
S. Albireo Pharma, Inc. – Boston, MA
T. Ortho Clinical Diagnostics, Inc. – Memphis, TN
U. Sanofi US Corporation – Bridgewater, NJ
V. SCYNEXIS, Inc. – Jersey City, NJ
W. Spero Therapeutics, Inc. – Cambridge, MA

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

X. HP Inc. – San Diego, CA

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

Y. Jubilant Radiopharma – Memphis, TN
Z. RxSave – Whitehall, PA
AA. Teleflex LLC – Olive Branch, MS
BB. Teleflex LLC – Plymouth, MN

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

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

CC. FH2 Pharma L.L.C – Las Vegas, NV

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

DD. Omnia Pharmacy Inc. – Las Vegas, NV
EE. QHR Pharmacy 3 – Las Vegas, NV

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

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

FF. AcariaHealth Pharmacy #26, Inc. – Tampa, FL
GG. Allergy Partners Therapeutics – Asheville, NC
HH. ARJ Infusion Services, LLC – Lenexa, KS
II. ARJ Infusion Services, LLC – Omaha, NE
JJ. Biologics by McKesson – Fort Worth, TX
KK. Birdi – Novi, MI
LL. CanyonCARE Rx – Tempe, AZ
MM. Heritage Biologics LLC – Lee's Summit, MO
NN. K Pharmacy, LLC – Armonk, NY
OO. Lemonaid Pharmacy – St. Louis, MO

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

PP. Golden Gate Veterinary Compounding Pharmacy, LLC
QQ. Progress Pharmacy – West Palm Beach, FL
RR. ReCept Pharmacy #1 – Fort Worth, TX
SS. Summit Pharmacy, Inc. – Phoenix, AZ

4.8 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Non-appearance (**FOR POSSIBLE ACTION**)

TT. Dia-Foot – Las Vegas, NV

Board discussion ensued.

Rolf Zakariassen disclosed that he has a business relationship with the Managing Pharmacist Edward Tambi for item 4EE but stated that he could participate in this matter fairly and without bias.

Rolf Zakariassen questioned the ownership for item 4GG as the ownership change will allow a practitioner to own the company entirely which is not allowed by Nevada law.

Board staff commented that the law may be specific to practitioners licensed in Nevada, but they requested to remove item so it can be investigated further.

President Park removed item 4DD and 4GG as the Board has questions regarding the applications.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda excluding agenda items 4DD and 4GG.

Second: Rolf Zakariassen

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

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

A. Nevada Health Rx, Inc. dba Prax-Rx (18-043-PH-S)
B. Scot Silber, RPH (18-043-RPH-S)

No representative was present on behalf of Prax-Rx and Scot Silber.

Sarah Bradley, Legal Counsel for the Nevada Board of Medical Examiners, served as legal counsel to the Board.

Courtney Lee, Nevada Board of Pharmacy General Counsel, noted that failure of a party to appear upon sufficient legal notice allows the Board to proceed to consider and dispose of the case without the parties. NRS 622A.350. Ms. Lee stated that no answer was filed by either Respondent which constitutes a waiver of right to a hearing. NRS 639.244. Ms. Lee prosecuted the case against Prax-Rx and Scot Silber regarding unlawful dispensing and prescribing of dangerous drugs and controlled substances, failure to report loss of drugs, and wholesaling and dispensing without a license.

Ms. Lee called Shirley Hunting as a witness.

Shirley Hunting, Board Coordinator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee questioned Ms. Hunting on the details of her serving the Notice of Intended Action and Accusation.

Ms. Lee requested that the proof of service for the Notice of Intended Action and Accusation be admitted as Exhibit 1.

President Park admitted Exhibit 1.

Ms. Lee called Kristopher Mangosing as a witness.

Kristopher Mangosing, Assistant Board Coordinator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee questioned Mr. Mangosing on the details of the 21-day notices served upon Respondents.

Ms. Lee requested that the proof of service of all 21-day notices be collectively admitted as Exhibit 2.

Ms. Lee requested that the Board move to make jurisdiction consistent with paragraph 1 of the Notice of Intended Action and Accusation.

Board Action:

Motion: Jade Jacobo moved to make jurisdiction consistent with paragraph 1 of the Notice of Intended Action and Accusation as proposed by Ms. Lee.

Second: Krystal Freitas

Action: Passed unanimously.

Ms. Lee requested the Board to make the Findings of Fact consistent with paragraphs 2-20 of the Noticed of Intended Action and Accusation.

Board Action:

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs 2-20 of the Notice of Intended Action and Accusation as proposed by Ms. Lee.

Second: Krystal Freitas

Action: Passed unanimously.

Ms. Lee requested the Board to make the Conclusions of Law consistent with paragraphs 21-37 of the Noticed of Intended Action and Accusation.

Board Action:

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 21-37 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Ms. Lee requested President Park admit the attorney's fees and investigative costs as Exhibit 3.

President Park admitted into the record the attorney's fees and costs as Exhibit 3.

Ms. Lee requested that the Board find the attorney's fees and costs of $2,380.77 were reasonable, necessary and actually incurred.

Board Action:

Motion: Wayne Mitchell moved to award the attorney's fees and costs of a $2,380.77 on the basis that they were reasonable, necessary and actually incurred.

Second: Rolf Zakariassen

Action: Passed unanimously.

Ms. Lee recommended the proposed discipline for Prax-Rx. The conditions/penalties include the following: 1) a fine of $10,000 within 30 days of the Order; 2) pay $1,785.77 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days of the Order; 3) license was not renewed and DEA registration was surrendered; if Prax-Rx seeks to obtain another license, Prax will be required to appear before the Board for approval; and 4) discipline will be reportable to the National Practitioner Data Bank.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the proposed discipline as presented by Ms. Lee.

Second: Wayne Mitchell

Action: Passed unanimously.

Ms. Lee recommended the proposed discipline for Scot Silber. The conditions/penalties include the following: 1) a fine of $5,000 within 30 days of the Order; 2) pay $595 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days of the Order; 3) discipline will be reportable to the National Practitioner Data Bank; and 4) Mr. Silber voluntarily surrendered his pharmacist

registration; Silber may not re-apply for reinstatement for a minimum of two years and must appear before the Board for approval.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the proposed discipline as presented by Ms. Lee.

Second: Rolf Zakariassen

Action: Passed unanimously.

C. Stephen Dubin, MD (20-020-CS-S)

This matter was continued to a future Board Meeting.

D. James Forsythe, MD, HMD (19-114-CS-N)

Marie Mirch appeared as counsel on behalf of James Forsythe.

James Forsythe was present for the hearing.

James Forsythe, Manon Singer (Infusion Nurse), and Valerie Kilgore (Office Manager) appeared and were sworn in by President Park.

President Park stated that Respondent filed a motion to dismiss the amended accusation or alternatively for a more definite statement, and the State filed an opposition to the motion.

President Park ruled to deny the motion to dismiss and proceed with the hearing.

Brett Kandt made an opening statement on the charges that Dr. Forsythe's practice had expired drugs and a "veterinary use only" drug in its inventory.

Mr. Kandt called Joseph Depczynski, retired Nevada State Board of Pharmacy Investigator, as a witness.

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

Mr. Kandt examined Mr. Depczynski on his investigation and upon foundation testimony from the witness requested that the following exhibits be entered into evidence: 1) documents bate-stamped 001-007 as Exhibit 1; 2) documents bate-stamped 008-009 as Exhibit 2; 3) documents bate-stamped as 0010-0011 as Exhibit 3; 4) documents bate-stamped as 0012 as

Exhibit 4; 5) documents bate-stamped 0015-0016 as Exhibit 5; 6) documents bate-stamped as 0017-0018 as Exhibit 6; 7) documents bate-stamped 0019 as Exhibit 7.

Ms. Mirch objected to the exhibits for pages 002-003, 005-007, 008-009, 0015-0016, 0017-0018. President Park overruled the objections and admitted Exhibits 1-7 into evidence.

Rosalie Bordelove, Chief Deputy Attorney General, appeared as Board counsel for this hearing, and Sarah Bradley was excused from the meeting at 10:30 AM.

Ms. Mirch cross-examined Mr. Depczynski, and the Board questioned Mr. Depczynski.

Ms. Mirch called Manon Singer, Dr. Forsythe's Infusion Nurse, as a witness.

Ms. Mirch examined Ms. Singer on her position and the events that occurred with the Board's investigation. Mr. Kandt cross-examined Ms. Singer, and the Board questioned Ms. Singer.

Ms. Mirch called Valerie Kilgore, Dr. Forsythe's Office Manager, as a witness.

Ms. Mirch examined Ms. Kilgore on her position and the events that occurred with the Board's investigation.

Ms. Mirch requested that a proposed exhibit labeled Forsythe Exhibit 12 be entered into evidence as Exhibit 12.

Mr. Kandt objected that there was no foundation for admission of the evidence. President Park overruled the objection and admitted Exhibit 12 into evidence after further foundation testimony by Ms. Kilgore.

Ms. Mirch requested that a proposed exhibit labeled Forsythe Exhibit 11 pages 1-2 be entered into evidence as Exhibit 11 after foundation testimony by Ms. Kilgore. Kandt had no objection and President Park admitted Exhibit 11 into evidence.

Ms. Mirch requested that a proposed Exhibit 8 be entered into evidence. Mr. Kandt objected that the evidence was not relevant or material and lacked any probative value. President Park sustained the objection and denied admission.

Mr. Kandt cross-examined Ms. Kilgore, and the Board questioned Ms. Kilgore.

Ms. Kilgore confirmed that the pictures taken were staged, and the cabinet in the picture was not the cabinet that held the expired dangerous drugs.

Ms. Mirch requested that the remainder of Forsythe Exhibit 11 pages 3-5 be entered into evidence after foundation testimony by Ms. Kilgore. Kandt had no objection and President Park admitted pages 3-5 of Forsythe Exhibit 11 into evidence.

Sophia Long, Senior Deputy Attorney General, appeared as Board counsel for this hearing, and Rosalie Bordelove was excused from the meeting at 1:30 PM.

Ms. Mirch called George Ransom as a witness.

George Ransom, Retired Certified Public Accountant, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Mirch questioned Mr. Ransom about Dr. Forsythe's inventory control system.

Mr. Kandt objected that Mr. Ransom's testimony on Dr. Forsythe's inventory control system subsequent to the investigation was not relevant or material and lacked any probative value.

President Park sustained the objection and there was no further testimony from Mr. Ransom.

Ms. Mirch called Amy Summers as a witness.

Amy Summers, Registered Pharmacist appeared and was sworn in by President Park prior to answering questions and offering testimony. Mr. Kandt stipulated that Ms. Summers qualified as an expert.

Ms. Mirch questioned Ms. Summers on her findings concerning Dr. Forsythe's practice.

Mr. Kandt objected that Ms. Summers testimony was not relevant or material and lacked any probative value as she was hired after the charges were filed against Dr. Forsythe.

President Park sustained the objection and advised Ms. Mirch to limit her questions to the timeframe in question.

The Board questioned Ms. Summers.

Ms. Mirch called Dr. James Forsythe as a witness.

Ms. Mirch examined Dr. Forsythe on his practice and the allegations against him. Mr. Kandt cross-examined Dr. Forsythe, and the Board questioned Dr. Forsythe.

Ms. Mirch and Mr. Kandt provided their closing arguments to the Board on this hearing.

Board discussion ensued.

Mr. Kandt requested that the Board make findings of fact consistent with paragraphs 1-5 of the First Amended Notice of Intended Action Accusation

<u>Board Action:</u>

Motion: Richard Tomasso moved to make findings of fact consistent with paragraphs 1-5 of the First Amended Notice of Intended Action and Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt requested that the Board make conclusions of law consistent with paragraphs 6-17 of the First Amended Notice of Intended Action and Accusation and find Dr. Forysthe guilty of all four causes of action.

Board Action:

Motion: Jade Jacobo moved to make conclusions of law consistent with paragraphs 6-17 of the First Amended Notice of Intended Action and Accusation and find Dr. Forsythe guilty of all four Causes of Action.

Second: Richard Tomasso

Action: Passed unanimously.

Gener Tejero joined the meeting by telephone at 4:36 PM.

Mr. Kandt provided documentation of attorney's fees and costs totaling $2,384.08 and requested that it be entered into evidence as Exhibit 9.

Ms. Mirch objected to any attorney's fees and costs prior to filing of the amended accusation.

Mr. Kandt responded that the attorney's fees and costs are very reasonable and do not account for his extra time worked on this case or Mr. Depczynski's time investigating the case.

President Park admitted the documentation of attorney's fees and costs into evidence as Exhibit 9.

Mr. Kandt requested that the Board find that the attorney's fees and costs of $2,384.08 were reasonable, necessary and actually incurred.

Board Action:

Motion: Jade Jacobo moved to award the attorney's fees and costs of $2,348.08 on the basis that they were reasonable, necessary and actually incurred.

Second: Wayne Mitchell

Action: Passed unanimously.

Mr. Kandt proposed the following penalties for Dr. Forsythe: 1) public reprimand; 2) respondent pay a $2,000 fine for each of the four causes of action within 30 days; 3) respondent pay $2,348.08 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days, order effective immediately.

Ms. Mirch requested that the Board take into consideration the costs that Dr. Forsythe incurred for expert witnesses and attorney's fees, and further argued that the fine recommended is excessive and opposed a public reprimand and reporting the discipline to the National Practitioner Data Bank.

Board discussion ensued regarding appropriate penalties.

Board Action:

Motion: Richard Tomasso moved to approve the following penalties for Dr. Forsythe: 1) public reprimand; 2) respondent pay a $5,000 fine for the four causes of action, for a total of $20,000, within 30 days; 3) respondent pay $2,348.08 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days; 4) board staff conduct an inspection of Dr. Forsythe's Office within 30 days; and 5) order effective immediately.

Second: Wayne Mitchell

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

Action: Motion carries.

E. Chad Hall, DO (21-108-CS-S)

This matter was continued to a future Board Meeting.

F. Ronald Smith, MD (20-212-CS-S)

This matter was continued to a future Board Meeting.

G. Kord T. Strebel, MD (19-053-CS-S)

This matter was continued to a future Board Meeting.

H. Thomas E. Strebel, RPH (19-053-RPH-S)

This matter was continued to a future Board Meeting.

I. Sircy M. Moore, DVM (21-111-CS-S)

This matter was continued to a future Board Meeting.

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

A. Sandra Bledsoe, D/B/A VIP Faces (21-042-S)

This matter was continued to a future Board Meeting.

B. Sandra Bledsoe, D/B/A Revenge MD (21-042-B-S/21-042-C-S)

This matter was continued to a future Board Meeting.

Public Comment January 12 2022, 5:00 PM

Jeffrey Setness wanted to discuss his scheduling for his agenda item.

John Hunt wanted to discuss his scheduling for his agenda item.

Board staff commented that they can contact Mr. Kandt to discuss the scheduling.

President Park recessed the meeting for the night and reconvened the meeting the next morning and performed the roll call. All Board members were present and a quorum was established.

Board Members Present:

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

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Peter Keegan	Darlene Nases	Joe Dodge
Courtney Lee	Leo Basch	Ken Scheuber	Luis Curras
Dena McClish	Christian Schonlau	Rosalie Bordelove	

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.

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 January 13 2022, 9:00 AM

Joseph Hardy, Nevada Senator, wants to make comments regarding Workshop Item 24B.

Board staff advised that his comments can be made when the item is addressed.

◈ WORKSHOP ◈

Thursday January 13, 2022 – 9:00 am

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

B. **Amendment to Nevada Administrative Code (NAC) 453B.** The proposed amendments conform the outdated language of NAC 453B to the changes made to NRS 453B in 2017 by Senate Bill 91. Specifically, the proposed changes to NRS 453B broaden the previously established Cancer Drug Donation Program to include prescription drugs generally. The proposed amendments also define "donated prescription drug" and establish requirements for a person or a pharmacy to participate in the Prescription Drug Donation Program.

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, provided background on the workshop item.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, provided the proposed language changes.

President Park opened public comment for this proposed regulation.

Joseph Hardy, Nevada Senator, commented that he worked with Board staff on the language and is in favor of the proposed regulation.

Samantha Chessie from Animal Policy Group questioned how this regulation may affect donated prescription drugs for veterinarian drugs.

Ms. Long provided clarification to Ms. Chessie as it will not affect veterinarian laws.

Liz McMenamin from the Retail Association of Nevada in favor of the proposed regulation. However, she is concerned about who the liability of the drugs falls on.

Mr. Hardy commented that this bill will protect everyone involved and will help others in need of medicine.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the proposed regulation for Amendment to Nevada Administrative Code (NAC) 453B and move to public hearing.

Second: Wayne Mitchell

Action: Passed unanimously.

A. **Amendment of Nevada Administrative Code (NAC) 453.510: Schedule I**. The proposed amendment to NAC 453.510 will add isotonitazene to the list of controlled substances listed in Schedule I.

Ms. Long provided background and the proposed language changes.

President Park opened public comment for this proposed regulation.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the proposed regulation for Amendment of Nevada Administrative Code (NAC) 453.510: Schedule I and moved to public hearing.

Second: Krystal Freitas

Action: Passed unanimously.

◈ PUBLIC HEARING ◈

Thursday January 13, 2022 – 9:00 am

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

A. **Amendment of Nevada Administrative Code (NAC 639).** The proposed amendments will add a new section to implement the provisions of Senate Bill 190, requiring the Board to adopt regulations that establish a protocol to allow a pharmacist to dispense a self-administered hormonal contraceptive to any patient. (LCB File R036-21)

Courtney Lee, Nevada Board of Pharmacy General Counsel, provided background on the proposed regulation.

President Park opened public comment for this public hearing item.

Ken Kunke from the Nevada Pharmacy Alliance commented that a registered pharmacist at doctor's office do not qualify for this regulation and would like this updated to have them included.

Lauren Paul from CVS Health commented her concerns and provided the following proposed changes: 1) requiring the pharmacy, and not the pharmacist, to report their intent to dispense self-administered hormonal contraceptives; 2) requiring pharmacist to complete one hour of continuing education, instead of two, in order to dispense self-administered hormonal contraceptives; 3) allowing a pharmacist to assess or evaluate a patient's blood pressure from the electronic health record or obtained the blood pressure by the pharmacist prior to dispensing self-administered hormonal contraceptives.

Adam Porath from Nevada Health System Pharmacists would like the language to include pharmacist who do not work in a dispensing role, but he is okay to address this issue later.

Liz McMenamin from the Retail Association of Nevada is in favor of the language and is okay to address the concerns later.

Board staff addressed comments and concerns of the public regarding the proposed regulation and the process of the language going to Legislative Counsel Bureau (LCB).

Adam Chesler from VillageMD requested the patient be provided with a list of providers that dispense self-administered hormonal contraceptives. In addition, he suggested that a process be in place to provide the records to the patient's primary care provider.

Ms. Long commented to the Board that a written statement from Krystal Riccio was provided for this public hearing item.

Krystal Riccio from Roseman University provided a written statement and asked the Board to consider allowing qualified pharmacists practicing outside of a licensed pharmacy to dispense or prescribe hormonal contraceptives.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt regulation for Amendment of Nevada Administrative Code (NAC 639) with amendments to modify CE requirement to one hour and to modify blood pressure language to evaluate as discussed.

Second: Krystal Freitas

Action: Passed unanimously.

B. **Amendment of Nevada Administrative Code (NAC) 639.501 Inspections; provision of self-assessment form**. The proposed amendment to NAC 639.501 will remove the requirement to complete an assessment of workplace and modifies the requirement of an annual inspection. (LCB File R165-20)

Mr. Wuest provided background on the proposed regulation.

President Park opened public comment for this public hearing item.

Liz McMenamin from Retail Association of Nevada is in support of the proposed language.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt proposed regulation for Amendment of Nevada Administrative Code (NAC) 639.501 Inspections; provision of self-assessment form.

Second: Wayne Mitchell

Action: Passed unanimously.

16. Applications for Out-of-State Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

A. Atrium Medical Corporation – Merrimack, NH – Background Check Not Required - Manufacturer (NAC 639.593(7)(d)) – Disclosure

Chad Carlton, President, and Brian Schaeffer, Quality Engineer, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan, Nevada Board of Pharmacy General Counsel, provided background on application and their disclosures regarding shipping products without proper licensure and being fined by the FDA for selling adulterated drugs.

The Board questioned Atrium about the last inspection results and what occurred with their disclosure regarding the FDA.

Mr. Carlton and Mr. Schaeffer answered questions to the Board's satisfaction

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve Out-of-State Wholesaler license for Atrium Medical Corporation pending staff's review of their 483 FDA Inspection and their corrective action plan.

Second: Jade Jacobo

Action: Passed unanimously.

B. Baxter Healthcare Corporation – Byhalia, MS – Background Check Not Required – VAWD-Accredited (NAC 639.593(7)(c)) – Disclosure

Lawrence Davis, Senior Quality Manager, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Katrina Reinhardt, Regulatory Deputy Counsel, appeared as counsel on behalf of Baxter Healthcare Corporation.

Mr. Wuest provided background on application and their disclosures regarding not correctly addressing mold at a manufacturing facility, improperly delegating final verification of prescriptions to a pharmacy technician, not notifying of a change in a timely manner, operating without a license, and selling prescriptions to an unpermitted location.

Ms. Reinhardt provided further clarification on disclosures to the Board.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve Out-of-State Wholesaler license for Baxter Medical Corporation.

Second: Rolf Zakariassen

Action: Passed unanimously.

C. Hilco Vision – Plainville, MA – Background Check completed in compliance with NRS 639.500 – No Disqualifying Events – Disclosure
D. Hilco Vision – Tucson, AZ – Background Check completed in compliance with NRS 639.500 – No Disqualifying Events – Disclosure

Rebecca Davis (Senior Regulatory Affairs) Jon Costa (Senior Operations Manager), Ken Miranda (Chief Operating Manager), Charles Hick (Distribution Manager) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background on application and disclosures regarding operating without the proper licensure and reciprocal action taken by another Board.

Ms. Lee questioned Hilco Vision on changes that occurred within the company to ensure that they remain compliant.

Mr. Costa and Mr. Miranda answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve the Out-of-State Wholesaler change on ownership (CHOW) application for Hilco Vision in Plainville, MA and Tucson, AZ.

Second: Jade Jacobo

Action: Passed unanimously.

13. Applications for Out-of-State Pharmacy License (NRS 639.2328) – Appearance (**FOR POSSIBLE ACTION**)

A. Amazon Pharmacy #005 - Kent, WA
B. Amazon Pharmacy #006 – Indianapolis, IN
C. Amazon Pharmacy #007 – Meridian, ID

Emily Haugh, Pharmacist and Government Affairs Manager, and Chris Rochon, Senior Compliance Manager, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan requested a Letter of Authorization from Ms. Haugh and Mr. Rochon to allow them to speak on behalf of the company.

Mr. Keegan provided background on the application and their disclosures regarding operating without the proper licensure.

The Board questioned Amazon Pharmacy on what changes have occurred to ensure that they are compliant.

Ms. Haugh and Mr. Rochon answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Pharmacy license for Amazon Pharmacy #005, Amazon Pharmacy #006, and Amazon Pharmacy #007 pending Letter of Authorization.

Second: Jade Jacobo

Action: Passed unanimously.

D. DiRx – Sunrise, FL

Briana Moe, Pharmacist in Charge, appeared and was sworn in by President Park prior to answering questions and offering testimony.

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

Joe Dodge, Nevada Board of Pharmacy Inspector, provided background on the application and their disclosures regarding not being properly licensed, sending prescriptions to the incorrect primary care physician, and failure to disclose disciplinary action on an application,

Mr. Dodge questioned Ms. Moe about the business model, inspection results, and further clarification of what occurred with their disclosures.

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

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve change of ownership for Out-of-State Pharmacy license for DiRx.

Second: Rolf Zakariassen

Action: Passed unanimously.

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

A. Dynamic Rx Labs LLC – Renton, WA

James Axtell (Co-founder and Co-Owner), and Quan Pho (Part-Owner and Pharmacist), and Angelique Williams (Pharmacist in Charge) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Chris Dang appeared as counsel on behalf of Dynamic Rx Labs.

Mr. Dodge provided background on application, their inspection results, and their disclosure regarding pharmacy technicians in training's registrations lapsing.

Mr. Dodge questioned Dynamic Rx on the change of ownership, experience of the pharmacist in charge, their business model, and their disclosures.

Mr. Axtell, Mr. Dang, and Ms. Williams answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve change of ownership for Out-of-State Compounding Pharmacy license for Dyanmic Rx Labs.

Second: Wayne Mitchell

Action: Passed unanimously.

B. Soleo Health Inc. – Dublin, OH

Jason Doenges, Pharmacist in Charge, appeared and was sworn in by President Park prior to answering questions and offering testimony.

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

Mr. Dodge provided background on application and disclosures regarding disorderly conduct.

Mr. Dodge questioned about the business model, products, inspection results, and Mr. Doenges disclosure.

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

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Out-of-State Compounding Pharmacy License for Soleo Health Inc. pending Letter of Authorization.

Second: Gener Tejero

Action: Passed unanimously.

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

Eclipse Mobility, LLC – Bountiful, UT

Landon Cleverly, Operations Director, and Travis Carlson, Managing Member, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Ms. Long provided background on application and their disclosure regarding a family member possessing or using a controlled substance.

Ms. Long questioned on the business model, Mr. Cleverly's experience with the products, and further clarification on their disclosure.

Mr. Cleverly and Mr. Carlson answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve Out-of-State Medical, Devices, Equipment and Gases License for Eclipse Mobility, LLC.

Second: Jade Jacobo

Action: Passed unanimously.

7. Petition for Reinstatement of Unrestricted Controlled Substance Registration pursuant to NRS 639.257

Craig Weingrow (17-066-CS-S)

Jeffrey Setness appeared as counsel on behalf of Craig Weingrow.

Craig Weingrow appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Setness is petitioning for reinstatement for Dr. Weingrow's unrestricted controlled substance registration.

Mr. Kandt provided background on charges for Dr. Weingrow to Board.

The Board questioned Dr. Weigrow on his probation status and his business model.

Dr. Weingrow answered questions to the Board's satisfaction.

Board discussion ensued.

Mr. Setness commented that Dr. Weingrow plans to prescribe only the drugs listed on his original Board Order. The only reason that he is applying for an unrestricted license is for insurance purposes.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to fully reinstate Dr. Craig Weingrow's Controlled Substance registration with conditions that he submits self-reports quarterly of every prescribed controlled substance prescription for five years from the date of Order.

Second: Jade Jacobo

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

Action: Motion carries.

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

A. Canyonlands Healthcare – Mesquite, NV

Andrew Lewandowski, Pharmacy Director, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background on application.

Mr. Dodge questioned on the business model and Mr. Lewandowski's experience, and future for the pharmacy.

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

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Nevada Pharmacy License for Canyonlands Healthcare pending favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

B. Complete Care Pharmacy – Las Vegas, NV

This matter was continued to a future Board Meeting.

17. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

A. Compass Health Brands Corp. – Reno, NV – Background Check completed in compliance with NRS 639.500 - No Disqualifying Events – No Disclosures

Jason Derbyshire, Facility Manager for Reno, and Anthony Shaw, Vice President of Quality, Regulatory, and Customer Service, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan provided background on application.

The Board questioned Mr. Derbyshire and Mr. Shaw on the business model, the products being shipped into Nevada, and Mr. Derbyshire's experience.

Mr. Shaw and Mr. Derbyshire answered questions to Board's satisfaction.

The Board staff requested an updated Designated Representative application to accurately reflect his experience with pharmacies or wholesalers.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Nevada Wholesaler License for Compass Health Brands Corp. pending updated Designated Representative application.

Second: Gener Tejero

Action: Passed unanimously.

B. J.W. Welding Supplies and Tools – Fallon, NV – Background Check Not Required - Manufacturer (NAC 639.593(7)(d)) – No Disclosures

John Craig, Owner, and Ben Craig, Fallon Facility Manager, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background on application.

Mr. Wuest questioned Mr. Craig on the business model and products being shipped into Nevada.

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

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Nevada Wholesaler License for J.W. Welding Supplies and Tools.

Second: Rolf Zakariassen

Action: Passed unanimously.

19. Request for Pharmacist Applicant to Retake the NAPLEX Exam (NRS 639.120(1)) – Appearance: **(FOR POSSIBLE ACTION)**

A. Bea Belarmino

Bea Belarmino appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Belarmino provided background on her appearance before the Board regarding another chance to take the NAPLEX exam.

The Board questioned Ms. Belarmino about her education and what she does to prepare for her exams.

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

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve Bea Belarmino to take one more attempt at the NAPLEX exam.

Second: Jade Jacobo

Board staff asked Ms. Belarmino the disclosure questions on the Application by Examination and stated that a new application must be submitted every time a person takes the NAPLEX exam.

Ms. Belarmino answered "no" to all questions asked.

Action: Passed unanimously.

C. Tsigereda Mulugeta

Tsigereda Mulugeta appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Mulugeta provided background on her appearance before the Board regarding another chance to take the NAPLEX exam.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Tsigereda Mulugeta to take one more attempt at the NAPLEX exam.

Second: Krystal Freitas

Board staff asked Ms. Mulugeta the disclosure questions on the Application by Examination and stated that a new application must be submitted every time a person takes the NAPLEX exam.

Ms. Mulugeta answered "no" to all questions asked.

Action: Passed unanimously.

23. Executive Secretary Report:

A. Financial Report

Christian Schonlau, Nevada Board of Pharmacy Chief Financial Officer, provided the financial report to the Board's satisfaction.

Board discussion ensued.

19. Request for Pharmacist Applicant to Retake the NAPLEX Exam (NRS 639.120(1)) – Appearance: **(FOR POSSIBLE ACTION)**

B. Arnold Castro

Arnold Castro appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Castro provided background on his appearance before the Board regarding another chance to take the NAPLEX exam.

The Board questioned Mr. Castro on if he has ever been licensed in Nevada, his disclosure that was dismissed, and why he wants to take the NAPLEX again.

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

Mr. Wuest commented that Richard Tomasso and Krystal Freitas were excused from the meeting and returned around 2:45 PM.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve Arnold Castro to take one more attempt at the NAPLEX exam.

Second: Richard Tomasso

Action: Passed unanimously.

8. Petition for Reconsideration of Denial of Controlled Substance Registration pursuant to NRS 639.139. **(FOR POSSIBLE ACTION)**

Victor Bruce

Rosalie Bordelove, Counsel for the Board, joined the meeting at 3:00 PM.

Victor Bruce appeared and was sworn in by President Park prior to answering questions and offering testimony.

John Hunt appeared as counsel on behalf of Dr. Bruce.

Mr. Kandt provided background on appearance regarding a petition for reconsideration of denial for Dr. Bruce's controlled substance registration.

Mr. Hunt commented that he provided a list of drugs that Dr. Bruce is requesting the Board to consider allowing him to have a controlled substance license with conditions.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve controlled substance registration for Dr. Victor Bruce with conditions that he is only able to prescribe from the list provided with the removal of Phentermine Hydrochloride, Tylenol with Codeine, Human Growth Hormone (HGH), and remove Neurontin and to modify Testosterone Cypionate to "Testosterone". In addition, Dr. Bruce will self-report monthly of the controlled substances that he prescribes from MyRx and must notify the Board immediately if he encounters any discrepancies.

Mr. Kandt suggested that motion be amended to include correct language.

Jade Jacobo amended her motion as recommended by Mr. Kandt.

Motion: Jade Jacobo moved to grant Dr. Victor Bruce's petition and to approve issuance of a controlled substance registration with the following conditions: 1) Dr. Bruce is only able to prescribe from the list provided with the removal of Phentermine Hydrochloride, Tylenol with Codeine, Human Growth Hormone (HGH), and Neurontin; 2) Modify the drug list for Testosterone Cypionate and change to "Testosterone"; 3) Dr. Bruce will self-report monthly the controlled substances that he prescribes from MyRx and must notify the Board immediately if he encounters any discrepancies.

Second: Richard Tomasso

Action: Passed unanimously.

9. Application for Pharmacist Registration Renewal (NRS 639.127) – Appearance. (**FOR POSSIBLE ACTION)**

Darrel Foth

This matter was continued to a future Board Meeting.

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

Eric Galey

Eric Galey appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan provided background on the application and his disclosures regarding using beyond use date drugs when compounding and misfiled a prescription.

Mr. Galey provided clarification of his disclosure to Board and reasons for requesting licensure in Nevada.

Board discussion ensued.

Board Action:

Motion: Rolf Zakariassen moved to approve Application for Pharmacist Registration by Reciprocation for Eric Galey.

Second: Wayne Mitchell

Action: Passed unanimously.

11. Application for Veterinarian Authority to Dispense Drugs (NAC 639.7423) – Appearance **(FOR POSSIBLE ACTION)**

A. Lesli Ann Hewitt-Spears

Lesli Ann Hewitt-Spears appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background on the application and disclosure regarding public reprimand due to missing drugs at her veterinary office.

The Board questioned Ms. Hewitt-Spears on what she plans to dispense, her reason for requesting a license, and what occurred with her disclosure.

Ms. Hewitt-Spears answered questions to the Board's satisfaction. She disclosed that she dispensed drugs prior to having a license and her office assistant occasionally assisted with the dispensation of drugs. She further clarified that she personally dispensed the controlled substances in her practice.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Veterinarian Authority to Dispense Drugs Registration for Lesli Ann Hewitt-Spears pending favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

B. Sircy Moore

This matter was continued to a future Board Meeting.

20. Application for Ambulatory Surgery Center License. – Appearance. **(FOR POSSIBLE ACTION)**

Comprehensive Surgical Care of Reno-Tahoe, LLC – Reno, NV

Erin Brown (Administrator), Brian Evans (Medical Director), Joel Rainwater (Chief Medical Officer), Lovnit Kaur (Pharmacist Consultant), and Carleen Cordova (Compliance Officer) appeared and were sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she knows Lovnit Kaur through Roseman University but stated that she could participate in this matter fairly and without bias.

Mr. Dodge provided background on application.

The Board questioned about the services being provided, what is Ms. Kaur's role, and who is the emergency contact at the location.

Ms. Kaur and Mr. Evans answered questions to the Board's satisfaction.

Mr. Dodge commented that one of the owners noted a disclosure on their Personal History application regarding two public reprimands by the Nevada Board of Medical Examiners.

Dr. Charles Virden appeared and was sworn in by President Park prior to answering questions and offering testimony.

The Board questioned Dr. Virden about the events that occurred with his disclosures.

Dr. Virden answered to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Ambulatory Surgery Center License for Comprehensive Surgical Care of Reno-Tahoe, LLC pending favorable inspection.

Second: Richard Tomasso

Action: Passed unanimously.

18. Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Appearance **(FOR POSSIBLE ACTION)**

    Anja Palazova

Anja Palazova appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background on appearance regarding Ms. Palazova requesting a to participate in the practice of pharmacy at site other than licensed pharmacy.

The Board questioned about her role and what her plans are with Aspen Rx Health.

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

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve Anja Palazova's request to engage in the practice of pharmacy at a site other than a licensed pharmacy at AspenRx Health for the services listed in the application.

Second: Jade Jacobo

Action: Passed unanimously.

21. Discussion and Possible Action on Adoption of Emergency Regulation pursuant to NRS 233B.0613 to authorize pharmacists and other healthcare professionals to dispense oral medications for the treatment of COVID-19 subject to certain conditions. **(FOR POSSIBLE ACTION)**

This matter was continued to a future Board Meeting.

22. 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).

General Counsel had no items to report for this matter.

23. Executive Secretary 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

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

Board discussion ensued.

26. Date and Location of Next Scheduled Board Meeting:

March 2-3, 2022 – Zoom

27. Public Comment January 13 2022, 5:00 PM

There was no public comment.

28. 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 (06/08/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☐ New MDEG		☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☒ Ownership Change*	* If making a change, provide current license number:	☒ 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 P00923	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Bioness Inc.

MDEG Physical Address: 25103 Rye Canyon Loop

City: Valencia State: CA Zip: 91355

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-211-9136 Website: www.bioventus.com/bioness/

Email: jacqueline.tenkhoff@bioventus.com

Name of MDEG Administrator (NAC 639.694): Anthony Otero

Type of MDEG products that will be sold (check all applicable)

☐ Medical Gases**	☐ Assistive Equipment
☐ Respiratory Equipment**	☐ Diabetic Supplies
☐ Life-sustaining equipment**	☐ Orthotics and Prosthetics
☐ Parenteral and Enteral Equipment**	☒ Others: functional electrical stimulation (FES) systems

** If providing these products, you are required 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):

Name: Telephone:

Days and Hours of Operation

Mon:	8:00am - 5:00pm
Tues	8:00am - 5:00pm
Wed:	8:00am - 5:00pm
Thurs:	8:00am - 5:00pm
Fri:	8:00am - 5:00pm
Sat:	Closed
Sun:	Closed
Holidays:	New Year, MLK, Memorial Day, 4th of July, Labor Day, Thanksgiving, Day after Thanksgiving, Christmas

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 Provider No. – 53444301

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: _____ 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: Delaware

Parent Company (if any): Perseus Intermediate Inc.

Corporation/Organization Name: Bioness Inc.

Mailing Address: 25103 Rye Canyon Loop

City: Valencia State: CA Zip: 91355

Telephone: 901-341-2902 Email: Michael.kiser@bioventus.com

Contact Person Name: Michael Kiser

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/	✓	✓	✓	✓

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 Kiser

Print Name of Authorized Person Submitting Application

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

11/16/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc

Bioness

LiveOn

CORPORATE NAME AND ADDRESS

Bioness Inc
25103 Rye Canyon Loop
Valencia, CA 91355

PHONE # 800-211-9136

FEIN# 20-1026859

Ownership

Officers:

NAME	TITLE	DOB	BUSINESS ADDRESS
Kenneth Reali	CEO	[redacted]	25103 Rye Canyon Loop Valencia, CA 91355
Gregory Anglum	CFO	[redacted]	25103 Rye Canyon Loop Valencia, CA 91355

Shareholder:

NAME	Tax ID	BUSINESS ADDRESS
Perseus Intermediate Inc. (100% owner)	86-3391520	4721 Emperor Blvd, Suite 400 Durham, North Carolina 27703

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	BIONESS INC.
File Number:	C2612017
Registration Date:	04/29/2004
Entity Type:	FOREIGN STOCK CORPORATION
Jurisdiction:	DELAWARE
Status:	ACTIVE (GOOD STANDING)

As of August 17, 2021 (Certification Date), the entity is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect 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 August 18, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: RMLN97Y

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at bebizfile.sos.ca.gov/certification/index.

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STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Bioness, Inc.
25103 Rye Canyon Loop
Valencia, CA 91355

LICENSE NUMBER: 48442
EXPIRATION DATE: 11/26/2022

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

Printed: 10/26/2020

OSP 07 102308

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 06/04/2021

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: Patricia Monne	
RSC Insurance Brokerage, Inc. 1350 Avenue of the Americas 18th Flor New York NY 10019	PHONE (A/C, No, Ext):	FAX (A/C, No):
	E-MAIL ADDRESS: pmonne@krautergroup.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Federal Insurance Co	20281
INSURED Bioness LLC 25103 Rye Canyon Loop 5 Valencia CA 91335	INSURER B: Great Northern Ins Co	20303
	INSURER C: Pacific Employers Insurance Company	22748C
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** CL216414736 **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 [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [X] LOC [ ] OTHER:			36055325	06/04/2021	06/04/2022	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
								$
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [X] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73615165	06/04/2021	06/04/2022	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
A	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			79837181	06/04/2021	06/04/2022	EACH OCCURRENCE	$ 15,000,000
							AGGREGATE	$ 15,000,000
								$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		71736619	05/04/2021	05/04/2022	[ ] 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 Liability			36012692	06/04/2021	06/04/2022		$10,000,000

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

Evidence of Coverage

CERTIFICATE HOLDER

Evidence of 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

RSC Insurance Brokerage Inc.

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Additional Named Insureds

Other Named Insureds

Bioventus LLC

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AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD®

ADDITIONAL REMARKS SCHEDULE

Page ____ of ____

AGENCY		NAMED INSURED
RSC Insurance Brokerage, Inc.		Bioness LLC
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: Notes

Professional Liability -Chubb Custom Insurance Company - Policy #36055326 - Effective 06/04/2021-06/04/2022 - $10,000,000 Limit Each Claim/Aggregate; The Global $10,000,000 Aggregate is shared by the Products/Completed Operations Liability and Professional Liability policies. Both poilicies are written on a "Claims -Made" basis.

Umbrella liability coverage follows form to the commercial general liability, auto liability, and employer's liability coverages only.

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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) Administrator Application

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Bioness INC. MDEG License # (if applicable) _____

Physical Address 25103 Rye Canyon Loop

City Valencia State CA Zip 91355

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-211-9136 Website www.bioventus.com/bioness

Licensing Company Email jacqueline.tenkhoff@bioventus.com

Section 2: Personal Information

First Anthony Middle _____ Last Otero

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

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

Mailing Address [redacted] Wakefield Rd

City Castaic State CA Zip 91384-3523

Telephone [redacted] Email tony.otero@bioventus.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 Pennsylvania		09/00 - 05/05	
Address	**City**	**State**	**Zip**
3451 Walnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Valencia High School		09/96 -- 05/00	
Address	**City**	**State**	**Zip**
27801 Dickason Dr	Valencia	CA	91355
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
01/86 -- current	[redacted] Wakefield Rd	Castaic	CA	91384
01/13 -- current	[redacted] Newhall Ave, #105	Santa Clarita	CA	91321
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 direct patient-care 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)	
Bioness Inc.		02/07 -- current	
Business Address	**City**	**State**	**Zip**
25103 Rye Canyon Loop	Valencia	CA	91355
Phone	**Title**	**Number of Employed Hours**	
661-362-4857	Director Commercial Support	31,154	
Description of Duties			
Direct service and support of all Bioness products provided to all end users, including facilities, distributors, and patients.			

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

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

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description 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, Anthony Otero, **certify that as the MDEG Administrator for** Bioness Inc.,

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

1. A.O. Have a high school diploma or its equivalent;
2. A.O. Have
   a. At least 1,500 hours of verifiable direct patient-care 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. A.O. 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. A.O. 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.

Anthony Otero
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Jan 11, 2022
Date

Board Use Only	Date Received:

4B

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 (06/08/2021)

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

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☐ New MDEG		☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☑ Ownership Change*	* If making a change, provide current license number: M P01612	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: US Expediters, LLC d/b/a CPAP.com

MDEG Physical Address: 13235 N Promenade Blvd

City: Stafford State: TX Zip: 77477

Mailing Address (if different from physical address): Same As above

City: State: Zip:

Telephone: 713-351-3419 Website: www.cpap.com

Email: regulatorylicensing@cpap.com

Name of MDEG Administrator (NAC 639.694): John W Goodman

Type of MDEG products that will be sold (check all applicable)

☐ Medical Gases**	☐ Assistive Equipment
☐ Respiratory Equipment**	☐ Diabetic Supplies
☐ Life-sustaining equipment**	☐ Orthotics and Prosthetics
☐ Parenteral and Enteral Equipment**	☑ Others: CPAP Machines, Masks and Supplies

** If providing these products, you are required 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):

Name: Not Applicable Telephone:

Days and Hours of Operation

Mon:	8am to 8pm CST
Tues	8am to 8pm CST
Wed:	8am to 8pm CST
Thurs:	8am to 8pm CST
Fri:	8am to 8pm CST
Sat:	8am to 5pm CST
Sun:	None
Holidays:	None

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))
Not Applicable

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: Not Applicable Credentials: _____ %: _____

Name: _____ 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: Not Applicable

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: State of Texas

Parent Company (if any): Somnum Bene LLC

Corporation/Organization Name: US Expediters, LLC d/b/a CPAP. com

Mailing Address: 13235 N Promenade Blvd

City: Stafford State: TX Zip: 77477

Telephone: 713-351-3419 Email: regulatorylicensing@cpap.com

Contact Person Name: Carolyn Goodman

Section 7: Partnership

Partnership Name: Not Applicable

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: Not Applicable

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/	✓	✓	✓	✓

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.

Carolyn Goodman

Print Name of Authorized Person Submitting Application

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

12/10/21

Date

Board Use Only	Date Received: _____	Amount: 500 check #31819

US Expediters, Inc. dba CPAP.com
13235 N. Promenade • Stafford, Texas 77477
Phone: (713) 351-3419 • Fax: (832) 342-9715

Nevada State Board Of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

December 10, 2021

Sent via Overnight Mail

Re: U.S. Expediters, Inc. d/b/a CPAP.com - Stock Sale and Change in Entity
License/Permit/Registration Number: P0161 2
Request for Temporary License

Ladies and Gentlemen:

Enclosed is a MDEG application reflecting a contemplated change in the ownership of U.S. Expediters, Inc. d/b/a CPAP.com (the "Company"). In addition to the contemplated change in ownership, the Company will transition from a Texas corporation to a Texas limited liability company, but it will retain the same Federal Tax ID Number. The Company operates one location in Texas and provides durable medical equipment to patients in certain other states.

Currently the stock of the Company is owned as follows:

- John W. Goodman – 41.5%
- John C. Goodman – 41.5%
- Zach Goodman – 17%

On or about December 20, 2021, the current stockholders of the Company expect to close on an F-Reorganization transaction, pursuant to which (i) Somnum Bene LLC will acquire 100% of the ownership interests in the Company and (ii) the Company name will transition to U.S. Expediters, LLC d/b/a CPAP.com. Both a pre- and a post-closing organization chart is included below for your reference.

There will be no significant changes in the Company's operations or its management team as a result of this transaction. The Company will continue to operate at the same location under the same Federal Tax ID Number.

Please note that the information included in the attached application will be effective on the date the anticipated transaction closes. In addition, the d/b/a of CPAP.com will be associated with U.S. Expediters, LLC in conjunction with the reorganization described above.

Request for Temporary License

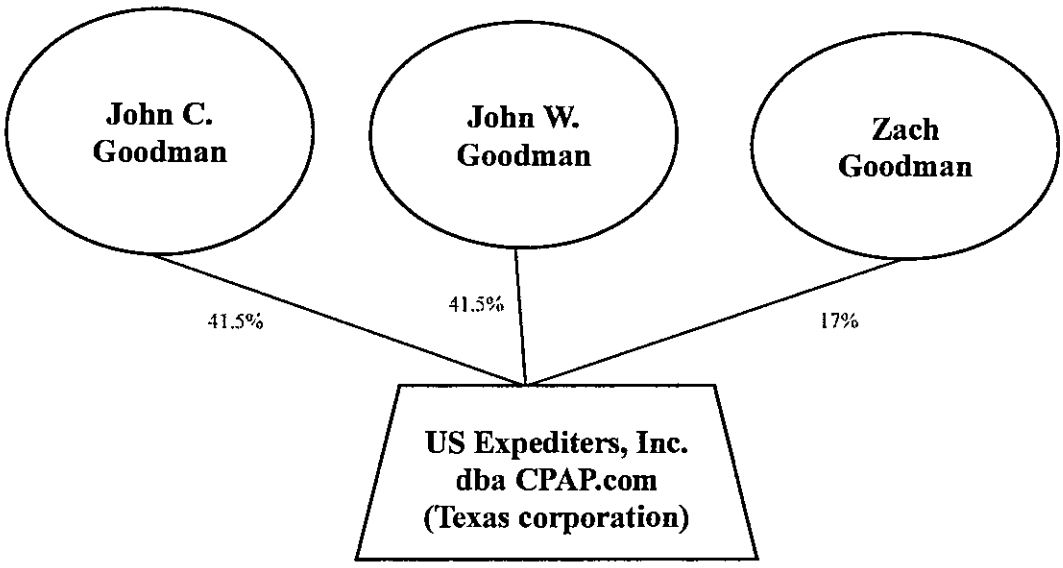
Pursuant to instructions from the Board's counsel, we request a temporary license or permission to continue to operate while this new change of ownership application is pending approval.

We are happy to answer any questions that you have regarding the transaction or the ownership structure of the Company. Should you require additional documentation or information, please contact Carolyn Goodman at 713-351-3419 or via email at regulatorylicensing@cpap.com.

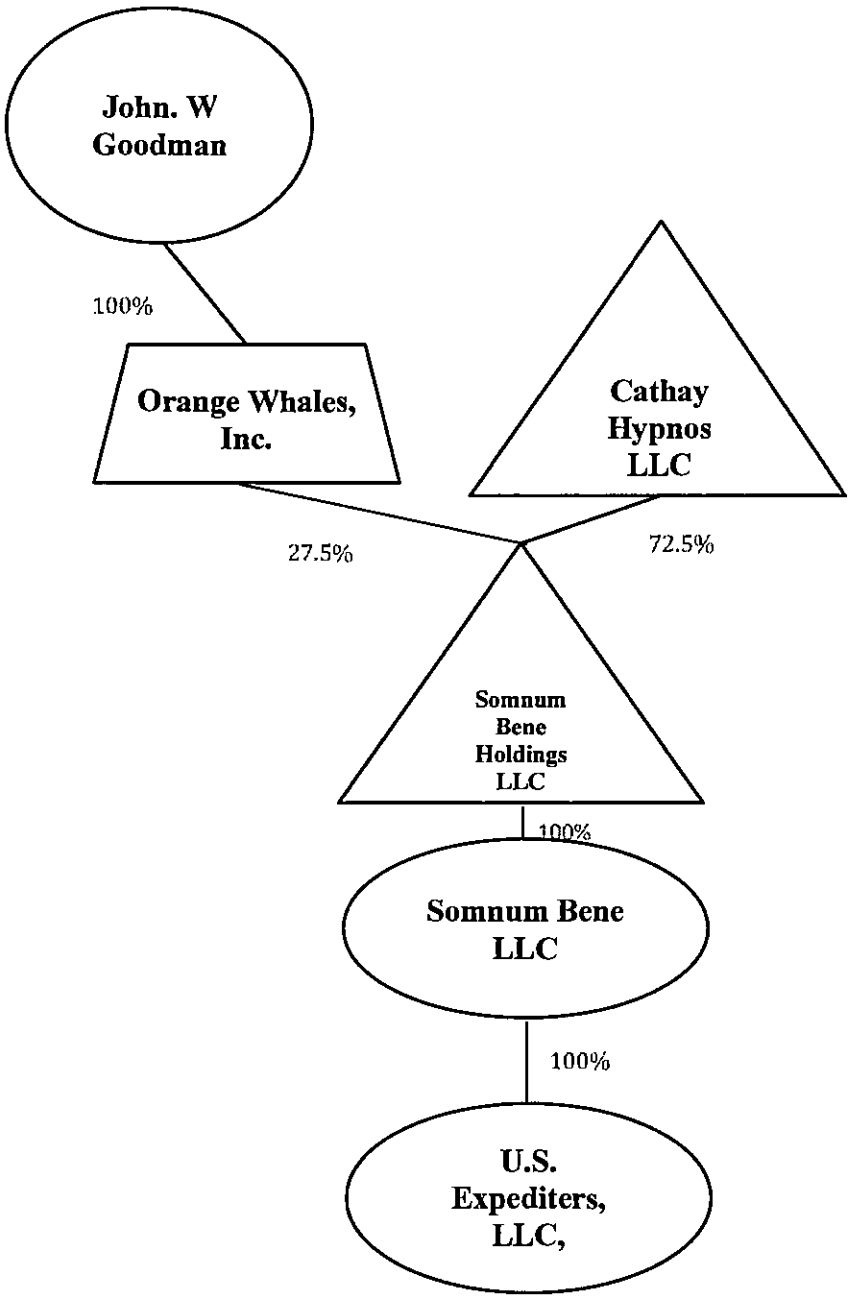
Sincerely,

John W. Goodman
CEO

Pre-Closing Ownership Structure of the Company



Post-Closing Ownership Structure of the Company



US Expediters, LLC. Officers Details

Name of Officers	Address	Officers
John W Goodman	[redacted] Abercombie Lane Sugar Land TX 77479	Officer
Carolyn Goodman	[redacted] Abercombie Lane Sugar Land TX 77479	Officer

Somnum Bene LLC – Officer Details

Name of Officers/Directors (if any)	Address	Title
Mark Woods	150 East 52nd Street, 20th Floor, New York, NY 10022	President
Andre Puong	150 East 52nd Street, 20th Floor, New York, NY 10022	CEO and Secretary

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, Articles Of Incorporation for U.S. EXPEDITERS, INC. (file number 142345500), a Domestic For-Profit Corporation, was filed in this office on November 27, 1996.

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 November 10, 2021.

John B. Scott
Secretary of State

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

US EXPEDITERS INC
13235 N PROMENADE DR
STAFFORD TX 77477

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

US EXPEDITERS INC DBA
CPAP.COM
13235 N PROMENADE
STAFFORD, TX 77477

Pursuant to Health and Safety Code, Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE DISTRIBUTOR

License # 1000207
Expires: June 14, 2023

NON-TRANSFERABLE

Commissioner

511421

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/18/2021

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: Melissa Bush
USI Southwest 9811 Katy Freeway, Suite 500 Houston, TX 77024 855 874-1450	PHONE (A/C, No, Ext): 713 343-5065 FAX (A/C, No): 713 490-4700 E-MAIL ADDRESS: Melissa.Bush@usi.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Great American E & S Insurance Company	37532
INSURER B : Massachusetts Bay Insurance Company	22306
INSURER C : Hanover Insurance Company	22292
INSURER D : Zurich American Insurance Company	16535
INSURER E :	
INSURER F :	

INSURED
US Expediters, Inc. DBA CPAP.com
13235 N Promenade
Stafford, TX 77477

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			PLE787085	11/15/2021	11/15/2022	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$500,000
	X Bl/PD Ded:2,500						MED EXP (Any one person)	$20,000
							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	$2,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			PLE787085	11/15/2021	11/15/2022	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	UMBRELLA LIAB / OCCUR			XSE787086	11/15/2021	11/15/2022	EACH OCCURRENCE	$3,000,000
	X EXCESS LIAB / X CLAIMS-MADE						AGGREGATE	$3,000,000
	DED / RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WDDH83461400	11/15/2021	11/15/2022	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (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
C	Inland Marine			RHDH79576705	11/15/2021	11/15/2022	$8,600,000 TIV	
D	Empl Practice			MPL833023800	11/15/2021	11/15/2022	$1,000,000/Ret: $15,000	

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

Location Address: 13235 Promenade
Landlord/Additional Insured: Ranger H&SA-TX GP LLC and its Subsidiaries are Additional Insured with respects to General Liability shown above per written contract or agreement. Coverage is Primary and Non Contributory per written contract or agreement.
The General Liability policy includes an automatic Additional Insured endorsement that provides Additional
(See Attached Descriptions)

CERTIFICATE HOLDER

Ranger H&SA-TX GP LLC c/o Steam
Realty Partners-Houston, LP
3040 Post Oak Blvd Ste 600
Houston, TX 77056

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)

Insured status to the Certificate Holder, only when there is a written contract or written agreement between the named insured and the certificate holder and with regard to work performed by or on behalf of the named insured. The General Liability policy provides a Blanket Waiver of Subrogation in favor of the same, when required by written contract. The General Liability policy contains a special endorsement with Primary and Noncontributory wording, when required by written contract.

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: US Expediters, LLC d/b/a CPAP.com

Physical Address: 13235 N Promenade Blvd

City: Stafford State: TX Zip: 77477

Mailing Address (if different from physical address): Same as Above

City: State: Zip:

Telephone: 713-351-3419 Website: www.cpap.com

Licensing Company Email: regulatorylicensing@cpap.com

Section 2: Personal Information

First: John Middle: W Last: Goodman

Alias(es, nicknames, name changes, etc.): Johnny

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

Mailing Address: [redacted] Abercombie Lane

City: Sugar Land State: TX Zip: 77479

Telephone: [redacted] Email: johnny.goodman@cpap.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: JWG

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)	
Texas A&M College			08/00 To 06/04	
Address		City	State	Zip
400 Bizzell St		College Station	TX	77843
Diploma/Degree obtained, if any				
Bachelor of Arts in Philosophy				
School Name			From - To (MM/YY – MM/YY)	
Elkins High School			08/96To 06/00	
Address		City	State	Zip
7007 Knights Ct		Missouri City	TX	77459
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
10/15 To 12/21	[redacted]Abercombie Lane	Sugar Land	TX	77479
01/07 To 10/15	5026 Bellmead Dr	Missouri City	TX	77459
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)
US Expediters, Inc. dba CPAP.com			04/05 to 12/21
Business Address	**City**	**State**	**Zip**
13235 N Promonade Blvd	Stafford	TX	77477
Phone	**Title**		
713-351-3419	President-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) Date

Applicant's initials JWG

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.

JOHN W Goodman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/21

Date

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

State of Texas, ss. County of Fort Bend

I, John W Goodman, 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

12/10/2021

Date

Subscribed and Sworn to before me this 10 day of December 2021

Notary Public Signature

JENNIFER SUMMERHAWK
Notary Public, State of Texas
Comm. Expires 02-11-2023
Notary ID# 131889027

(Seal)

Applicant's initials JWG

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) Administrator Application

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: US Expediters, LLC d/b/a CPAP.com — MDEG License # (if applicable): P01612

Physical Address: 13235 N Promenade Blvd

City: Stafford — State: TX — Zip: 77477

Mailing Address (if different from physical address): Same as Above

City: _____ — State: _____ — Zip: _____

Telephone: 713-351-3419 — Website: www.cpap.com

Licensing Company Email: regulatorylicensing@cpap.com

Section 2: Personal Information

First: John — Middle: W — Last: Goodman

Alias(es, nicknames, name changes, etc.): Johnny

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

Mailing Address: [redacted] Abercombie Lane

City: Sugar Land — State: TX — Zip: 77479

Telephone: [redacted] — Email: johnny.goodman@cpap.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)	
Texas A&M Universtiy		08/00 To 06/04	
Address	**City**	**State**	**Zip**
750 Agronomy Road Suite 1601	College Station	TX	77843
Diploma/Degree obtained, if any			
Bachelor of Arts in Philosophy, Minor in Business			
School Name		**From - To (MM/YY – MM/YY)**	
Elkins High School		08/96 To 06/00	
Address	**City**	**State**	**Zip**
7007 Knights Ct	Missouri City	TX	77459
Diploma/Degree obtained, if any			
High School			
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
10/15 to 12/21	[redacted] Abercombie Lane	Suagr Land	TX	77479
From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/07 to 10/15	5026 Bellmead Dr	Missouri City	TX	77459
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 direct patient-care 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)	
US Expediters, Inc. d/b/a CPAP.com			04/05-12/21	
Business Address		**City**	**State**	**Zip**
13235 N Promenade Blvd		Stafford	TX	77477
Phone	**Title**		**Number of Employed Hours**	
713-351-3419	President-CEO		38,000 hours	
Description of Duties				

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

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

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description 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, John W Goodman, **certify that as the MDEG Administrator for**

US Expediters, LLC d/b/a CPAP.com,

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

1. JWG Have a high school diploma or its equivalent;
2. JWG Have
   a. At least 1,500 hours of verifiable direct patient-care 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. JWG 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. JWG 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.

JOhn W Goodman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/2021
Date

Board Use Only	Date Received:

Olivia Mora

From: Johnny Goodman <johnny.goodman@cpap.com>
Sent: Wednesday, January 12, 2022 10:32 AM
To: Olivia Mora
Subject: Re: MDEG Application - US Expediters - Stafford, TX - Need more information

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Howdy,

There was a typo in my last answer, to be very clear:

No, I am not the subject of a court order for the support of a child.

Thanks,

Johnny

On 1/12/22 12:12 PM, Olivia Mora wrote:

> Thank you for the quick response.
>
> Have a good day,
> **Olivia Mora**
> **Licensing Specialist**
> **Nevada State Board of Pharmacy**
> **(775) 850-1440**
> **o.mora@pharmacy.nv.gov**

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

4C

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 (06/08/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☒ New MDEG		☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*	* If making a change, provide current license number:	☒ 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: DRUGSOURCE, INC.

MDEG Physical Address: 2020 LUNT AVE

City: ELK GROVE VILLAGE State: IL Zip: 60007

Mailing Address (if different from physical address): NO

City: _____ State: _____ Zip: _____

Telephone: 847-258-1920 Website: shopping.drugsourceinc.com

Email: deanbartello@drugsourceinc.com

Name of MDEG Administrator (NAC 639.694): Dean Bartello

Type of MDEG products that will be sold (check all applicable)

☐ Medical Gases**	☒ Assistive Equipment
☐ Respiratory Equipment**	☐ Diabetic Supplies
☐ Life-sustaining equipment**	☐ Orthotics and Prosthetics
☐ Parenteral and Enteral Equipment**	☐ Others:

** If providing these products, you are required 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):

Name: _____ Telephone: _____

Days and Hours of Operation

Mon:	8:30A-6:00P Central
Tues	8:30A-6:00P Central
Wed:	8:30A-6:00P Central
Thurs:	8:30A-6:00P Central
Fri:	8:30A-6:00P Central
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? SEE APPENDIX A	✔	
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))
N/A Email Response from Dean Burtello on 9/21/2021
Does not bill Medicare or Medicaid directly. Billing is done by
Medicare Advantage plans. - DM 9/21

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: N/A _____ Credentials: _____ %: _____

Name: _____ 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: Illinois

Parent Company (if any): _____

Corporation/Organization Name: Drugsource, Inc.

Mailing Address: 2020 Lunt Ave

City: Elk Grove Village State: IL Zip: 60007

Telephone: 847-258-1920 Email: deanbartello@drugsourceinc.com

Contact Person Name: Dean Bartello

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/	✓	✓	✓	✓

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.

Dean Bartello

Print Name of Authorized Person Submitting Application

Dean Bartello

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

9/9/2021

Date

Board Use Only	Date Received: _____	Amount: 500 Check # 26095

Section 2 Question 3.

All our discipline is a result of a single incident regarding the failure to file a timely zero report. This is summary. We are also attaching all documents, orders, agreements and a complete description.

On July 22, 2011 disciplinary action was taken against DrugSource, Inc. by the Colorado Board of Pharmacy. We submitted our "zero" report to their Electronic Prescription Drug Monitoring Program two (2) days late. Pharmacy violated sections 12-22-125(1)(c) and 12-22-708, C.R.S. Specifically, the Board found that the pharmacy failed to submit data to the Colorado Prescription Drug Monitoring Program for the June 16-25, 2011 reporting period. Drugsource agreed to pay a fine.

As a result of this issue, Hawaii found Drugsource failed to report the Colorado Order within thirty days. The agreement required DrugSource to pay a fine, but the Agreement specifically provided that DrugSource was not admitting any violation of Hawaii of law or rule.

However, Louisiana issued a letter of reprimand because we did not disclose the Hawaii settlement. Drugsource paid a fine

Illinois fined us based on the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois.

DrugSource is committed to following all applicable laws in the states where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

Dean Bartelle
Sign

9/9/2021
date

Section 9

DrugSource, Inc.
Officers and Directors

Officers

Name	Dean Bartello
Title	President/Secretary
Percent of Ownership	100%
Business Address	2020 Lunt Avenue Elk Grove Village, IL 60007
Phone	847-258-1962
Fax Number	847-258-1914

Directors

Names	Dean L. Bartello Rosann B. Bartello

Section 9

File Number 5776-723-5

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 I am the keeper of the records of the Department of Business Services. I certify that

DRUGSOURCE, INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON APRIL 13, 1994, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 1ST *day of* SEPTEMBER *A.D.* 2021 .

Authentication #: 2124403080 verifiable until 09/01/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/11/2021

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, Inc.
2850 Golf Road
Rolling Meadows IL 60008

CONTACT NAME: Bonnie Kristoffersen
PHONE (A/C, No, Ext): 630-694-4417 **FAX (A/C, No):** 630-228-6971
E-MAIL ADDRESS: bonnie_kristoffersen@ajg.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: General Casualty Company of Wisconsin	24414
INSURER B: Regent Insurance Company	24449
INSURER C: Accredited Specialty Insurance Company	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED
Drug Source Inc.
2020 Lunt Ave.
Elk Grove Village, IL 60007

COVERAGES **CERTIFICATE NUMBER:** 730214264 **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	
B	X COMMERCIAL GENERAL LIABILITY			BPK000050103	10/1/2021	10/1/2022	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							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			BCA000030903	10/1/2021	10/1/2022	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)	$
								$
A	X UMBRELLA LIAB X OCCUR			BUM000039003	10/1/2021	10/1/2022	EACH OCCURRENCE	$ 4,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 4,000,000
	DED X RETENTION $ 10,000							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			BWC000345802	10/1/2021	10/1/2022	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
C	Cyber			2CIAIL17S302457000	10/1/2021	10/1/2022	Limit Retention	$4,000,000 $100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Included in the General Liability policy is Pharmacist Professional Liability
Fiduciary Liability provided by: The Hanover Insurance Company - LHCA11557808; limit of $1,000,000. Effective 10/1/2021 to 10/1/2022
Employee Theft included in the Package Policy #BPK0000501; Limit of $250,000; Effective 10/1/2021 to 10/1/2022

CERTIFICATE HOLDER

DrugSource, Inc.
2020 Lunt Avenue
Elk Grove Village IL 60007

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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Section 9

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
054.016204
051.036281

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:
03/31/2022

LICENSED PHARMACY

COMMUNITY

DRUGSOURCE INC
DEAN BARTELLO
2020 LUNT AVE
ELK GROVE VILLAGE, IL 60007

DEBORAH HAGAN
SECRETARY

CECILIA ABUNDIS
ACTING DIRECTOR

The official status of this license can be verified at www.idfpr.com

14235890

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: 1824491

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 DRUGSOURCE, INC.

Physical Address 2020 LUNT AVE

City ELK GROVE VILLAGE State IL Zip 60007

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone 847-258-1920 Website shopping.drugsourceinc.com

Licensing Company Email deanbartello@drugsourceinc.com

Section 2: Personal Information

First DEAN Middle LOUIE Last BARTELLO

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] LUNT AVE

City ELK GROVE VILLAGE State IL Zip 60007

Telephone [redacted] Email deanbartello@drugsourceinc.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 639.1291)	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 DB

[redacted]

School Name		From - To (MM/YY – MM/YY)	
University of Illinois-Chicago-Pharmacy School		1982-1986	
Address	City	State	Zip
833 S. Wood St	Chicago	IL	60612
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Loyola University		1980-1982	
Address	City	State	Zip
1032 W Sheridan Rd	Chicago	IL	60660
Diploma/Degree obtained, if any			
No degree -- Pre-pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Holy Cross High School		1976-1980	
Address	City	State	Zip
300 80th Ave	River Grove	IL	60171
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			

[redacted]

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2007-current	[redacted] Shelley Ct	Elk Grove Village	IL	60007
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DB

[redacted]

Business Name		From - To (MM/YY – MM/YY)	
Drugsource, Inc.		1994-current	
Business Address	**City**	**State**	**Zip**
2020 Lunt Ave	Elk Grove Village	IL	60007
Phone	**Title**		
847-258-1962	President/CEO		
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			

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.

Applicant's initials DB

Section B: 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.) SEE APPENDIX A	✔	
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? SEE APPENDIX A	✔	
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)? SEE APPENDIX A	✔	
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 DB

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
Various	Various	Various	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Various		Various		
Reason/Charge				
FAILURE TO TIMELY FILE ZERO REPORT OR FAILURE TO REPORT DISCIPLINE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Various			DISCIPLINE	
Name of Business/Industry/Entity				
DRUGSOURCE, INC				

Provide explanation below:

All our discipline is a result of a single incident regarding the failure to file a timely zero report.
This is summary. We are also attaching all documents, orders, agreements and a complete description.

On July 22, 2011 disciplinary action was taken against DrugSource, Inc. by the Colorado Board of Pharmacy. We submitted our "zero" report to their Electronic Prescription Drug Monitoring Program two (2) days late. Pharmacy violated sections 12-22-125(1)(c) and 12-22-708, C.R.S. Specifically, the Board found that the pharmacy failed to submit data to the Colorado Prescription Drug Monitoring Program for the June 16-25, 2011 reporting period. Drugsource agreed to pay a fine.

As a result of this issue, Hawaii found Drugsource failed to report the Colorado Order within thirty days. The agreement required DrugSource to pay a fine, but the Agreement specifically provided that DrugSource was not admitting any violation of Hawaii of law or rule.

However, Louisiana issued a letter of reprimand because we did not disclose the Hawaii settlement. Drugsource paid a fine

Illinois fined us based on the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois.

DrugSource is committed to following all applicable laws in the states where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

Dean Bartelle
Original Signature (electronic, copies or stamps not accepted)

9/9/2021
Date

Applicant's Initials DB

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
Various	Various	Various	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Various		Various		
Reason/Charge				
FAILURE TO TIMELY FILE ZERO REPORT OR FAILURE TO REPORT DISCIPLINE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Various			DISCIPLINE	
Name of Business/Industry/Entity				
DRUGSOURCE, INC				

Provide explanation below:

All our discipline is a result of a single incident regarding the failure to file a timely zero report.
This is summary. We are also attaching all documents, orders, agreements and a complete description.

On July 22, 2011 disciplinary action was taken against DrugSource, Inc. by the Colorado Board of Pharmacy. We submitted our "zero" report to their Electronic Prescription Drug Monitoring Program two (2) days late. Pharmacy violated sections 12-22-125(1)(c) and 12-22-708, C.R.S. Specifically, the Board found that the pharmacy failed to submit data to the Colorado Prescription Drug Monitoring Program for the June 16-25, 2011 reporting period. Drugsource agreed to pay a fine.

As a result of this issue, Hawaii found Drugsource failed to report the Colorado Order within thirty days. The agreement required DrugSource to pay a fine, but the Agreement specifically provided that DrugSource was not admitting any violation of Hawaii of law or rule.

However, Louisiana issued a letter of reprimand because we did not disclose the Hawaii settlement. Drugsource paid a fine

Illinois fined us based on the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois.

DrugSource is committed to following all applicable laws in the states where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

Dean Bartlett
Original Signature (electronic, copies or stamps not accepted)

9/9/2021
Date

Applicant's Initials DB

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
Various	Various	Various	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Various		Various		
Reason/Charge				
FAILURE TO TIMELY FILE ZERO REPORT OR FAILURE TO REPORT DISCIPLINE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Various			DISCIPLINE	
Name of Business/Industry/Entity				
DRUGSOURCE, INC				

Provide explanation below:

All our discipline is a result of a single incident regarding the failure to file a timely zero report.
This is summary. We are also attaching all documents, orders, agreements and a complete description.

On July 22, 2011 disciplinary action was taken against DrugSource, Inc. by the Colorado Board of Pharmacy. We submitted our "zero" report to their Electronic Prescription Drug Monitoring Program two (2) days late. Pharmacy violated sections 12-22-125(1)(c) and 12-22-708, C.R.S. Specifically, the Board found that the pharmacy failed to submit data to the Colorado Prescription Drug Monitoring Program for the June 16-25, 2011 reporting period. Drugsource agreed to pay a fine.

As a result of this issue, Hawaii found Drugsource failed to report the Colorado Order within thirty days. The agreement required DrugSource to pay a fine, but the Agreement specifically provided that DrugSource was not admitting any violation of Hawaii of law or rule.

However, Louisiana issued a letter of reprimand because we did not disclose the Hawaii settlement. Drugsource paid a fine

Illinois fined us based on the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois.

DrugSource is committed to following all applicable laws in the states where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

Dean Bartell
Original Signature (electronic, copies or stamps not accepted)

9/9/2021
Date

Applicant's initials DB

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.

DEAN BARTELLO

Print Name (First, Last)

Dean Bartello — 9/9/2021

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

---

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

State of ILL. _____, ss. County of Cook

I, Dean Bartello, 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.

Dean Bartello — 9/9/2021

Original Signature — **Date**

Subscribed and Sworn to before me this 9 day of Sept.

Rosann B Bartello

Notary Public Signature

OFFICIAL SEAL
ROSANN B. BARTELLO
Notary Public - State of Illinois
My Commission Expires 4/12/2022

(Seal)

Applicant's initials DB

APPENDIX A

Disciplinary Matters as of June, 2018

In summary, DrugSource's three (3) disciplinary matters to date relate to a single disciplinary violation - its failure to timely file "zero" reports in 2011 with the Colorado Board of Pharmacy. To resolve that matter, DrugSource entered into a 2011 Stipulation and Final Agency Order issued by the Colorado State Board of Pharmacy ("Colorado Order") and paid a $5,000 fine. DrugSource reported the Colorado disciplinary action to the Hawaii Board of Pharmacy when DrugSource's license was next up for renewal. However, DrugSource was unaware of the fact that Hawaii law required it to report the Colorado discipline to Hawaii within thirty days of the disciplinary decision. Since DrugSource admittedly had failed to report that discipline to Hawaii within the thirty day period, DrugSource entered into a Settlement Agreement with the Hawaii Department of Commerce and Consumer Affairs ("Hawaii Settlement"), by which DrugSource agreed to pay a $1,000 fine. Because the documentation of the Hawaii Settlement used the term "Settlement" and nowhere used the term "Disciplinary Order", and because the Agreement contained language to the effect that DrugSource was not admitting to any violation of Hawaii law, DrugSource mistakenly did not believe that the Hawaii Settlement constituted disciplinary action. As a result, DrugSource erroneously failed to report the Hawaii Settlement on its 2017 renewal application with the Louisiana Board of Pharmacy. This resulted in DrugSource's entry into a Consent Agreement with the Louisiana Board of Pharmacy, whereby it agreed to pay a $5,000 fine for such error ("Louisiana Consent Agreement").

A more detailed discussion of those settlements and orders follows.

1. Colorado Order. $5,000 fine with 10% Surcharge and compliance terms. The Colorado Order was based on allegations that DrugSource failed to comply with the data submission requirements of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP") for the reporting periods of January 1-10, 2011 and June 16-25, 2011 in that DrugSource failed to file a "zero" report with the PDMP indicating no dispensing transactions. DrugSource actually did file the required report, but it did so two (2) days late. DrugSource stipulated that such conduct was a violation of sections 12-22-125(1)(c) and 12-22-708, C.R.S. DrugSource paid the $5,000 fine and 10% surcharge imposed for that violation, and has thereafter fully complied with the data submission requirements of Colorado's PDMP.

2. Hawaii Settlement. DrugSource entered into a Settlement Agreement with the Hawaii Department of Commerce and Consumer Affairs on November 19, 2015. The Agreement required DrugSource to pay a $1,000 fine, but the Agreement specifically provided that DrugSource was not admitting to any violation of Hawaii of law or rule. The Hawaii Settlement resolved allegations by the Hawaii Department of Commerce and Consumer Affairs that DrugSource failed to timely report the Colorado Order within thirty days of that disciplinary decision, in violation of Hawaii Revised Statutes Sections 436B-19(13) and (15). Hawaii discovered this violation when DrugSource disclosed the existence of the Colorado Order on its next application for renewal of its Hawaii license after the entry of that Order.

3. Louisiana Consent Agreement. DrugSource entered into the Louisiana Consent Agreement in June 2018, and that Agreement imposed the following sanctions against DrugSource: a Letter of Reprimand, a

$5,000 fine and a $250 charge for administrative costs. The Louisiana Consent Agreement settled allegations by the Louisiana Board of Pharmacy regarding DrugSource's failure to disclose the Hawaii Settlement on its 2017 Application for Renewal of Pharmacy Permit violated La. R.S. 37:1241(A)(1), (A)(2), (A)(6). (A)(7) and (A)(22). DrugSource had erroneously believed that the Hawaii Settlement was not reportable because it did not involve an admission of any violation of Hawaii law and at all times referred to a "settlement" as opposed to a "disciplinary order". Nevertheless, to avoid the cost and time associated with administrative and judicial proceedings, DrugSource consented to the Louisiana Consent Agreement and sanctions.

4. Illinois Consent Order. We have been disciplined by the Illinois Department of Financial and Professional Regulation. Our Illinois License number is 054.016204. On February 18, 2020, the Acting Director of the Illinois Department of Financial and Professional Regulation, Cecilia Abundis, signed a Consent Order which reprimanded Drugsource, Inc. A copy of this consent order is attached.
This reprimand is the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois. In summary, DrugSource's disciplinary matters to date all relate to a single incident – its failure to timely file "zero" reports in 2011 with the Colorado Board of Pharmacy. The Colorado discipline, along with the resulting discipline in Hawaii and Louisiana, has been previously reported to your Board. The Illinois Board imposed essentially the same discipline that had been previously imposed against Drugsource, Inc. by the pharmacy boards of Colorado, Hawaii and Louisiana.

DrugSource is committed to following all applicable laws in the States where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-004984

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF DRUGSOURCE INC., REGISTRATION NO. OSP 5070,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Drugsource Inc. ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2011-004984 as follows:

1. On August 17, 1998, Respondent Pharmacy became registered by the Board as a non-resident prescription drug outlet in the State of Colorado and was issued Registration No. OSP 5070 ("Colorado Registration").

2. The Board has jurisdiction over Respondent Pharmacy, its Colorado Registration, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2010), otherwise known as the Pharmaceuticals and Pharmacists Act.

3. Respondent Pharmacy's address of record with the Board and current location is 2020 Lunt Avenue, Elk Grove Village, IL 60007.

4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.

5. On January 14, 2011, Board staff initiated a Complaint against Respondent Pharmacy because it failed to comply with the data submission requirements of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP") for the reporting period of January 1 through January 10, 2011.

6. Respondent Pharmacy subsequently failed to submit the required data to the PDMP reporting dispensing transactions of controlled substances in the State of Colorado for the reporting period of June 16 through June 25, 2011, and did not submit a "zero" report indicating no dispensing transactions for said reporting period as required by Board rule.

7. Respondent Pharmacy admits that the conduct described above constitutes a violation of §§12-22-125(1)(c) and 12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's Colorado Registration pursuant to Board Policy 30-8.

DISPOSITION

$5,000.00 Fine with 10% Surcharge and Terms

8. **Fine with Surcharge.** Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S. Respondent Pharmacy shall pay a fine of **Five Thousand Dollars and No Cents ($5,000.00).** Respondent Pharmacy 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 Pharmacy 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 Pharmacy submits this signed Final Agency Order to the Board.

9. **Compliance with PDMP.** At all times Respondent Pharmacy is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP. Respondent Pharmacy understands and acknowledges that future violations of PDMP reporting requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period, shall lead to additional penalties pursuant to Board Policy 30-8.

10. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. To have a 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 §12-22-125, C.R.S.; and

    d. To appeal this Board order.

    Respondent Pharmacy freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

11. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

12. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent Pharmacy shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmaceuticals and Pharmacists Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceutical and pharmacists in the State of Colorado.

13. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency 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 its 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 Pharmacy 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 this case. 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 of a Board member or representative.

ACCEPTED AND AGREED BY

Dean Bartello Dated: 7/29/11
Authorized Agent of Respondent Pharmacy

Subscribed and sworn to before me in the County of Cook, State of Ill., this 29 day of July, 2011 by Dean Bartello, in his/her capacity as an authorized agent of Drugsource Inc.

OFFICIAL SEAL
ROSANN CASELLA
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:6/14/14

My commission expires: 6-14-14

Rosann Casella
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 4th DAY OF August, 2011.

State Board of Pharmacy

BY: For
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, postage prepaid, at Denver, Colorado this 22nd day of July 2011, addressed as follows:

Drugsource Inc.
Attn: Dean Bartello, RPH
2020 Lunt Avenue
Elk Grove Village, IL 60007

Lauri A. Rose
Lauri A. Rose

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, postage prepaid, at Denver, Colorado this 4th day of August 2011, addressed as follows:

Drugsource Inc.
Attn: Dean Bartello, RPH
2020 Lunt Avenue
Elk Grove Village, IL 60007

Agent of the Board

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

2015 NOV 25 P 1:54
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

2016 JAN 21 P 3:07
DEPT. OF COMMERCE
AND CONSUMER AFFAIRS
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of	)	PHA 2015-13-L
	)	
	)	SETTLEMENT AGREEMENT PRIOR TO
DRUGSOURCE INC.,	)	FILING OF PETITION FOR DISCIPLINARY
	)	ACTION AND BOARD'S FINAL ORDER;
Respondent.	)	EXHIBIT "1"
	)	
	)	

24104221 1

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent DRUGSOURCE INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under license number PMP 542. The

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

license was issued on or about November 23, 2007. The license will expire or forfeit on or about December 31, 2015.

2. Respondent's mailing address for purposes of this action is 2020 Lunt Avenue, Elk Grove Village, Illinois 60007.

3. RICO received a request for investigation from the Board of Pharmacy after Respondent reported disciplinary action taken by the State of Colorado on a November 10, 2011 renewal application submitted in Hawaii.

4. Respondent attached a copy of an August 4, 2011 Stipulation and Final Agency Order issued by the Colorado State Board of Pharmacy (hereinafter "the Colorado Order") (Exhibit "1").

5. The Colorado Order was based on allegations Respondent failed to submit required data to Colorado's prescription drug monitoring program. The Colorado Order imposed a $5,000.00 fine.

6. RICO alleges that disciplinary action was taken against Respondent by the State of Colorado and that Respondent failed to timely report the action.

7. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to report).

8. The Board has jurisdiction over the subject matter herein and over the parties hereto.

//

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the August 4, 2011 Stipulation and Final Agency Order issued by the Colorado State Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2015-13-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again,

Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof: contains the entire agreement of the parties: and may only be modified. changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: NOVEMBER 19, 2015.

DRUGSOURCE INC.
Respondent
By: Dean Bartelle
Its PRESIDENT

DATED: Honolulu, Hawaii, November 24, 2015.

DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF DRUGSOURCE INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO(S). PHA 2015-13-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

Kerri Okamura
KERRI OKAMURA
Chairperson

1/21/16
DATE

GARRETT A. LAU
Vice Chairperson

Marcella Chock
MARCELLA CHOCK

Mary Jo Keefe
MARY JO KEEFE

CAROLYN S. J. MA

PVL 07/01/15

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

On this 19TH day of NOV, 2015, before me personally appeared DEAN L BARTELLO, to me known to be the person described, and who executed the foregoing instrument on behalf of DRUGSOURCE, INC as its PRESIDENT, and acknowledged that he/she executed the same as his/her free act and deed.

This SEVEN -page SETTLEMENT AGREEMENT document dated NOVEMBER 19, 2015 was acknowledged before me by DEAN L BARTELLO this 19TH day of NOVEMBER, 2015, in the City of ELK GROVE VILLAGE in the County of COOK, in the State of ~~Hawaii~~. ILLINOIS

Stanley H Fingerhut
Name:
Notary Public, State of ILLINOIS

My Commission expires: 8-11-18

OFFICIAL SEAL
STANLEY H FINGERHUT
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/11/18

Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov

August 16, 2018

Drug Source, Inc.
ATTN: Dean L. Bartello, PIC
2020 Lunt Ave
Elk Grove Village, IL 60007-5606

RE: Case No. 18-0260 – PHY.005900 – Drug Source, Inc. *d/b/a* Drug Source

Dear Pharmacist-in-Charge Bartello:

Please find the enclosed Board Order approved and issued by the Louisiana Board of Pharmacy this week in the above referenced matter.

Sincerely,

Carlos M. Finalet, III
General Counsel

In compliance with Act 2013-655, the board gives notice to its licensees and applicants of their opportunity to file a complaint about the board's actions or procedures. You may submit such complaints to one or more of the following: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr., Baton Rouge, LA 70809; 225.925.6496, cfc@pharmacy.la.gov (2)Committee on House & Governmental Affairs, La. House of Representatives; PO Box 94062, Baton Rouge, LA 70804; 225.342.2403; chrisg@legis.la.gov (3)Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845, sgg@legis.la.gov

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

DRUG SOURCE, INC.

LOUISIANA PHARMACY PERMIT NO. 5900 **Case No. 18-0260**

****

CONSENT AGREEMENT

WHEREAS, DRUG SOURCE, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 5900, 2020 Lunt Ave Elk Grove Village, IL 60007-5606, was disciplined during calendar Year 2015 by Board Order issued by the Hawaii Board of Pharmacy on November 24, 2015.

WHEREAS, Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal of Pharmacy Permit for Year 2017 (Its application for the previous year was submitted prior to the effective date of the Board Order at issue).

WHEREAS, such action constitutes a violation 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. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent 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.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **Louisiana Pharmacy Permit No. 5900 belonging to DRUG SOURCE, INC. is issued a Letter of Reprimand.**

2. **DRUG SOURCE, INC. is ordered to pay a fine of $5,000.00 and to reimburse the Board $250.00 for administrative costs, with total payment due the Board of $5,250.00, 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 and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review 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 provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: 1598776098

Medicare Provider Number (if in the possession of one): 132362000J

I, DEAN BARTELLO, authorized to act on behalf of and acting on behalf of DRUG SOURCE, 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.

"OFFICIAL SEAL"
MARISOL RODRIGUEZ
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 09/27/21

SIGNED, AGREED TO AND ENTERED ON THIS 18TH DAY OF JUNE, 2018.

DRUG SOURCE, INC.
Louisiana Pharmacy Permit No. 5900

State of Illinois
County of COOK
Signed and attested before me on 6/18/18 [Date] by
Dean L. Bartello [Name of person(s)].

Dean Bartello
BY: Authorized Representative

Dean Bartello
(Signature of Notary Public)

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

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 August 15, **2018**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron
President and Hearing Officer for the Board

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	Complainant,	Case No. 2018-06152
v.		
DRUGSOURCE INC., License No 054.016204,	Respondent.	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Samara Colter, and Respondent DrugSource Inc. ("Respondent"), through its attorney Michael B. Brohman of Roetzel & Andress, hereby agree to the following:

STIPULATIONS

Respondent holds Illinois pharmacy license no. 054.016204, which is presently in active status. Respondent also previously held Hawaii pharmacy license no. PMP-542 and Louisiana pharmacy license no. PHY.005900-NR. On or about January 21, 2016, Respondent entered into a settlement agreement with the Hawaii Board of Pharmacy which required Respondent to pay a one thousand dollar ($1,000.00) fine due to its failure to report discipline by the Colorado Board of Pharmacy. On or about August 15, 2017, Respondent entered into a Consent Agreement with the Louisiana Board of Pharmacy, in which it was issued a reprimand to its Louisiana pharmacy license and required to pay a five thousand dollar ($5,000.00) fine, due to its failure to report the discipline entered by the Hawaii Board of Pharmacy. The aforementioned conduct, if proven to be true, would constitute grounds for disciplinary action against Respondent's pharmacy license on the authority of 225 ILCS 85/30(a)(8).

Respondent admits that the information recited herein is accurate and complete. At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to contest any charges brought and present mitigating evidence, the right to counsel, and the right to administrative

review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Board of Pharmacy ("Board") or Acting Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Acting Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Acting Director. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Acting Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Acting Director. A copy of any original signature(s) shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Respondent and the Department agree, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Samara Cotter, and Respondent, agree:

A. Respondent's pharmacy license no. 354.016204 shall be reprimanded;

B. Respondent shall pay a four thousand dollar ($4,000.00) fine within sixty (60) days of the effective date of this Consent Order. The fee is to be paid by personal check, corporate check, cashier's check, or personal money order. Said check shall be made payable to "Illinois Department of Financial and Professional Regulation" and mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086;

C. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes, including the National Association of Boards of Pharmacy. This Consent Order will be available to the general public;

D. This Consent Order shall become effective upon the Director's signature, as dated below.

Signatures on following page.

2/5/2020
Date

Department Attorney Samara Cutler

2/3/2020
Date

Respondent DrugSource Inc.

Date

Respondent's Attorney Michael B. Brohman of Roetzel & Andress

Date

Illinois Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 18th day of February, 2020.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY DEBORAH HAGAN

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2018-06152
License No. 054.016204

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) Administrator Application

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG DRUGSOURCE, INC. MDEG License # (if applicable) _____

Physical Address 2020 LUNT AVE

City ELK GROVE VILLAGE State IL Zip 60007

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone 847-258-1920 Website shopping.drugsourceinc.com

Licensing Company Email deanbartello@drugsourceinc.com

Section 2: Personal Information

First Dean Middle Louie Last Bartello

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

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

Mailing Address [redacted] LUNT AVE

City ELK GROVE VILLAGE State IL Zip 60007

Telephone [redacted] Email deanbartello@drugsourceinc.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 Illinois-Chicago-Pharmacy School			1982-1986	
Address		City	State	Zip
833 S Wood St		Chicago	IL	60612
Diploma/Degree obtained, if any				
BS Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Loyola University			1980-1982	
Address		City	State	Zip
1032 W Sheridan Rd		Chicago	IL	60606
Diploma/Degree obtained, if any				
No degree -- Pre-pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Holy Cross High School			1976-1980	
Address		City	State	Zip
300 80th Ave		River Grove	IL	60171
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				

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
2007-current	[redacted] Shelley Ct	Elk Grove Village	IL	60007
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 direct patient-care 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)
DRUGSOURCE, INC.			1994 TO CURRENT
Business Address	**City**	**State**	**Zip**
2020 LUNT AVE	ELK GROVE VILLAGE	IL	600007
Phone	**Title**	**Number of Employed Hours**	
847-258-1962	PRESIDENT-CEO		
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)
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			

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)	
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)	
N/A			
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. SEE. APPENDIX 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 # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Various	Various	Various	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Various		Various		
Reason/Charge				
FAILURE TO TIMELY FILE OR FAILURE TO REPORT DISCIPLINE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
VARIOUS			DISCIPLINE	
Name of Business/Industry/Entity				
DRUG SOURCE, INC				

Provide explanation below:

All our discipline is a result of a single incident regarding the failure to file a timely zero report. This is summary. We are also attaching all documents, orders, agreements and a complete description.

On July 22, 2011 disciplinary action was taken against DrugSource, Inc. by the Colorado Board of Pharmacy. We submitted our "zero" report to their Electronic Prescription Drug Monitoring Program two (2) days late. Pharmacy violated sections 12-22-125(1)(c) and 12-22-708, C.R.S. Specifically, the Board found that the pharmacy failed to submit data to the Colorado Prescription Drug Monitoring Program for the June 16-25, 2011 reporting period. Drugsource agreed to pay a fine.

As a result of this issue, Hawaii found Drugsource failed to report the Colorado Order within thirty days. The agreement required DrugSource to pay a fine, but the Agreement specifically provided that DrugSource was not admitting any violation of Hawaii of law or rule.

However, Louisiana issued a letter of reprimand because we did not disclose the Hawaii settlement. Drugsource paid a fine.

Illinois fined us based on the result of previously reported discipline in other states and is not the result of anything that occurred in the state of Illinois.

DrugSource is committed to following all applicable laws in the states where it is licensed and conducts its business and takes these disciplinary matters seriously. As a result, it has adopted internal procedures to make sure that these violations do not recur.

Dean Bartell
Original Signature (electronic, copies or stamps not accepted)

9/9/2021
Date

I, DEAN BARTELLO, **certify that as the MDEG Administrator for**

DRUGSOURCE, INC,

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

1. DB Have a high school diploma or its equivalent;
2. DB Have
   a. At least 1,500 hours of verifiable direct patient-care 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. DB 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. DB 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.

Dean Bartello
Print Name (First, Last)

Dean Bartello
Original Signature (electronic, copies or stamps not accepted)

9/9/2021
Date

Board Use Only	Date Received:

4D

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(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 MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☒ Non Publicly Traded Corporation – Pages 1,2,3,5
☐ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: Lantz Medical, INC

Physical Address: 7750 Zionsville Rd #800 Indianapolis, IN 46268
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 7750 Zionsville Rd #800

City: Indianapolis State: IN Zip Code: 46268

Telephone: 866-236-8889 Fax: 877-406-4872

E-mail: info@lantzmedical.com Website: www.lantzmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8A to 5P Tue: 8A to 5P Wed: 8A to5P Thu: 8A to 5P Fri: 8A to 5P Sat: NA to NA Sun: NA to NA Holidays: NA to NA

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Perry Mervar

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: ROM devices, CPMs, Orthotics

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

MCR- 5916600001

Please see attached list of Medicaid provider numbers

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name. NA

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) 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)? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

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 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.

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 MDEG provider or wholesaler 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.

Original Signature of Person Authorized to Submit Application, no copies or stamps

SUANE P. KELLY
Print Name of Authorized Person

9/22/2021
Date

Board Use Only	Received:	Amount: $500 check 13690

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: N/A

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

License Contact Person: _____

Ownership Information – Complete Section 1 or 2

Do not use N/A in this section – Section 1 or 2 must be completed.

Section 1: List the corporations four largest shareholders:
(Name and percentage of ownership)

1. TL Indiana Holdings %: 100%

2. _____ %: _____

3. _____ %: _____

4. _____ %: _____

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Include with the application for a publicly traded corporation

List of officers and directors.

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.

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Indiana

Parent Company if any: TL Indiana Holdings, INC

Corporation Name: Lantz Medical, INC

Mailing Address: 7750 Zionsville Rd #800

City: Indianapolis State: IN Zip: 46268

Telephone: 866-236-8889 Fax: 877-406-4872

Contact Person: Jennifer Addington

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) TL Indiana Holdings, INC 7750 Zionsville Rd #800 Indianapolis, IN 46268
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 105

3) What was the price paid per share? $0.00 Par Value

4) What date did the corporation actually receive the cash assets? 12/27/2019

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.

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited _____

Partnership Name: N/A

Mailing Address: _____

City:_____ State:_____ Zip: _____

Telephone:_____ Fax: _____

Contact Person: _____

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
_____	_____	_____
_____	_____	_____

List names of 4 largest partners and percentage of ownership:

Name:_____ %: _____

Name:_____ %: _____

Name:_____ %: _____

Name:_____ %: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: N/A

List all previous names: _____

Social Security Number: _____

Date of Birth: _____

Place of Birth: City:_____ State:_____ Country: _____

Citizenship: USA_____ other _____

If applicable, list Naturalization Number:_____ Passport Number: _____

Current residence address: _____ City:_____

State: _____ Zip Code: _____ Telephone Number: _____ Fax Number:_____

Previous address (last 5 years):
Address:_____ City:_____ State:__ Zip Code:_____

Address:_____ City:_____ State:__ Zip Code:_____

Address:_____ City:_____ State:__ Zip Code:_____

Address:_____ City:_____ State:__ Zip Code:_____

Business Name: _____

Current Business Address: _____

City:_____ State:_____ Zip Code: _____

Telephone Number:_____ Fax Number: _____

Previous Employment (last 5 years):

Name:_____ Address: _____

City:_____ State:_____ Zip Code: _____

Name:_____ Address: _____

City:_____ State:_____ Zip Code: _____

Name:_____ Address: _____

City:_____ State:_____ Zip Code: _____

LANTZ MEDICAL
Motion For Life
7750 Zionsville Road #800
Indianapolis, IN 46268
Phone: 317-536-4870
Fax: 317-536-4872
Toll Free: 1-866-236-8889

Lantz Medical Medicaid Contracts

Updated 09/22/2021

Medicaid, Arizona - 477734

Medicaid, Colorado - 1629037304

Medicaid, Idaho - 1629037304

Medicaid, Illinois - 203319340001

Medicaid, Indiana - 300001010

Medicaid, Iowa - 1629037304

Medicaid, Kentucky - 1629037304

Medicaid, Michigan - 1629037304

Medicaid, New Jersey - 0745731

Medicaid, Ohio - 0434000

Medicaid, Tennessee - 1533452

Medicaid, Wisconsin - Forward Health

Medicaid, Wisconsin - Children's Community Health Plan

7750 Zionsville Road #800
Indianapolis, IN 46268
Phone: 317-536-4870
Fax: 317-536-4872
Toll Free: 1-866-236-8889

September 2021

List of officers and directors.

Lantz Medical, Inc.

President & CEO – Shane Kelly
Secretary & Treasurer – Thierry Arduin
CFO – John Ervin

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/10/2021

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 Shepherd Insurance, LLC 111 Congressional Boulevard Suite 100 Carmel IN 46032	CONTACT NAME: Carrie Bolton PHONE (A/C, No, Ext): (317) 846-5554 FAX (A/C, No): (317) 846-5444 E-MAIL ADDRESS: cbolton@shepherdins.com
INSURED Lantz Medical, Inc. 7750 Zionsville Road Suite 800 Indianapolis IN 46268	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Citizens Insurance Company Of America — 31534 INSURER B: Allmerica Financial Benefit Insurance Company — 41840 INSURER C: The Hanover Insurance Company — 22292 INSURER D: INSURER E: INSURER F:

COVERAGES CERTIFICATE NUMBER: CL219943372 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 [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [X] LOC [ ] OTHER			Z7W-D688861-03	09/07/2021	09/07/2022	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			AWW-D688856-03	09/07/2021	09/07/2022	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ N/A			U7W-D688858-03	09/07/2021	09/07/2022	EACH OCCURRENCE AGGREGATE	$ 4,000,000 $ 4,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			W2W-D689210-03	09/07/2021	09/07/2022	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
C	Life Sciences Blended Liability Policy - Products Liability			LHW-D688857-03	09/07/2021	09/07/2022	Aggregate Limit Claim Limit Claim Deductible	$5,000,000 $5,000,000 $10,000

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

Commercial General Liability Broadening Endorsement Form #421-2915 06 15 Included (Additional Insured - Primary & Non-Contributory / Additional Insured By Contract, Agreement or Permit / Blanket Waiver of Subrogation); Commercial General Liability Enhancement Endorsement - Life Sciences Form #421-3587 06 16 Included (Aggregate Limit Per Location); Business Auto Coverage Broadening Endorsement Form #461-0155 (9-97) Included (Blanket Waiver of Subrogation Applies Per Written Contract).

CERTIFICATE HOLDER	CANCELLATION
Lantz Medical, Inc. 7750 Zionsville Rd Suite 800 Indianapolis IN 46268	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 Carrie Bolton

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Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Home Medical Equip Service Provider

License Number	Expire Date
69000081A	12/31/2023

Lantz Medical, Inc.

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

Home Medical Equip Service Provider

License Number	Expire Date
69000081A	12/31/2023

Lantz Medical, Inc.

Signature _____

REGISTERED RETAIL MERCHANT CERTIFICATE

INDIANA DEPARTMENT OF REVENUE
100 N SENATE AVE
INDIANAPOLIS IN 46204-2253
(317) 232-2240

LANTZ MEDICAL INCORPORATED
7750 ZIONSVILLE RD STE 800
INDIANAPOLIS IN 46268-5128

IS AUTHORIZED TO COLLECT INDIANA RETAIL SALES TAX AT THE ADDRESS ABOVE IF DIFFERENT FROM BELOW.

FEIN	20-3319340
LOC ID	0122639995-001
ISSUED	**December 02, 2021**
EXPIRES	**December 31, 2023**

THIS LICENSE:
IS NOT TRANSFERRABLE TO ANY OTHER PERSON.
IS NOT SUBJECT TO REBATE.
IS VOID IF ALTERED.

LANTZ MEDICAL INCORPORATED
7750 ZIONSVILLE RD STE 800
INDIANAPOLIS IN 46268-5128

Robert J. Zeunert J.

COMMISSIONER

MUST BE DISPLAYED BY MERCHANT IN THE LOCATION SHOWN

---------- (Cut or Fold Here) ----------

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, HOLLI SULLIVAN, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

LANTZ MEDICAL, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on August 08, 2005, and was in existence or authorized to transact business in the State of Indiana on September 22, 2021.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.

In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, September 22, 2021

HOLLI SULLIVAN
SECRETARY OF STATE

2005081100384 / 20212219174

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on October 22, 2021.

STOCK POWER

FOR GOOD AND VALUABLE CONSIDERATION, the receipt and sufficiency of which is hereby acknowledged, the undersigned hereby assigns, conveys and transfers to TL Indiana Holdings, Inc. all of the shares of Lantz Medical, Inc. (the "Company") owned by him, including, without limitation, forty-five (45) shares of Class B common stock which are represented by Certificate Nos. 3 and 12 and which are registered in the name of the undersigned on the books of the Company.

The undersigned hereby irrevocably constitutes and appoints each of the President and Secretary of the Company as the undersigned's attorney to transfer such shares on the books of the Company, with full power of substitution in the premises.

IN WITNESS WHEREOF, the undersigned has executed this Stock Power effective as of December 27, 2019.

Perry L Mervar

Perry Mervar

US.125965628.01

STOCK POWER

FOR GOOD AND VALUABLE CONSIDERATION, the receipt and sufficiency of which is hereby acknowledged, the undersigned hereby assigns, conveys and transfers to TL Indiana Holdings, Inc. all of the shares of Lantz Medical, Inc. (the "Company") owned by him, including, without limitation, the fifty-one (51) shares of Class A common stock which are represented by Certificate No. 10 and nine (9) shares of Class B common stock which are represented by Certificate No. 11 all of which are registered in the name of the undersigned on the books of the Company.

The undersigned hereby irrevocably constitutes and appoints each of the President and Secretary of the Company as the undersigned's attorney to transfer such shares on the books of the Company, with full power of substitution in the premises.

IN WITNESS WHEREOF, the undersigned has executed this Stock Power effective as of December 27, 2019.

Ted Brown

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) Administrator Application

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Lantz Medical, Inc. MDEG License # (if applicable) _____

Physical Address 7750 Zionsville Rd, Suite 800

City Indianapolis State IN Zip 46268

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 317-536-4870 Website www.lantzmedical.com

Licensing Company Email jaddington@lantzmedical.com

Section 2: Personal Information

First Perry Middle L Last Mervar

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

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

Mailing Address [redacted] South Christian Dr

City Nineveh State IN Zip 46164

Telephone [redacted] Email pmervar@lantzmedical.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)	
Roncalli High School		1984 - 1988	
Address	**City**	**State**	**Zip**
3300 Prague Rd	Indianapolis	IN	46227
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Indiana University/Purdue University - Indianapolis (IUPUI)		1992 - 1997	
Address	**City**	**State**	**Zip**
420 University Blvd	Indianapolis	IN	46202
Diploma/Degree obtained, if any			
Bachelors Degree - Occupational Therapy			

School Name		From - To (MM/YY – MM/YY)	
University of Indianapolis		2017 - 2019	
Address	**City**	**State**	**Zip**
1400 E Hanna Ave	Indianapolis	IN	46227
Diploma/Degree obtained, if any			
Masters Degree of Strategic Leadership and Design			

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
2015 - 2020	[redacted] Friendship Dr	Indianapolis	IN	46217
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2010 - 2015	841 Burgess Hill Dr	Westfield	IN	46
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 direct patient-care 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)	
Lantz Medical, Inc.			08/05 - Present	
Business Address		**City**	**State**	**Zip**
7750 Zionsville Rd, Ste 800		Indianapolis	IN	46268
Phone	**Title**		**Number of Employed Hours**	
317-536-4870	Vice President of Clinical Education		40/week x 16 years	
Description of Duties				
Co-owner and founder of Lantz Medical. Provided patient service since 2005. Currently Vice President of Clinical Ed.				

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

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

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description 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, Perry Mervar, **certify that as the MDEG Administrator for**

Lantz Medical, Inc.,

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

1. PLM Have a high school diploma or its equivalent;
2. PLM Have
   a. At least 1,500 hours of verifiable direct patient-care 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. PLM 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. PLM 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.

Perry Mervar
Print Name (First, Last)

Perry L. Mervar, MS, OT
Original Signature (electronic, copies or stamps not accepted)

10/1/2021
Date

Board Use Only	Date Received:

Olivia Mora

From: Perry L. Mervar <pmervar@lantzmedical.com>
Sent: Tuesday, January 11, 2022 11:51 AM
To: Olivia Mora
Cc: Perry L. Mervar
Subject: Re: MDEG Administrator Application for Lantz Medical Inc

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Olivia,

I would be classified as:

Administrator for MDEG purposes.

I appreciate your help in the process.

Regards,

Perry L. Mervar MS, OT
Vice President of Clinical Education
Office: 317-536-4870 X239 - Mobile: 317-339-1113 Fax: 844-271-1204
pmervar@lantzmedical.com

LANTZ MEDICAL
Motion For Life

Lantz Medical
7750 Zionsville Rd., Suite 800
Indianapolis, IN 46268
www.lantzmedical.com

HIPAA E-mail Disclaimer
PRIVILEGED/CONFIDENTIAL TRANSMISSION: The materials enclosed with this transmission are the private confidential property of Lantz Medical, and the materials are privileged communications intended solely for the recipient, use, benefit and information of the intended recipient. If you are not the intended recipient, you are hereby notified that any review, disclosure, copying, distribution, or the taking of any other action in reliance on the contents of this transmission are strictly prohibited, and may result in legal liability on your part. If you have received this transmission in error, please notify us immediately at (317) 536-4870 and arrange for return of this transmission to Lantz Medical. Thank you.

From: Olivia Mora <o.mora@pharmacy.nv.gov>
Sent: Tuesday, January 11, 2022 2:00:47 PM
To: Perry L. Mervar <pmervar@lantzmedical.com>
Subject: MDEG Administrator Application for Lantz Medical Inc

You don't often get email from o.mora@pharmacy.nv.gov. Learn why this is important

Hello Perry,

After reviewing the MDEG Administrator Application. I have the following question.

Are you an owner, part of the list of officers for Lantz Medical Inc, or will be only the MDEG Administrator?

If you can please let me know. Thank you.

Olivia Mora
Licensing Specialist
Nevada State Board of Pharmacy
(775) 850-1440
o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

4E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks 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 Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

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 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: American Regent, Inc.

Physical Address: 6610 New Albany Rd East

City: New Albany State: OH Zip Code: 43054

Telephone Number: 6144362222 Fax Number: 8552689580

Toll Free Number: _____

E-mail: Licensing@americanregent.com Website: www.americanregent.com

Facility Manager: Granger McLaughlin

Professional qualifications and experience of facility manager: Please see attached CV

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☑ Practitioners ☑ Hospitals ☑ Wholesalers
☑ Other: Veterinarians

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☑ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☑ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑ IN PROCESS
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: American Rengent, Inc.
Address: 26 Precision Drive, Shirley, NY 11967

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

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 ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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, site 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.

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 pharmacy 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.

Gretchen Fritz

Original Signature of Person Authorized to Submit Application, no copies or stamps

Gretchen Fritz - VP, CLO & Corporate Secretary

Print Name of Authorized Person

26 APR 2024

Date

Board Use Only	Date Processed:	Amount: 500 Check # 812356

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: New York

Parent Company if any: Daiichi Sankyo, Inc.

Mailing Address: 6610 New Albany Rd East

City: New Albany State: OH Zip: 43054

Telephone: 6144362222 Fax: 8552689580

Contact Person: Jennifer Minter

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 Business Address

b) N/A
Name Business Address

c) N/A
Name Business Address

d) N/A
Name Business Address

2) Provide the number of shares issued by the corporation. *Please see attached letter*

3) What was the price paid per share? *Please see attached letter*

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation

List of officers and directors

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.

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, 2023.

American Regent, Inc.

6610 NEW ALBANY ROAD EAST

NEW ALBANY, OH 43054

License Number: 0132000087

Wholesaler - Category 3

Expiration Date: June 30, 2023

CLASS: Wholesaler - Category 3
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
Granger McLaughlin	

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

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 AMERICAN REGENT, INC., a New York corporation, having qualified to do business within the State of Ohio on March 15, 2019 under License No. 4305336 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 9th day of December, A.D. 2021.

Ohio Secretary of State

Validation Number: 202134300850

85/525 1:4
AMERICAN REGENT, INC.
6610 NEW ALBANY RD E
NEW ALBANY, OH 43054-8730

10002652 . 2/001141-1/1-0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0612057	06-30-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N	DISTRIBUTOR	11-17-2021

AMERICAN REGENT, INC.
AMERICAN REGENT, INC.
6610 NEW ALBANY RD E
NEW ALBANY, OH 43054-8730

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
RA0612057	06-30-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N	DISTRIBUTOR	11-17-2021

AMERICAN REGENT, INC.
AMERICAN REGENT, INC.
6610 NEW ALBANY RD E
NEW ALBANY, OH 43054-8730

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)

Drug Establishments Current Registration Site

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

New Search

Search Results for **American Regent, Inc.**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
American Regent, Inc.	2410375	002033710	ANALYSIS; MANUFACTURE; STERILIZE;	5 Ramsey Road, Shirley, New York (NY) 11967, United States (USA)	12/31/2022
American Regent, Inc.	3003433784	116981917	ANALYSIS;	960 Crupper Avenue, Columbus, Ohio (OH) 43229, United States (USA)	12/31/2022
American Regent, Inc.	3005761472	606821721	MANUFACTURE;	4150 Lyman Drive, Hilliard, Ohio (OH) 43026, United States (USA)	12/31/2022
American Regent, Inc.	3010209784	027223179	MANUFACTURE;	6610 New Albany Road East, New Albany, Ohio (OH) 43054, United States (USA)	12/31/2022

Showing 1 to 4 of 4 entries

Previous 1 Next

Data Current through: Tuesday, Dec 7, 2021

Return to Drug Firm Annual Registration Status Home Page

Verified MS
12/29/21

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

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **AMERICAN REGENT**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
American Regent, Inc.	3010209784	027223179	MANUFACTURE;	6610 New Albany Road East, New Albany, Ohio (OH) 43054, United States (USA)	12/31/2021
American Regent, Inc.	2410375	002033710	ANALYSIS; MANUFACTURE; STERILIZE;	5 Ramsey Road, Shirley, New York (NY) 11967, United States (USA)	12/31/2021
American Regent, Inc.	3003433784	116981917	ANALYSIS;	960 Crupper Avenue, Columbus, Ohio (OH) 43229, United States (USA)	12/31/2021
American Regent, Inc.	3005761472	606821721	MANUFACTURE;	4150 Lyman Drive, Hilliard, Ohio (OH) 43026, United States (USA)	12/31/2021

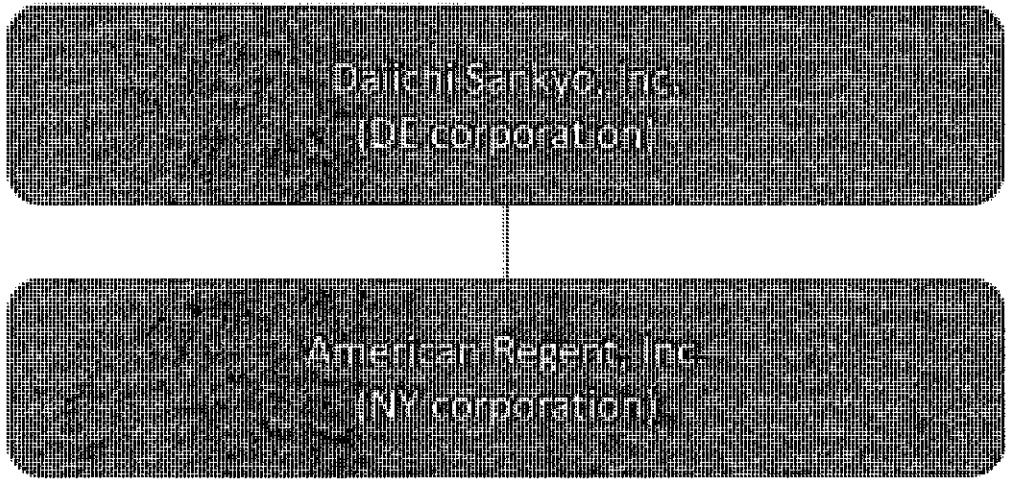
Showing 1 to 4 of 4 entries

Previous1Next

Data Current through: Friday, Feb 5, 2021

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Corporate Organizational Chart



(Formerly Luitpold Pharmaceuticals, Inc.)

AMERICAN REGENT™

Corporate Officers

Paul Diolosa
Title: President/ CEO American Regent, Inc.
Residence Address: [redacted]Balaton Ave, Lake Ronkonkoma, NY 11779
(631) 924-4000

Gretchen Fritz
Title: Secretary
Residence Address: [redacted]Punch Bowl Road, Morristown, NY 07960
(631) 924-4000

Joseph Boyle
Title: Treasurer
Residence Address: [redacted] Hardley Drive, Cranbury, NJ 08512
(631) 924-4000

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 American Regent, Inc.

Physical Address 6610 New Albany Rd East

City New Albany State OH Zip 43054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Granger Middle _____ Last McLaughlin

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

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

Mailing Address [redacted] New Albany Rd East

City New Albany State OH Zip 43054

Telephone [redacted] Email gmclaughlin2@americanregent.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 _____

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)	
Licking Valley High School			08/1985-05/1989	
Address	City		State	Zip
100 Hainsview Dr NE	Newark		OH	43055
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
West Liberty State University			08/1991 - 12/1994	
Address	City		State	Zip
208 University Dr	West Liberty		WV	26074
Diploma/Degree obtained, if any				
BS - Exercise Physiology				
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
02/1971-Current	[redacted] Brownsville Rd	Newark	OH	43055
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)	
American Regent, Inc.			01/2020 - Current	
Business Address		**City**	**State**	**Zip**
6610 New Albany Rd E		New Albany	OH	43054
Phone	**Title**		**Number of Employed Hours**	
614-436-2222	Director - Logistics		3360	
Description of Duties				
Responsible for warehousing, transportation and distribution of pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Covetrus (Formerly Henry Schein Animal Health)			12/2015 - 01/2020	
Business Address		**City**	**State**	**Zip**
3820 Twins Creek Drive		Columbus	OH	43204
Phone	**Title**		**Number of Employed Hours**	
614-272-0406	Director of Operations		6240	
Description of Duties				
Responsible for warehousing, transportation and distribution of pharmaceutical products.				

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				

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)	
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)	
N/A			
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, Granger McLaughlin, **certify that as the designated representative for** American Regent, 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

Granger McLaughlin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-14-21

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.

Granger McLaughlin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-14-21

Date

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

State of Ohio, ss. County of Franklin

I, Granger McLaughlin, 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

12-14-21

Date

Subscribed and Sworn to before me this 14th day of December, 2021

Notary Public Signature

JENNIFER MINTER - NOTARY PUBLIC
COMM EXP: FEB 4, 2025
STATE OF OHIO
(Seal)

Applicant's initials

GRANGER STEWART MCLAUGHLIN

[redacted] Brownsville Road, Newark, Ohio 43056
[redacted]
www.linkedin.com/in/grangermclaughlin/

SUMMARY

Supply Chain Executive with a track record of developing and leading complex solutions that consistently meet financial, operational, quality and organizational goals. An energetic leader of corporate and field teams recognized for building and developing leaders through change management. Excels at establishing and building professional relationships within the organization and industry while instituting best practices through effective management of professional staff and industry metrics. Areas of expertise include:

- P&L Management
- Leadership
- Multi-site Management
- New Facility layout
- Six Sigma (Green Belt)
- Matrix Relationships
- Capital planning/budgeting
- Distribution Management
- Project Management

PROFESSIONAL EXPERIENCE

American Regent — January 2020 to Present

DIRECTOR OF DISTRIBUTION AND WAREHOUSE

Responsible for all company warehouses located in Ohio and New York. Provide strategic vision and tactical direction for the coordination of the receipt, storage, transportation and delivery of goods. Lead and develop staff members in Receiving, Distribution, Warehouse, and Logistics operations, to support company goals. Develop and modify Key Performance Indicators, Standard Operating Procedures, and harmonizing processes across network. Plan, organize, and manage company's internal inventory operations and activities in the area of raw materials and components, which include controlled substances, vendors, planning, warehousing, contract manufacturers, shipping and receiving, and overall customer satisfaction, both internally and externally.

Henry Schein Animal Health/ Covetrus — December 2015 to January 2020

DIRECTOR OF OPERATIONS (2016 - Current)

Lead and directed the startup of new distribution business resulting in over $10M in incremental Operating Income. Designed and managed construction of 120,000 square foot distribution center in Columbus, Ohio. Responsible for all facets of the successful implementation to include full P&L development and execution, managing construction of retrofitting existing building to include capital allocation, recruiting and hiring all team members, transportation routing, Regulatory compliance, selection of new manufacturing partners, development and execution of KPI metrics. Managed relationship between the general contractor and the city officials to ensure compliance during construction.

- Lead $1.7MM in capital expense for construction build out to 30% favorability.
- Doubled year over year operating income contribution.
- Operationalized a third party logistics business to generate $1M in incremental service fees.
- Awarded Verification and Accreditation of Wholesale Distributor (VAWD) designation by NABP.
- Developed and lead cross-functional teams to implement 18 new manufacturing supplier partners in 2 years and managing strategic relationships with key suppliers through Quarterly Business Reviews.
- Develop cost to serve pricing models to validate operational profitability.

MANAGER CENTRAL ZONE (2015-2016)
Led the Central Zone operations of four distribution centers located in Texas, Ohio, Kentucky and Pennsylvania. Accountable for Operational expense, Capital and Profit and Loss budgeting. Directed, developed and built new leadership team across all sites through the implementation of Key Performance Metrics. Executed inbound and outbound logistics strategies that drove operational improvements in productivity, retention, and order fulfillment. Development and execution of operational and sales budget for Central Zone. Collaborate with regional sales leaders to identify, improve, and innovate ways to improve operational efficiency that deliver the best customer experience.

- Directed 125 team members in 274,000 square feet including controlled substances and vault locations and $80MM in inventory assets.
- Lead productivity improvement of 20% and reduced turnover on team of 130 by 15%
- Managed 40% sales growth of over $425MM

DHL Supply Chain North America, Exel

MANAGER, BUSINESS DEVELOPMENT August 2014 to December 2015
Create advanced supply chain solutions focused on efficiency and cost savings. Nurture relationships with new and existing customers in the development of solutions focused on Logistics in the Warehousing and Distribution services as well as other solutions within DPDHL Supply Chain's portfolio. Facilitate new business opportunities, seek to understand their business objectives and organizational goals through proactive account management. Manage a team of cross functional internal business partners in the development of specific responses to Request for Proposal bid activity.

Innotrac, Corp

SENIOR DIRECTOR, CLIENT SERVICES October 2013 to June 2014
Responsible for managing 3PL contracts, executive relationships and achievement of strategic growth strategies of major clients. Mentor, train and guide a team of Account Managers and Directors in the day-to-day client management focused on growing revenue and profit for the company and the client. Develop key performance metrics tied to contractual obligations for review during quarterly business reviews.

Cardinal Health, LLC, Dublin, OH 2002 to 2013

SUPPLY CHAIN EXECUTIVE, Hospital Supply Solution (2010–2013)
Led consultative engagements to assess, develop solution project plans, write, negotiate and execute contracts to the satisfaction of our customer. Promoted the capabilities and services from all Cardinal Health business units by serving as the industry leader in supply chain management resulting in service fees.

- Initiated and created a separate P&L to support business case which led to growing Inventory Management Service offerings into national offering.
- Grew service offering from $85k to $1.3M in service fees in three years representing 27% of business unit.
- Designed and staffed specific solutions to meet customer needs that supported strategic customer wins/retention.
- Built team of field based managers and onsite analyst to support sales and customers expectations.

DIRECTOR, MARKETING PRODUCT MANAGEMENT, Hospital Supply (2008–2010)
Developed, launched, and managed new and existing service offerings for Hospital Supply customers. Provided sales training and Market leadership for regional sales teams. Managed a team of office and field based market managers responsible for the marketing collateral, business impact and execution of service offerings.

- Developed the go-to-market strategy and sales positioning for Inventory Management offerings.
- Developed and led Regional and National sales training and identified sales targets and metrics.
- Lead corporate and field team to manage Inventory management offerings through KPI metrics.
- Grew Inventory Management offering customers by 200% and sales by $1M.

DIRECTOR, Business Development and Sales, Pharmaceutical Repackaging *(2007 – 2008)*
Developed and marketed Pharmaceutical Repackaging service offerings focused on driving pharmacy operational efficiencies, patient safety, and profitability within all classes of trade within the pharmacy businesses by utilizing our cGMP facility.

- Developed and launched a new Physician Dispensing repackaging solution that met the unique needs for dispensing of a limited formulary of medications from the physician office.
- Developed alternative distribution solution for Track and Trace Florida customers requesting controlled Rx.
- Implemented pedigree distribution model for national long term care customer and national retail independent chain resulting in $24M and $200M in sales respectfully.
- Led ReadyScan® pouch growth by over 60% in FY'08 through strategic additions.
- Customized arbitrage offering to meet customers' specific needs that increased their operational efficiencies.

DISTRIBUTION MANAGER, Supply Chain Services, Medical *(2005 – 2007)*
Managed 230K sq. ft. distribution center processing over 2.4M parcels annually between two business units. Managed all aspects of distribution including Receiving, Put away, Pick, Pack and Shipping of Medical Surgical, Ambulatory Care, Lab & IV products to over 400 customers in region. Provided leadership, direction, training and guidance to a team of 60 employees with 8 direct reports. Fully supported sales, inventory, customer service and transportation teams to meet all customer expectations relative to service, timely delivery, fill rates and quality control within the distribution environment. Supported safety, quality and regulatory training programs.

- Selected to lead the first implementation for new warehouse technologies (Auto Put away, Pick to Voice) throughout WMS.
- Managed $3.5M budget to 5% favorability.
- Decreased discrepancies with ValueLink® Customer by 57% FY06 and increased productivity by 3%
- Awarded "Distribution Center of the Year" among 48 distribution centers nationally.

LOGISTICS MANAGER *(2002 – 2005)*
Contracted materials management manager of Grant Medical Center; a 640 beds, Ohio Health managed facility. Managed the LUM inventory and a team of 30 employees, which included the receiving dock, supply and linen distribution and a $2M operating budget.

- Reduced customer's inventory by over $100K while increasing item count and fill rate by 10% and improved turn rate by 50%.
- Successfully managed the transition and responsibility of a $500K linen distribution and staff of seven.
- Implemented Lean/Six Sigma process improvements for staffing and 39 asset locations.
- Managed $270,000 daily asset inventory, supplying all hospital supplies totaling $3.2M annually.

EDUCATION

West Liberty University, West Liberty, West Virginia
Bachelor of Science degree

INDUSTRY/PROFESSIONAL ASSOCIATIONS, CERTIFICATIONS

Certified Designated Representative – California Board of Pharmacy, Florida Board of Pharmacy
Association Resource for Healthcare and Materials Management (ARHMM), American Marketing Association, American College Healthcare Executives, Marketing Leadership Council (2010-2013)

Employee Name	Location ID
Adjei-Manu, Michael	Ohio New Albany
Adoma, Nana	Ohio New Albany
Ahmed, Imran	Ohio New Albany
Alberson, Daniel	Ohio New Albany
Alicea, Gladys	Ohio New Albany
Alvarez, Jenny	Ohio New Albany
Amin, Biren	Ohio New Albany
Ampofo, Gloria	Ohio New Albany
Andrade, David	Ohio New Albany
Andrews, Rebecca	Ohio New Albany
Anyarambhatla, Gopal	Ohio New Albany
Arhin, Michael	Ohio New Albany
Armstrong, Jared	Ohio New Albany
Asare, Florence	Ohio New Albany
Ault, Rick	Ohio New Albany
Aurelien, Donadoni	Ohio New Albany
Baker, Dustin	Ohio New Albany
Bates, Joshua	Ohio New Albany
Baughman, Jonathan	Ohio New Albany
Baum, Thea	Ohio New Albany
Belford, Mark	Ohio New Albany
Bell, Benjamin	Ohio New Albany
Bell, Brailyn	Ohio New Albany
Bell, Brianna	Ohio New Albany
Bice, Susan	Ohio New Albany
Billy, Joshua	Ohio New Albany
Bini, Pascale	Ohio New Albany
Blackman, Mark	Ohio New Albany
Boateng, Stephen	Ohio New Albany
Bozeman, Michael	Ohio New Albany
Bozeman, Phenia	Ohio New Albany
Breidenbaugh, Kari	Ohio New Albany
Brown, Adam	Ohio New Albany
Brown, Ernest	Ohio New Albany

Bruemmer, Andrew	Ohio New Albany
Brunner, David	Ohio New Albany
Bryant, Sidney	Ohio New Albany
Burchfield, Madison	Ohio New Albany
Butler, Karen	Ohio New Albany
Cahill, Benjamin	Ohio New Albany
Cain, Katrina	Ohio New Albany
Caldwell, Thomas	Ohio New Albany
Camboni, Marybeth	Ohio New Albany
Cannella, Janice	Ohio New Albany
Caslow, Susan	Ohio New Albany
Castaldi, Jennifer	Ohio New Albany
Centofanti, Lindsay	Ohio New Albany
Cesear, James	Ohio New Albany
Chede, Laxmi	Ohio New Albany
Chen, Shi	Ohio New Albany
Chhith, Calvary	Ohio New Albany
Christenson, Beau	Ohio New Albany
Chupka, Thomas	Ohio New Albany
Civcic, Vedran	Ohio New Albany
Close, Jennifer	Ohio New Albany
Cocklin, Lauren	Ohio New Albany
Coe, Valerie	Ohio New Albany
Coffee, John	Ohio New Albany
Conti, Deanna	Ohio New Albany
Cook, Greg	Ohio New Albany
Cottrell, LaVonté	Ohio New Albany
Coy, Anastasia	Ohio New Albany
Cramer, Jodi	Ohio New Albany
Cutie, John	Ohio New Albany
Darfus, Leila	Ohio New Albany
Das, Subhradeep	Ohio New Albany
Dean, Melissa	Ohio New Albany
Decker, Sam	Ohio New Albany
Derr, Whitney	Ohio New Albany
DeRussy, Dina	Ohio New Albany
Deshmukh, Vaidehi	Ohio New Albany
Dickess, Christopher	Ohio New Albany
Dowe Sr., Gerald	Ohio New Albany
Drake, Iris	Ohio New Albany

Drennen, Steven	Ohio New Albany
Duako, Regina	Ohio New Albany
Ducay, Daron	Ohio New Albany
Duong, Jason	Ohio New Albany
Dury, Ellen	Ohio New Albany
Elmagdoub, Zahraa	Ohio New Albany
Eltman, Maria	Ohio New Albany
Epperly, Amy	Ohio New Albany
Ernst, Elizabeth	Ohio New Albany
Erpenbeck, Jacob	Ohio New Albany
Erwine, Jay	Ohio New Albany
Falcone, Christopher	Ohio New Albany
Fife, Erin	Ohio New Albany
Finzer, Brant	Ohio New Albany
Flick, Aaron	Ohio New Albany
Flittner, Rudolf	Ohio New Albany
Flores, Catherine	Ohio New Albany
Frimpomaa, Millicent	Ohio New Albany
Frost, John	Ohio New Albany
Fusselman, Gregory	Ohio New Albany
Gabriel, Adam	Ohio New Albany
Gambrell, Dakota	Ohio New Albany
Gazinski, Thomas	Ohio New Albany
Gicev, Dragan	Ohio New Albany
Glover, Stephanie	Ohio New Albany
Goodlow, Delon	Ohio New Albany
Gorla, Srinivasa	Ohio New Albany
Gory, Chelsea	Ohio New Albany
Gray, Allison	Ohio New Albany
Gyampoh, Samuel	Ohio New Albany
Hall, Jack	Ohio New Albany
Hannah, Charles	Ohio New Albany
Harris, Ryan	Ohio New Albany
Haver, Jason	Ohio New Albany
Heltz, Tony	Ohio New Albany
Hoobler, Dennis	Ohio New Albany
Horne, Marcia	Ohio New Albany
Howard, Henry	Ohio New Albany
Hoy, Chelsea	Ohio New Albany
Hubena, Soretti	Ohio New Albany
Huguely, Catherine	Ohio New Albany

Jaber, Jenin	Ohio New Albany
Jaleta, Kassahun	Ohio New Albany
James, Erini	Ohio New Albany
James, Roshan	Ohio New Albany
Janes, Christine	Ohio New Albany
Jenkins, Korina	Ohio New Albany
Jewell, Brent	Ohio New Albany
Johnson, Donald	Ohio New Albany
Johnson, Kara	Ohio New Albany
Johnson, Kevin	Ohio New Albany
Johnston, Leslie	Ohio New Albany
Karki, Rajeep	Ohio New Albany
Karnai, Elek	Ohio New Albany
Kasonga, Beya	Ohio New Albany
Kee, Darlene	Ohio New Albany
Kemmer, Susan	Ohio New Albany
Kim, Jeongah	Ohio New Albany
Kimble, Tim	Ohio New Albany
Koch, John	Ohio New Albany
Konko, Lex	Ohio New Albany
Koranteng, Rita	Ohio New Albany
Kratzer, Michael	Ohio New Albany
Kroeger, Thomas	Ohio New Albany
Kumar, Amit	Ohio New Albany
Kwast, Kerry	Ohio New Albany
Landgraver, Brian	Ohio New Albany
Landy, Thomas	Ohio New Albany
Leroy, William	Ohio New Albany
Lisska, Paul	Ohio New Albany
Luke, Spencer	Ohio New Albany
Mann, Calvin	Ohio New Albany
Marfo, Stephen	Ohio New Albany
Markette, Gary	Ohio New Albany
Mathias, Steven	Ohio New Albany
Mccann, Emily	Ohio New Albany
McCollum, Jessica	Ohio New Albany
Mckee, Michael	Ohio New Albany
Mclaughlin, Granger	Ohio New Albany
McMahon, Eamonn	Ohio New Albany
Mensah, Cyril	Ohio New Albany
Merritt, Leah	Ohio New Albany
Miller, Colbert	Ohio New Albany
Minter, Jennifer	Ohio New Albany
Mohamed, Meriem	Ohio New Albany

Morasse, Rick	Ohio New Albany
Moro, Edward	Ohio New Albany
Morris, Alexander	Ohio New Albany
Morrison, William	Ohio New Albany
Moskos, Nathan	Ohio New Albany
Moss, Dianne	Ohio New Albany
Muhlenkamp, Katherine	Ohio New Albany
Neely, Anthony	Ohio New Albany
Nehrbass, Samantha	Ohio New Albany
Nguyen, Hiep	Ohio New Albany
Nixon, Derek	Ohio New Albany
O'Malley, Ryan	Ohio New Albany
Obringer, Mason	Ohio New Albany
Ochiai, Atsushi	Ohio New Albany
Ofori, Ruth	Ohio New Albany
Olive, Joshua	Ohio New Albany
Opoku, Eric	Ohio New Albany
Osei, Elizabeth	Ohio New Albany
Osentoski, Lindsay	Ohio New Albany
Pannell, Steven	Ohio New Albany
Parikh, Heni	Ohio New Albany
Patel, Bhoomi	Ohio New Albany
Patel, Jigar	Ohio New Albany
Patel, Jyoti	Ohio New Albany
Patel, Nainesh	Ohio New Albany
Patel, Priyanka	Ohio New Albany
Patel, Saral	Ohio New Albany
Patterson, James	Ohio New Albany
Paul, James	Ohio New Albany
Peace, Sean	Ohio New Albany
Peck, Michelle	Ohio New Albany
Pelaketiyage, Lisa	Ohio New Albany
Perry, Kelsey	Ohio New Albany
Pisano, Robert	Ohio New Albany
Poff, Tyler	Ohio New Albany
Poku, Kwame	Ohio New Albany
Poulin, Denise	Ohio New Albany
Purushothaman Nair, Vipin	Ohio New Albany
Rains, Kristan	Ohio New Albany
Robbins, Melanie	Ohio New Albany
Rodriguez, Gil	Ohio New Albany
Roettger, Michelle	Ohio New Albany

Rogers, Dillon	Ohio New Albany
Roush, David	Ohio New Albany
Rutaihwa, Evelyn	Ohio New Albany
Ryan, Timothy	Ohio New Albany
Sadhukha, Tanmoy	Ohio New Albany
Salem, Ahmed	Ohio New Albany
Saunders, Arianne	Ohio New Albany
Saw, Sebastian	Ohio New Albany
Schmidt, Jerilyn	Ohio New Albany
Schmidt, Raymond	Ohio New Albany
Shepherd, Sarah	Ohio New Albany
Sheth, Nilesh	Ohio New Albany
Shinsky, Joshua	Ohio New Albany
Shrestha, Maya	Ohio New Albany
Simmerman, Frances	Ohio New Albany
Simmerman, Sarah	Ohio New Albany
Smith, Kathleen	Ohio New Albany
Sow, Kadiatou	Ohio New Albany
St-Marc, Judith	Ohio New Albany
Steere, William	Ohio New Albany
Stiers, Gregory	Ohio New Albany
Strawser, Jonathan	Ohio New Albany
Strong, Lynn	Ohio New Albany
Sullinger, Joshua	Ohio New Albany
Tassos, Nicholas	Ohio New Albany
Taylor, Jerry	Ohio New Albany
Terry, Amy	Ohio New Albany
Tewelde, Natnael	Ohio New Albany
Thesing, Anthony	Ohio New Albany
Thompson, Jeannette	Ohio New Albany
Thompson, Kevin	Ohio New Albany
Thompson, Tavia	Ohio New Albany
Todorova, Monika	Ohio New Albany
Tomashuk, Timothy	Ohio New Albany
Trupp, Robert	Ohio New Albany
Turner, Stephanie	Ohio New Albany
Villiers, Kevin	Ohio New Albany
Wade, Amy	Ohio New Albany
Walker, Colton	Ohio New Albany

Walp, Nicholas	Ohio New Albany
Weaver, John	Ohio New Albany
Wehrung, Daniel	Ohio New Albany
Wetmore, David	Ohio New Albany
White, Curtis	Ohio New Albany
White, Natasha	Ohio New Albany
Wilcox, Chelsi	Ohio New Albany
Wills, Veronica	Ohio New Albany
Wilson, Benjamin	Ohio New Albany
Wilson, Hilary	Ohio New Albany
Winn, Jermaine	Ohio New Albany
Winston, David	Ohio New Albany
Wood, Hilary	Ohio New Albany
Woodard, Scott	Ohio New Albany
Wright, Kendall	Ohio New Albany
Yarnevic, Kari	Ohio New Albany
Yazid, Ghiles	Ohio New Albany
Yeh, Jihee	Ohio New Albany
Young Jr, Kevin	Ohio New Albany
Young, Joseph	Ohio New Albany
Zhang, Ting	Ohio New Albany
Zhang, Xinyi	Ohio New Albany
Zhang, Xiufang	Ohio New Albany
Zhong, Meng	Ohio New Albany
Ziba, Taonga	Ohio New Albany
Zuercher, Brian	Ohio New Albany

AMERICAN REGENT™

Disciplinary Action History – American Regent, Inc.

Ohio Board of Pharmacy – April, 2021

American Regent, Inc. Wholesale Distributor and Manufacturer licensee, located at 6610 New Albany Road East, New Albany, OH 43054, has never been disciplined.

However, American Regent, Inc. Analytical Lab licensee, located at 6610 New Albany Road East, New Albany, OH 43054, was disciplined for allegedly failing to verify a supplier. American Regent, Inc. has paid a fine to the Ohio Board of Pharmacy.

5 Ramsey Road \\ Shirley, NY 11967
T 631.924.4000 \\ F 631.924.1731 \\ americanregent.com

A Daiichi Sankyo Group Company

STATE OF OHIO BOARD OF PHARMACY

American Regent
c/o Gopal Anyarambhatla
6610 New Albany Road, East
New Albany, OH 43054

Re: Settlement Agreement
License No 02-72000032

April 2, 2021

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of **April 2, 2021**. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Paula Economus

Paula Economus
Legal Administrative Assistant

Enclosure: April 2, 2021 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 7019 2280 0000 1171 9897

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0526
I-2020-1052

American Regent Inc.
c/o Gopal Anyarambhatla
6610 New Albany Road East
New Albany, Ohio 43054

License No. 02-72000032

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 American Regent Inc. (American Regent) for the purpose of resolving all issues between the parties relating to the Board investigation of illegal purchases of dangerous drugs from an unlicensed entity. Together, the Board and American Regent are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. American Regent is a licensed Terminal Distributor of Dangerous Drugs under license number 02-72000032.

FACTS

1. The Board initiated an investigation of American Regent, Terminal Distributor of Dangerous Drugs license number 02-72000032, related to American Regent's illegal purchases of dangerous drugs from an unlicensed entity.

2. On or about March 10, 2021 the Board sent a Notice of Opportunity for Hearing to American Regent, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial 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. American Regent neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 10, 2021; 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. American Regent agrees to pay to the Board a monetary penalty the amount of $125.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. American Regent agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. American Regent agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by American Regent of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to American Regent by the Board and will NOT discharge American Regent from any obligation under the terms of this Agreement.

6. American Regent agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. American Regent understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom American Regent will operate.

9. American Regent waives its right to a hearing and 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. 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:

Anyarambhatla — Mar 24 2021

Gopal Anyarambhatla, on behalf of,
American Regent Inc., Respondent — Date of Signature

Attorney for Respondent (if applicable) — Date of Signature

Jennifer Rudell, RPh — April 2, 2021

Jennifer Rudell, RPh, President,
State of Ohio Board of Pharmacy — Date of Signature

April 2, 2021

Henry Appel, Ohio Assistant Attorney General — Date of Signature

TRAVELERS

Travelers Casualty and Surety Company of America

License No. N/A

RIDER

To be attached to and form part of Bond No. 107260257.

Issued on behalf of American Regent, Inc. as Principal, and in favor of Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to Add the Address:

Add: 6610 New Albany Rd East, New Albany, OH 43054

to: n/a

☐ 3. The Surety hereby gives its consent to change the _____:

from: _____

to: _____

This rider shall become effective as of April 19, 2021.

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated April 19, 2021.

Travelers Casualty and Surety Company of America

By: Marisol Mojica

Marisol Mojica
Attorney-in-Fact

Accepted: Nevada State Board of Pharmacy
Obligee

By: _____

or American Regent, Inc.
Principal

By: [signature]

S-4111 (8/66)

ACKNOWLEDGEMENT

NOTE: Persons signing in more than one capacity (i.e. president and as individual) must be acknowledged for each capacity.

State of **New Jersey**
County of **Hudson** } SS

On the **16th** day of **September** 2020 Before me, **Victoria L. Ernest**, personally appeared **Marisol Mojica as Attorney in Fact of the Travelers Casualty and Surety Company of America** ☐ 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.

MY COMMISSION EXPIRES
AUGUST 09, 2023

Victoria L. Ernest
Notary Public *(seal)*

OPTIONAL

☐ Individual ☐ Corporate Officer ☒ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General
☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

State of NEW JERSEY
County of MERCER } SS

On the 26th day of OCTOBER 2020 Before me, RAKESH PATEL, personally appeared JOSEPH J Bglin ☐ 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.

RAKESH PATEL
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES OCT. 4, 2024

Rakesh Patel
Notary Public *(seal)*

OPTIONAL

☒ Individual ☒ Corporate Officer ☐ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General
☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

State of _____
County of _____ } SS

On the _____ day of _____ 20 Before me, _____, personally appeared _____ ☐ 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.

Notary Public *(seal)*

OPTIONAL

☐ Individual ☐ Corporate Officer ☐ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General
☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

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 **Marisol Mojica** of **JERSEY CITY** **New Jersey**, 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.**

HARTFORD, CONN. HARTFORD, CONN. CORPORATE SEAL

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 NOTARY PUBLIC CONNECTICUT

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 **16th** day of **September**, **2020.**

HARTFORD, CONN. HARTFORD, CONN. CORPORATE SEAL

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.

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

HARTFORD, CONNECTICUT 06183

FINANCIAL STATEMENT AS OF DECEMBER 31, 2019

CAPITAL STOCK $ 6,480,000

ASSETS		LIABILITIES & SURPLUS	
CASH AND INVESTED CASH	$ 90,238,215	UNEARNED PREMIUMS	$ 1,079,715,557
BONDS	3,590,884,327	LOSSES	772,047,572
STOCKS	297,933,044	LOSS ADJUSTMENT EXPENSES	174,714,866
INVESTMENT INCOME DUE AND ACCRUED	37,250,410	COMMISSIONS	46,970,467
OTHER INVESTED ASSETS	3,986,514	TAXES, LICENSES AND FEES	14,728,588
PREMIUM BALANCES	263,364,263	OTHER EXPENSES	43,134,646
NET DEFERRED TAX ASSET	52,134,926	CURRENT FEDERAL AND FOREIGN INCOME TAXES	12,674,197
REINSURANCE RECOVERABLE	31,203,529	REMITTANCES AND ITEMS NOT ALLOCATED	17,964,746
SECURITIES LENDING REINVESTED COLLATERAL ASSETS	3,732,602	AMOUNTS WITHHELD / RETAINED BY COMPANY FOR OTHERS	26,565,278
RECEIVABLES FROM PARENT, SUBSIDIARIES AND AFFILIATES	11,831,826	RETROACTIVE REINSURANCE RESERVE ASSUMED	826,255
ASSUMED REINSURANCE RECEIVABLE AND PAYABLE	567,396	POLICYHOLDER DIVIDENDS	11,482,845
OTHER ASSETS	3,574,968	PROVISION FOR REINSURANCE	9,837,205
		ADVANCE PREMIUM	2,140,883
		PAYABLE FOR SECURITIES LENDING	3,732,602
		CEDED REINSURANCE NET PREMIUMS PAYABLE	46,059,812
		OTHER ACCRUED EXPENSES AND LIABILITIES	421,937
		TOTAL LIABILITIES	$ 2,263,017,456
		CAPITAL STOCK	$ 6,480,000
		PAID IN SURPLUS	433,803,760
		OTHER SURPLUS	1,683,400,804
		TOTAL SURPLUS TO POLICYHOLDERS	$ 2,123,684,564
TOTAL ASSETS	$ 4,386,702,020	TOTAL LIABILITIES & SURPLUS	$ 4,386,702,020

STATE OF CONNECTICUT)

COUNTY OF HARTFORD) SS

CITY OF HARTFORD)

MICHAEL J. DOODY, BEING DULY SWORN, SAYS THAT HE IS VICE PRESIDENT - FINANCE, OF TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, AND THAT TO THE BEST OF HIS KNOWLEDGE AND BELIEF, THE FOREGOING IS A TRUE AND CORRECT STATEMENT OF THE FINANCIAL CONDITION OF SAID COMPANY AS OF THE 31ST DAY OF DECEMBER, 2019.

Michael J. Doody

VICE PRESIDENT - FINANCE

SUBSCRIBED AND SWORN TO BEFORE ME THIS
26TH DAY OF MARCH, 2020

NOTARY PUBLIC

SUSAN M. WEISSLEDER
Notary Public
My Commission Expires November 30, 2022

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. 107260257

Application/License No. _____

American Regent , Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 26 Precision Drive, Shirley, NY 11967 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (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 1 Tower Square, Hartford, CT 06183 (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 September 16, 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.

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 16th day of September, 20 20.

APPLICANT/PRINCIPAL

COMPANY
American Regent, Inc.

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Marisol Mojica, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Paul Rafferty, As-To-Surety

Witness Yaritza Rosario, As-To-Surety

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

ACKNOWLEDGEMENT

NOTE: Persons signing in more than one capacity (i.e. president and as individual) must be acknowledged for each capacity.

State of **New Jersey**
County of **Hudson** } SS

On the **19th** day of **April** 2021 Before me, **Victoria L. Ernest**, personally appeared **Marisol Mojica as Attorney in Fact of the Travelers Casualty and Surety Company of America** ☐ 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.

Victoria L. Ernest
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50087965
MY COMMISSION EXPIRES August 9, 2023

Notary Public *(seal)*

OPTIONAL

☐ Individual ☐ Corporate Officer ☒ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General ☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

State of New Jersey
County of Mercer } SS

On the 20 day of May 2020 Before me, Timothy Moomaw, personally appeared Joseph Boyle ☐ 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.

TIMOTHY MOOMAW
NOTARY PUBLIC
NEW JERSEY 50080229
EXP 5/8/22

Notary Public *(seal)*

OPTIONAL

☒ Individual ☒ Corporate Officer ☐ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General ☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

State of _____
County of _____ } SS

On the _____ day of _____ 20 Before me, _____, personally appeared _____ ☐ 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.

Notary Public *(seal)*

OPTIONAL

☐ Individual ☐ Corporate Officer ☐ Attorney-in-Fact ☐ Partner – Limited ☐ Partner – General ☐ Trustee ☐ Guardian or Conservator ☐ Titles(s): ____ ☐ Other: ____

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 **Marisol Mojica** of **JERSEY CITY** **New Jersey**, 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 **19th** day of **April**, **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-in-Fact and the details of the bond to which the power is attached.

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

HARTFORD, CONNECTICUT 06183

FINANCIAL STATEMENT AS OF DECEMBER 31, 2020

CAPITAL STOCK $ 6,480,000

ASSETS		LIABILITIES & SURPLUS	
CASH AND INVESTED CASH	$ 239,403,348	UNEARNED PREMIUMS	$ 1,121,070,380
BONDS	3,831,156,861	LOSSES	1,003,200,666
STOCKS	109,074,035	LOSS ADJUSTMENT EXPENSES	163,346,678
INVESTMENT INCOME DUE AND ACCRUED	36,856,709	COMMISSIONS	48,805,693
OTHER INVESTED ASSETS	4,970,512	TAXES, LICENSES AND FEES	13,561,421
PREMIUM BALANCES	277,653,788	OTHER EXPENSES	42,506,558
NET DEFERRED TAX ASSET	55,188,715	CURRENT FEDERAL AND FOREIGN INCOME TAXES	4,865,484
REINSURANCE RECOVERABLE	32,553,518	REMITTANCES AND ITEMS NOT ALLOCATED	8,646,391
RECEIVABLES FROM PARENT, SUBSIDIARIES AND AFFILIATES	34,876,347	AMOUNTS WITHHELD / RETAINED BY COMPANY FOR OTHERS	42,228,250
OTHER ASSETS	4,155,794	POLICYHOLDER DIVIDENDS	12,353,304
		PROVISION FOR REINSURANCE	7,930,280
		ADVANCE PREMIUM	1,867,512
		CEDED REINSURANCE NET PREMIUMS PAYABLE	63,102,972
		RETROACTIVE REINSURANCE RESERVE ASSUMED	800,763
		OTHER ACCRUED EXPENSES AND LIABILITIES	568,668
		TOTAL LIABILITIES	$2,534,855,020
		CAPITAL STOCK	$6,480,000
		PAID IN SURPLUS	433,803,760
		OTHER SURPLUS	1,650,750,847
		TOTAL SURPLUS TO POLICYHOLDERS	$2,091,034,607
TOTAL ASSETS	$ 4,625,889,627	TOTAL LIABILITIES & SURPLUS	$4,625,889,627

STATE OF CONNECTICUT)

COUNTY OF HARTFORD) SS.

CITY OF HARTFORD)

MICHAEL J. DOODY, BEING DULY SWORN, SAYS THAT HE IS VICE PRESIDENT - FINANCE, OF TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, AND THAT TO THE BEST OF HIS KNOWLEDGE AND BELIEF, THE FOREGOING IS A TRUE AND CORRECT STATEMENT OF THE FINANCIAL CONDITION OF SAID COMPANY AS OF THE 31ST DAY OF DECEMBER, 2020.

Michael J. Doody

VICE PRESIDENT - FINANCE

SUBSCRIBED AND SWORN TO BEFORE ME THIS
26TH DAY OF MARCH, 2021

NOTARY PUBLIC

SUSAN M. WEISSLEDER
Notary Public
My Commission Expires November 30, 2022

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Is your facility a reverse distributor? ☐ Yes ☒ No

☒ 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: Currax Pharmaceuticals LLC dba Cypress, Hawthorn and Macoven

Physical Address: 155 Franklin Rd, Suite 450

City: Brentwood State: TN Zip: 37027

Mailing Address (if different from physical address): 155 Franklin Rd, Suite 450

City: Brentwood State: TN Zip: 37027

Telephone: (615) 507-9111 Website: www.curraxpharma.com

Name of Designated Representative (DR): Terry Evans

Licensing Company Email: statelicense@curraxpharma.com DR Email: statelicense@curraxpharma.com

☒ Pharmacies	☒ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	☒ Controlled Substances
☐ Hospitals	☐ Hypodermic Devices
☒ Wholesalers	☐ Veterinary Legend Pharmaceuticals
☐ Others:	☐ 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

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.

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:** _____

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: DE

Parent Company (if any): Currax Holdings USA LLC

Corporation/Organization Name: Currax Pharmaceuticals LLC

Mailing Address: 155 Franklin Rd, Suite 450

City: Brentwood State: TN Zip: 37027

Telephone: (615) 507-9111 Email: tevans@curraxpharma.com

Contact Person Name: Terry Evans

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 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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Terry Evans
Print Name of Authorized Person Submitting Application

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

11/15/2021
Date

Board Use Only	Date Received: _____	Amount: 500 check # 14638 ✓

Received 12/17/21

30338

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000006917
EXPIRATION DATE: 09/30/2023

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
MANUFACTURER
CURRAX PHARMACEUTICALS LLC DBA CYPRESS

COMMISSIONER OF HEALTH

CURRAX PHARMACEUTICALS LLC DBA CYPRESS
HAWTHORN AND MACOVEN
155 FRANKLIN RD, STE 450
BRENTWOOD TN 37027-4646

12729723
30338

State of Tennessee
Department of Health

BOARD OF PHARMACY
MANUFACTURER
CURRAX PHARMACEUTICALS LLC DBA CYPRESS
HAWTHORN AND MACOVEN
155 FRANKLIN RD, STE 450
BRENTWOOD TN 37027

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006917
EXPIRATION DATE: 09/30/2023

CONTROLLED SUBSTANCE REGISTRATION

ASSISTANT COMMISSIONER: HEALTH LICENSURE & REGULATION

COMMISSIONER

Last Updated: 12/2/2021

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 1

Click here to return to the search page

1

Currax Pharmaceuticals LLC dba Cypress
Hawthorn and Macoven 155 Franklin Rd, Ste 450
Brentwood, TN 37027
615-507-9111

Rank: Manufacturer
3PL Address:
420 International Blvd, Suite
Brooks, KY 40109

Facility License Number: 00006917
Status: Licensed
Date of Original Licensure: 09/13/2021
Date of Expiration: 09/30/2023
No Disciplinary Actions

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0248686	11-30-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	11-01-2021

INTEGRATED COMMERCIALIZATION SOLUTIONS, LLC
420 INTERNATIONAL BLVD STE 500
BROOKS, KY 401095309

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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420 INTERNATIONAL BLVD STE 500
BROOKS, KY 401095309

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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)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CURRAX PHARMACEUTICALS 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 TWENTIETH DAY OF JANUARY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CURRAX PHARMACEUTICALS LLC" WAS FORMED ON THE FOURTEENTH DAY OF FEBRUARY, A.D. 2019.

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

Jeffrey W. Bullock, Secretary of State

7282124 8300

SR# 20220193544

Authentication: 202445871

Date: 01-20-22

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

Currax
pharmaceuticals LLC

DESCRIPTION OF OPERATIONS

Currax Pharmaceuticals LLC ("Currax") is a specialty pharmaceutical business focused on acquiring and commercializing prescription drugs within the U.S. market. Currax provides a range of both Branded and generic pharmaceutical products.

THIRD-PARTY LOGISTICS

Currax's products are manufactured by contract manufacturers and distributed to customers by their third-party logistics provider, Integrated Commercialization Solutions, LLC ("ICS"). Currax utilizes the following ICS location for distribution of product:

Integrated Commercialization Solutions, LLC
420 International Blvd, Suite 500
Brooks, KY 40109

CONTRACT MANUFACTURER

Currax uses the following contract manufacturers to produce product:

Halo Pharmaceutical Inc.
30 North Jefferson Rd., Whippany, NJ 07981
FDA Establishment Identifier – 2211084
Mrs. Patricia Lipari
(973) 428-4343

Patheon Pharmaceuticals Inc.
2110 E Galbraith Rd., Cincinnati, OH 45237
FDA Establishment Identifier – 1510437
Mrs. Kristen Perkins
(513) 948-7964

Contract Pharmacal Corporation
135 Adams Avenue, Hauppauge, NY 11788
FDA Establishment Identifier – 2427358
Mrs. Brandy McCrary
(336) 252-3415

PRODUCTS

As a virtual manufacturer, Currax does not manufacture, distribute or store product. At no time does any contract manufacturers own Currax's products, contract with Currax's customers, invoice or sell Currax drugs. Currax's products are controlled substances. Accordingly, Currax has provided the DEA registration of their 3PL provider, ICS.

Labeler Codes: 42847, 44183, 60258

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PIN IT (HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

±

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

PRINT

Current through December 02, 2021

You have searched Finished drug products

Search Results: *'44183'*

Back to Search Page () | **Search Again ()**

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 Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
doxepin hydrochloride	44183-103-30	3 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC dba Cypress, Hawthorn, Macoven	44183-103	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA AUTHORIZED GENERIC	30 TABLET in 1 BOTTLE (44183-103-30)
doxepin hydrochloride	44183-106-30	6 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC dba Cypress, Hawthorn, Macoven	44183-106	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA AUTHORIZED GENERIC	30 TABLET in 1 BOTTLE (44183-106-30)
Sumatriptan Succinate and Naproxen Sodium	44183-850-09	85 mg/1, 500 mg/1	TABLET	ORAL	NDA021926	Currax Pharmaceuticals LLC dba Cypress, Hawthorn, Macoven	44183-850	sumatriptan succinate and naproxen sodium	SUMATRIPTAN SUCCINATE; NAPROXEN SODIUM	HUMAN PRESCRIPTION DRUG	02/15/2018	N/A	NDA AUTHORIZED GENERIC	9 TABLET in 1 BOTTLE (44183-850-09)

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

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PIN IT (HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

EMAIL (MAILTO:?&SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

PRINT

Current through December 02, 2021

You have searched Finished drug products

Search Results: *'42847'*

Back to Search Page () | **Search Again ()**

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 Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Onzetra Xsail	42847-311-08	11 mg/1	CAPSULE	NASAL	NDA208099	Currax Pharmaceuticals LLC	42847-311	sumatriptan succinate	SUMATRIPTAN SUCCINATE	HUMAN PRESCRIPTION DRUG	10/01/2015	N/A	NDA	8 POUCH in 1 CARTON (42847-311-08) > 2 CAPSULE in 1 POUCH	Serotonin 1d Receptor Agonists [MoA], Serotonin 1b and Serotonin 1d Receptor Agonist [EPC], Serotonin 1b Receptor Agonists [MoA]
Silenor	42847-103-60	3 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-103	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	500 TABLET in 1 BOTTLE (42847-103-60)	Tricyclic Antidepressant [EPC]
Silenor	42847-106-50	6 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-106	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	500 TABLET in 1 BOTTLE (42847-106-50)	Tricyclic Antidepressant [EPC]
Silenor	42847-106-03	6 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-106	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	30 TABLET in 1 BLISTER PACK (42847-106-03)	Tricyclic Antidepressant [EPC]
Silenor	42847-103-03	3 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-103	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	30 TABLET in 1 BLISTER PACK (42847-103-03)	Tricyclic Antidepressant [EPC]
Silenor	42847-103-10	3 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-103	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	100 TABLET in 1 BOTTLE (42847-103-10)	Tricyclic Antidepressant [EPC]
Silenor	42847-106-10	6 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-106	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	100 TABLET in 1 BOTTLE (42847-106-10)	Tricyclic Antidepressant [EPC]
Silenor	42847-103-30	3 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-103	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	30 TABLET in 1 BOTTLE (42847-103-30)	Tricyclic Antidepressant [EPC]
Silenor	42847-106-30	6 mg/1	TABLET	ORAL	NDA022036	Currax Pharmaceuticals LLC	42847-106	doxepin hydrochloride	DOXEPIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2010	N/A	NDA	30 TABLET in 1 BOTTLE (42847-106-30)	Tricyclic Antidepressant [EPC]
Treximet	42847-850-09	85 mg/1, 500 mg/1	TABLET, FILM COATED	ORAL	NDA021926	Currax Pharmaceuticals LLC	42847-850	Sumatriptan Succinate and Naproxen Sodium	SUMATRIPTAN SUCCINATE; NAPROXEN SODIUM	HUMAN PRESCRIPTION DRUG	04/25/2008	N/A	NDA	9 TABLET, FILM COATED in 1 BOTTLE (42847-850-09)	Serotonin 1d Receptor Agonists [MoA], Serotonin 1b and Serotonin 1d Receptor Agonist [EPC], Serotonin 1b Receptor Agonists [MoA], Cyclooxygenase Inhibitors [MoA], Anti-Inflammatory Agents, Non-Steroidal [CS], Nonsteroidal Anti-Inflammatory Drug [EPC]

Showing 1 to 10 of 10 entries Previous 1 Next

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

Currax
pharmaceuticals LLC

OWNERSHIP

Currax Pharmaceuticals LLC dba Cypress, Macoven, Hawthorn, ("Currax"), is virtual manufacturer of pharmaceutical products. Currax is a privately-held, 100% wholly-owned subsidiary of Currax Holdings USA, LLC. Currax is incorporated in the state of Delaware.

COMPANY INFORMATION

Currax Pharmaceuticals LLC dba Cypress, Macoven, Hawthorn
155 Franklin Street, Suite 450
Brentwood, TN 37027
Phone: (615) 507-9111
Tax ID: 83-3588974

CORPORATE OFFICERS

Terry Evans, Chief Operating Officer
Business Address: 155 Franklin Street, Suite 450, Brentwood, TN 37027

Michelle Parsons, Chief Financial Officer
Business Address: 155 Franklin Street, Suite 450, Brentwood, TN 37027

Erika Tooman, General Counsel, Senior Vice President
Business Address: 155 Franklin Street, Suite 450, Brentwood, TN 37027

Currax pharmaceuticals LLC

EMPLOYEE LIST

Gabrielle	Bocquet
Susan	Figert
Amy	Rosenblum
Audra	Strunk
Jason	Richardson
Loren	Massey
Robert	Churchill
Christian	Chapman
Derrick	Gastineau
William	Cline
Sharmili	Datta
Courtnei	Patton
Aaron	Chesnut
William	Kirkland
Anna	Nicholas
Grace	Pryor
Brett	Elliott
Samuel	Sharpe
Carly	Hunt
Dayna	Bauman
Emily	Baird
Dale	McBay
Brent	Couey
Joseph	Edwards
Stephanie	Hall
Tami	Vitek
Ryan	Detwiler
Carie	Brueckner
Victoria	Self
Carlee	Parsons
Tracy	Munoz-Maines
Stephen	Webb
George	Hampton
Michelle	Parsons
Terrence	Evans

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: Currax Pharmaceuticals LLC dba Cypress, Hawthorn and Macoven

Physical Address: 155 Franklin Rd, Suite 450

City: Brentwood State: TN Zip: 37027

Mailing Address (if different from physical address): 155 Franklin Rd, Suite 450

City: Brentwood State: TN Zip: 37027

Telephone: (615) 507-9111 Website: www.curraxpharma.com

Licensing Company Email: statelicense@curraxpharma.com

Section 2: Personal Information

First: Terry Middle: Lee Last: Evans

Alias(es, nicknames, name changes, etc.): N/A

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

Mailing Address: [redacted] Franklin Rd, Suite [redacted]

City: Brentwood State: TN Zip: 37027

Telephone: [redacted] Email: statelicense@curraxpharma.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: 08/1986 to: 01/1990

Military Occupation/Specialty: Aircraft Mechanic

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?		X

Applicant's initials: TLE

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)	
Trevecca Nazarene University		09/94 - 06/98	
Address	City	State	Zip
333 Murfreesboro Pike	Nashville	TN	37210
Diploma/Degree obtained, if any			
BA Management and Human Relations			
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
03/10 - Present	[redacted] Cherokee Road	Hendersonville	TN	37075
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 TLE

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: Currax Pharmaceuticals LLC			From - To (MM/YY – MM/YY): 05/19 - Present	
Business Address: 155 Franklin Rd, Suite 450		City: Brentwood	State: TN	Zip: 37027
Phone: (615) 507-9111	Title: Chief Operating Officer		Number of Employed Hours: 4,640+	
Description of Duties: See Attached Resume				

Business Name: Horizon Pharma			From - To (MM/YY – MM/YY): 07/11 - 01/19	
Business Address: 150 Saunders Road		City: Lake Forest	State: IL	Zip: 60045
Phone: (224) 383-3880	Title: SVP Managed Care & Trade		Number of Employed Hours: 14,000+	
Description of Duties: See Attached Resume				

Business Name: Graceway Pharma			From - To (MM/YY – MM/YY): 06/08 - 07/11	
Business Address: 340 M.L.K. Jr Blvd		City: Bristol	State: TN	Zip: 37620
Phone: (423) 274-2100	Title: Sr. Director Trade		Number of Employed Hours: 6,000+	
Description of Duties: See Attached Resume				

Business Name: Medicis Pharma			From - To (MM/YY – MM/YY): 10/98 - 06/08	
Business Address: 7720 Dobson Road		City: Scottsdale	State: AZ	Zip: 85256
Phone: (212) 599-2000	Title: Director Trade Operations		Number of Employed Hours: 20,000+	
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.

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:

_____ _____

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

Applicant's initials _____

I, Terry Evans, **certify that as the designated representative for**

Currax Pharmaceuticals LLC dba Cypress, Hawthorn and Macoven,

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

Terry Evans
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/2021
Date

Applicant's initials TE

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.

Terry Evans
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/2021
Date

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

State of Tennessee, ss. County of Williamson

I, Terry L. Evans, 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

11/15/2021
Date

Subscribed and Sworn to before me this 15 day of November.

Carie Brueckner
Notary Public Signature

CARIE BRUECKNER
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 3-3-2025

(Seal)

Applicant's initials TLE

Terry Evans

[redacted] Franklin Rd, Brentwood, TN 37027

[redacted]

Tevans@curraxpharma.com

Profile

Experienced Pharmaceutical Executive with a proven track record of meeting and exceeding corporate objectives within several areas of responsibility. Multiple years of increasing responsibility and success. Talented and resourceful problem solver skilled in Driving Results, Strategic Thinking, Business Operations, Project & Budget Management, Executive Leadership and Customer Service. Multiple years of maximizing top and bottom-line revenue and exceeding expectations with successful solutions across multiple disciplines.

Skill Sets

Sales	Sales Leadership
Managed Care Leadership	Corporate Trade Executive
Consulting - Business Development	3PL & Supply Chain Management
New Pharma Business Start-up	Business Development
Pharmacy Network	10 new product launches
Project Management	5X Presidents Club winner

Experience

Currax Pharmaceuticals — May **2019 – Present**

Chief Operating Officer

Responsible for business operations that includes: Scientific & Medical Affairs, Global Distribution, Technical Operations & Supply Chain, Data Analytics, Pharmacy Programs & Facilities.

Horizon Pharma — **July 2011 – Jan 2019**

SVP Managed Care & Trade

Responsible for leading teams that included Sales, Marketing, Global Distribution, Market Access, Government pricing & Contracts and Business Operations. Enhanced patient access by launching HUB, consolidating 3PL, retooling sample program and launching PAP. Successfully led multiple negotiations with Wholesalers, PBM's, Health Plans that saved over $40M.

Graceway Pharmaceuticals — **June 08 – July 2011**

Sr Director Trade Relations

Responsible for maintaining all Key National Account relationships, managing appropriate inventory, interfacing with accounting on gross to net, chargebacks, AR and payment terms. Successfully renegotiated multiple Distribution Agreements and Returns Policies as well as stratifying business risk by contracting and selling direct with CVS and Walgreens. Established fact basis for changing returns process and provider to outsource allowing for full transparency and cost savings for company. Two new drug launched.

Medicis Pharmaceuticals — **October 98 - June 08**

Director Trade Operations

Ten years of progressively more responsible roles through Sales, Training, National Accounts, Trade and Operations. Five NDA launches and 5-line extension launches. Multiple performance awards including Top 5% awards, 8-time quarterly MVP, 3-time Presidents Club, District of the Year. Helped the company grow from $50M in gross revenues to $800M. Total responsibility for designing and building company's first copay assistance program and 12 seat call centers. Subsequently owned marketing relationship and gross to net with 3 brands copay card programs. Negotiated company's distribution channel of cosmetic line "buy and bill" direct to physicians through McKesson. Negotiated all of the first distribution agreements in company history. Aggregated all Trade Sales data, inventory positions and closed every quarter from Jan 07 through June 08 exceeding gross revenue targets.

Education

Trevecca Nazarene University, Nashville TN — **1998**

BA, Management & Human Relations

Military

United States Air Force, Sergeant, Travis AFB, CA, *Honorably Discharged* — **1990**

Bond No. LPM9312632

RIDER

To be attached to and form a part of Pharmaceutical Wholesaler Surety Bond, No. LPM9312632

dated the 30th day of January, 2020 issued by

Fidelity and Deposit Company of Maryland as Surety, on behalf of

Currax Pharmaceuticals, LLC , as Principal,

in the penal sum of Twenty Five Thousand Dollars and 00/100

Dollars ($ 25,000.00), and in favor of Nevada State Board of Pharmacy

In consideration of the premium charged for the attached bond, it is hereby agreed that the attached bond be amended as follows:

Amend Principal Address to 115 Franklin Road, Suite 450, Brentwood, TN 37027

Provided, However, that the attached bond shall be subject to all its agreements, limitations and conditions except as herein expressly modified, and further that the liability of the Surety under the attached bond and the attached bond as amended by this rider shall not be cumulative.

This rider shall become effective as of the 30th day of July, 2021

Signed, sealed and dated this 22nd day of July, 2021

ATTEST:

PRINCIPAL

Currax Pharmaceuticals, LLC

By

ACCEPTED:

Fidelity and Deposit Company of Maryland

By

Donna M. Chiancone, Attorney-in-Fact

Surety Phone No. 856-552-4986

GEN90004ZZ1001f

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. LPM9312632

Application/License No. _____

Currax Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10N Park Place, Suite 201, Morristown, NJ 07960 (Address of Applicant/Principal), as PRINCIPAL, and Fidelity & Deposit Company of Maryland (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1299 Zurich Way, 5th Floor, Schaumburg, IL 60196-1056 (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 22, 2020 (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 30th day of January, 20 20.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY

Surety Company's Representative

Donna M. Chiancone, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Karen A. Read

Witness Lori N. Baybutt

Countersigned by:

Nevada ~~Resident~~ Non-Resident Agent
Donna M. Chiancone, Nevada License #545412

Bond Number LPM9312632

Obligee Nevada State Board of Pharmacy

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 Donna M. Chiancone, 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 19th day of June, 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

SEAL

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 19th day of June, 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, 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 30th day of January, 2020.

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

THE FIDELITY AND DEPOSIT COMPANY

OF MARYLAND
1299 Zurich Way Schaumburg, IL 60196

Statement of Financial Condition
As Of December 31, 2018

ASSETS

Bonds		$ 245,255,635
Stocks		22,855,569
Cash and Short Term Investments		3,092,872
Reinsurance Recoverable		73,242,781
Federal Income Tax Recoverable		42,258
Other Accounts Receivable		4,801,363
TOTAL ADMITTED ASSETS		$ 349,290,278

LIABILITIES, SURPLUS AND OTHER FUNDS

Reserve for Taxes and Expenses		$ 106,785
Ceded Reinsurance Premiums Payable		46,727,605
Remittances and Items Unallocated		125,000
Payable to parents, subs and affiliates		28,621,373
Securities Lending Collateral Liability		0
TOTAL LIABILITIES		$ 75,580,762
Capital Stock, Paid Up	$ 5,000,000	
Surplus	268,709,716	
Surplus as regards Policyholders		273,709,716
TOTAL		$ 349,290,478

Securities carried at $162,739,508 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, 2018 would be $349,736,423 and surplus as regards policyholders $274,155,661.

I, DENNIS F. KERRIGAN, 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, 2018.

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 20th day of March, 2019.

Notary Public

KATHERINE R SCHULTZ
Official Seal
Notary Public - State of Illinois
My Commission Expires Nov 16, 2019

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler (Virtual Manufacturer)		☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	■ 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)

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Noven Therapeutics, L.L.C., dba Grove Pharmaceuticals

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 305-253-5099 Website: www.noven.com

Name of Designated Representative (DR): Arlette Azua

Licensing Company Email: Permits@noven.com DR Email: aazua@noven.com

Entities the Wholesaler will Serve	**Products to be Handled or Wholesaled**
☐ Pharmacies	■ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	■ Controlled Substances -3PL
☐ 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.

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: Aspen API Inc
Address: 2136 South Wolf Rd City: De Plaines State: IL Zip: 60018

Name: Chattem Chemicals Inc.
Address: 3708 ST Elmo Ave City: Chattanooga State: TN Zip: 37409

Name: SpecGx LLC
Address: 385 Marshall Ave City: Webster Grove State: MD Zip: 63119

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

State of Incorporation: Delaware
Parent Company (if any): Hisamitsu Pharmaceutical Co., Inc.
Corporation Name: Noven Therapeutics, L.L.C., dba Grove Pharmaceuticals
Mailing Address: 1960 SW 144th Street
City: Miami State: FL Zip: 33186
Telephone: 305- 964-3323 Email: Permits@noven.com
Contact Person Name: Arlette Azua

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 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 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**	✓			
• **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.

Arlette Azua

Print Name of Authorized Person Submitting Application

GB

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

7/22/21

Date

Processed 9/1/21

Board Use Only	Date Received: _____	Amount: $500 Check # 0015305711

NOVEN THERAPEUTICS, LLC

Written Explanation as to Why No DEA Registration is Provided

Noven Therapeutics, LLC dba Grove Pharmaceuticals is a "virtual distributor" that does not handles drugs either for manufacturing or distribution. Noven Therapeutics, LLC does not take physical possession of drugs at any time or under any circumstances. Our 3PL (Cardinal Health, DEA Registration RC0229965) distributes our products.

Noven Therapeutics, LLC dba Grove Pharmaceuticals is mainly a financial institution that tracks sales of our products. Our products are manufactured under contract by drug manufacturers who ship the drugs directly to our Third Party Logistics (3PL) Company Cardinal Health. This 3PL distributes our drugs to wholesalers nationwide.

THIRD PARTY LOGISTICS (3PL) COMPANY

3PL NAME	Cardinal Health dba Specialty Pharmaceutical Services
DEA REGISTRATION	RC0229965
CONTACT NAME	Christie Stewart, Manager, Regulatory Management
ADDRESS	15 Ingram Blvd., La Vergne, TN 37086
TELEPHONE	(615) 287-0482

11960 SW 144th Street • Miami, Florida 33186
305-253-5099 • Fax: 305-251-1887
www.noven.com

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through April 20, 2021

You have searched Finished drug products

Search Results: *'Noven Therapeutics, LLC'*

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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
CombiPatch (estradiol/norethindrone acetate transdermal system)	68968-0514-8	.05 mg/d, .14 mg/d	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA020870	Noven Therapeutics, LLC	68968-0514	estradiol/norethindrone acetate transdermal system	ESTRADIOL; NORETHINDRONE ACETATE
CombiPatch (estradiol/norethindrone acetate transdermal system)	68968-0525-8	.05 mg/d, .25 mg/d	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA020870	Noven Therapeutics, LLC	68968-0525	estradiol/norethindrone acetate transdermal system	ESTRADIOL; NORETHINDRONE ACETATE
Daytrana	68968-5552-3	10 mg/9h	PATCH	TRANSDERMAL	NDA021514	Noven Therapeutics, LLC	68968-5552	methylphenidate	METHYLPHENIDATE
Daytrana	68968-5553-3	15 mg/9h	PATCH	TRANSDERMAL	NDA021514	Noven Therapeutics, LLC	68968-5553	methylphenidate	METHYLPHENIDATE
Daytrana	68968-5554-3	20 mg/9h	PATCH	TRANSDERMAL	NDA021514	Noven Therapeutics, LLC	68968-5554	methylphenidate	METHYLPHENIDATE
Daytrana	68968-5555-3	30 mg/9h	PATCH	TRANSDERMAL	NDA021514	Noven Therapeutics, LLC	68968-5555	methylphenidate	METHYLPHENIDATE
Estradiol	68968-3425-8	.025 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-3425	estradiol	ESTRADIOL
Estradiol	68968-3410-8	.1 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-3410	estradiol	ESTRADIOL
Estradiol	68968-3475-8	.075 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-3475	estradiol	ESTRADIOL
Estradiol	68968-3450-8	.05 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-3450	estradiol	ESTRADIOL
Estradiol	68968-3437-8	.0375 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-3437	estradiol	ESTRADIOL

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name
Minivelle	68968-6637-8	.0375 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-6637	estradiol	ESTRADIOL
Minivelle	68968-6610-8	.1 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-6610	estradiol	ESTRADIOL
Minivelle	68968-6650-8	.05 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-6650	estradiol	ESTRADIOL
Minivelle	68968-6625-8	.025 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-6625	estradiol	ESTRADIOL
Minivelle	68968-6675-8	.075 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA203752	Noven Therapeutics, LLC	68968-6675	estradiol	ESTRADIOL
SECUADO	68968-0172-3	3.8 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA212268	Noven Therapeutics, LLC	68968-0172	ASENAPINE	ASENAPINE
SECUADO	68968-0173-3	5.7 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA212268	Noven Therapeutics, LLC	68968-0173	ASENAPINE	ASENAPINE
SECUADO	68968-0174-3	7.6 mg/d	FILM, EXTENDED RELEASE	TRANSDERMAL	NDA212268	Noven Therapeutics, LLC	68968-0174	ASENAPINE	ASENAPINE

Showing 1 to 19 of 19 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

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NOVEN THERAPEUTICS, 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 THIRTIETH DAY OF AUGUST, A.D. 2021.

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

Jeffrey W. Bullock, Secretary of State

3830491 8300

SR# 20213117267

Authentication: 204041094

Date: 08-30-21

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

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

NOVEN THERAPEUTICS, LLC
GROVE PHARMACEUTICALS
11960 SOUTHWEST 144TH STREET
MIAMI FL 33186

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

20249 ISSUED: 06/13/2021

PRESCRIPTION DRUG MANUFACTURER
NOVEN THERAPEUTICS, LLC
GROVE PHARMACEUTICALS

HAS REGISTERED under the provisions of Ch 499 FS
Expiration date: JUN 30, 2023 L2106130000108

DETACH HERE

RON DESANTIS, GOVERNOR

JULIE I. BROWN, SECRETARY

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

LICENSE NUMBER	
20249	

The PRESCRIPTION DRUG MANUFACTURER
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: JUN 30, 2023

NOVEN THERAPEUTICS, LLC
GROVE PHARMACEUTICALS
11960 SW 144 ST
MIAMI FL 33186

ISSUED: 06/13/2021 DISPLAY AS REQUIRED BY LAW SEQ # L2106130000108

Employee List - Noven Companies

Last Name	First Name
Abello	Teresa
Abou Baker	Cecilia
Acosta	Evelyn
Aguilar	Martha
Aikens	Clement
Almodovar Torres	Jose
Alvarez	Lucia
Alvarez	Oscar
Alvarez	Ybel
Andrade	Natalie
Andriuoli	Julio
Arenas	Diana
Ares	Marcos
Arias	Jessica
Avino	Salvatore
Aybar	Jose
Azua	Arlette
Balakrishnan	Kanan
Balliram	Jamie
Batson	Josanne
Benavides	Brian
Benitez	Julio
Bermudez	Roger
Berrios	Maribel
Bilbao	Maria
Bishaw	Mireille
Bonne	Somi
Bou	Judith
Bouzas	Lourdes
Bowers	Carrie
Bravo	Carlos
Brutus	Hans
Buckley	Devin
Byreddy	Sandeep
Caballero	Rossana
Cabrales	Brian
Cacioppo-Sorvill	Celeste
Calderon Correa	Damarys
Calderon Cruz	Sharlim
Calero	Edgardo
Campbell	Brendan
Capera	Lisa
Cardenas	Ludys
Cardona	Elizabeth
Cardona	Maria
Carrasquillo	Denelisse
Cartas	Delia
Casellas	Christian
Castelli	Mariacristina

Castrillon	Yudi
Castro	Benjamin
Castro	Osmar
Cata	Mixilexi
Chacin	David
Chin	Marilisa
Chinea	Tahamara
Choi	John
Cid	Ana
Cinnante	Dennis
Clavijo	Raisa
Comin	Raul
Conde	Denise
Contreras	Nathan
Corneille	Stephenson
Couso	Delsy
Cuevas	Eduardo
Curtis	Taryn
Desai	Saloni
Diaz	Alexis
Diaz	Armando
Diaz	Myra
Doddapaneni	Jagadeesh
Dominguez	Leslie
Donayre	Maria
Duncan	Cari
Escobar	Monica
Evans	Akeem
Felipe	Emily
Fernandez	Juan
Fernandez	Omar
Fonseca	Ana
Fonseca	Jose
Fonvil	Sam
Fornos	Mivis
Fraga	Allana
Francis	Martha
Francois	Jesula
Franqui	Olga
Freire	Santiago
Fuentes	Gualberto
Fundora Arza	Angel
Galeano	John
Galeano	Maria
Galeano	Yasna
Galy	Michael
Garces	Nicolas
Garcia Diaz	Nuria
Garcia Giraldelli	Marcio
Garriga	Nilda
Gatti	Cynthia
Gavrilas	Cristian

Gibson	Eric
Gilzean	Shanice
Gomez	Efrain
Gomez	Harley
Gonzalez	Griselvia
Gonzalez	Ismary
Gonzalez	Sueheith
Gonzalez	Susana
Gonzalez	Vanessa
Gonzalez Perez	Pedro
Goytia Cruz	Provimar
Guerra	Evelyn
Hahn	Sheryll
Haj-Ibrahim	Houda
Harrison	Patricia
Herbert	Andrew
Hernandez	Daylin
Hernandez	Diana
Hernandez	Hector
Heximer	Anuradha
Higo	Naruhito
Jarvis	Brenda
Jean	Adeline
Jean-Baptiste	Farah
Jefferson	Travis
Jimenez	Catalina
Jimenez	Diana
Jimenez	Juan
Jimenez	Luis
Jinete	Christian
Julian	Carmen
Kadiwar	Gautam
Katayama	Ken
Kaufman	Astrid
Kelly	Matthew
Khan	Mahwish
Khodadadi	Farzan
Kibria	Farhana
Kiuchi	Takehito
Klauss	Gunnar
Komaroff	Marina
Kulakofsky	Joshua
Lacayo	Promise
Lacotera	Verda
Lagomasino Carreras	Jose
Lambert	Robert
Lamenta	Stephanie
Lanzas	Jorge
Lara Flores	Joarce
Laurence	Samantha
Lawson	Raphael
Lebron	Carlos

Lee	Kenneth
Lippman	Joel
Lopez	Mercedes
Loyola Otero	Norberto
Lozano	Oscar
Luis Barrios	Osmany
Machuca Perez	Keysa
Macias Vazquez	Erika
Maestri	Johan
Manikonda	Prithvi Chandh
Marrero Cruz	Evy
Martinez	Cesar
Martinez	Jorge
Martinez	Jorge
Martinez	Jose
Martinez	Ricardo
Martinez	Wallie
Martinez-Ortiz	Ferdinand
Mathews	Reena
Meeves	Suzanne
Merida	Adam
Mohammed	Abdul Gaffar
Molina	Bresnier
Mondal	Deboprosad
Montalvo	Elena
Montoya	Angelica
Motamedi	Sahar
Munoz	Carlos
Murphy	Dennis
Navarrete	Erick
Negron	Che-Aufier
Nguyen	Viet
Noa Lima	Elizabeth
Noriega	Jose
Noyola	Carlos
Nunez	Marta
Obando	Johanna
Ocampo	Germanico
Orizondo	Matilde
Ortiz	Ben
Osorio	Mario
Osunde	Eseohen
Pastrana	Dennis
Pau	Leslie
Pavon Blanchet	Alexey
Pena	Alejandro
Perez	Elsa
Perez	Humberto
Perez	Marvin
Perez	Violetta
Perez Campana	Edelmira
Pernas	Enrique

Pierre	Patricia
Pire	Geidy
Purcell	Andrew
Ramirez	Luis
Ramon	Maritza
Ramos	David
Redd	Michael
Reynaldo	Marilyn
Richemond	Philoria
Richemond	Rose
Rios	Gerardo
Rivera	Alicia
Rivera	Roxana
Rivera Cordero	Marielis
Rivera Gonzalez	Lemuel
Rivera Sepulveda	Laymarie
Rivero	Yeniser
Rodrigues	Claudio
Rodriguez	Arnaldo
Rodriguez	Carlos
Rodriguez	Daniel
Rodriguez	Ivan
Rodriguez	Loreli
Rodriguez	Miguel
Rodriguez	Reyna
Rodriguez	Rolando
Rodriguez Gonzalez	Maydel
Rojas	Lissette
Romero	Dina
Romero	Lazara
Romero	Valeria
Roque	Jandro
Rosario	Maria
Sakhdari	Setareh
Salas	Jackeline
Salcedo	Joan
Saltos	Karina
Sanabria	Cassandra
Sandoval	Kathia
Santana Fuentes	Mabel
Sautie Castellanos	Beatriz
Sevilla	Belen
Shankar	Gayathri
Shao	Fei
Sharp	James
Shelley	Josie
Sintas	Jose
Soberats	Luis
Solivan	Armando
Sonobe	Atsushi
Sorbara	Matthew
Soto	Jessica

Space	Ryan
St. Elien	Sheila
Stade	David
Stamler	Ella
Starling	Brittney
Sterling	Chris
Stewart	Winn
Suarez	Margarita
Suzuki	Satoshi
Tanaka	Hiroyuki
Taylor	Iran
Thomas	Brent
Thomas	Candace
Tong	Suk
Trajtman	Angel
Valls	Ana
Vargas	Edgardo
Vargas	Luis
Vasquez	Jackson
Vellon Jr.	Bernardo
Vergel	Rodrigo
Villacres	Yamile
Villatoro	Alma
Vivero	Yanira
Wascura	Joseph
Wasserman	Patricia
Waters	Robert
Williams	Anthony
Yano	Toru
Yoshioka	Kazuki
Zayas	Eleodoro
Zequeira	Consuelo
Zuniga	Teresa

List of Officers, Noven Therapeutics, LLC.

1) Naruhito Higo

Chairman & Chief Executive Officer

2) John Choi

Vice President, Chief Financial Officer & Treasurer

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 Noven Therapeutics

Physical Address 11960 SW 144th Street

City Miami State FL Zip 33186

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 305-964-3323 Website www.noven.com

Licensing Company Email Permits@noven.com

Section 2: Personal Information

First Arlette Middle _____ Last Azua

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address Same as above

City _____ State _____ Zip _____

Telephone [redacted] Email aazua@noven.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 AA

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, Huizenga School of Business		09/2007-06/2009	
Address	**City**	**State**	**Zip**
3301 College Ave	Fort Lauderdale	FL	33314
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Florida International University		09/1998-05/2005	
Address	**City**	**State**	**Zip**
11200 SW 8th St	Miami	Fl	33199
Diploma/Degree obtained, if any			
• Master of Science in Chemistry (May, 2005). • Bachelor of Science in Chemistry (Dec, 2002).			

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
06/2001-Present	[redacted] SW 18 St	Miami	FL	33175
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)	
Noven Pharmaceutical, Inc.			05/2006-Present	
Business Address		City	State	Zip
1960 SW 144th Street		Miami	FL	33186
Phone	Title		Number of Employed Hours	
305- 964-3166	Manager, Regulatory Affairs		28,800+	
Description of Duties				
Manager of regulatory affairs				

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

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

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

Applicant's initials AA

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 AA

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

Applicant's initials AA

I, Arlette Azua, **certify that as the designated representative for**

Noven Therapeutics,

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

Arlette Azua

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/22/21

Date

Applicant's initials AA

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.

Arlette Azua

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/22/21

Date

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

State of Florida, ss. County of Miami-Dade

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

7/22/21

Date

Subscribed and Sworn to before me this 22nd day of July.

Notary Public Signature

Notary Public State of Florida
Sheryll K Hahn
My Commission GG 128585
Expires 08/27/2021

(Seal)

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: Noven Therapeutics, L.L.C., dba Grove Pharmaceuticals

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-253-5099 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: John Middle: S Last: Choi

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

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

Mailing Address: [redacted] Mountain Run

City: Boonton State: NJ Zip: 07005

Telephone: [redacted] Email: JChoi@noven.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: JC

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 Utah		09/90-06/92	
Address	City	State	Zip
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Master of Business Administration (MBA)			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		01/86-06/90	
Address	City	State	Zip
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Bachelor of Arts Accounting (BAA)			

School Name		From - To (MM/YY – MM/YY)	
Hankuk University of Foreign Studies		03/83-06/85	
Address	City	State	Zip
107 Imun-ro, Imun-dong, Dongdaemun-gu	Seoul	So. Korea	
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Seoul High School		03/80-02/83	
Address	City	State	Zip
197 Hyoryeong-ro, Seocho 3(sam)-dong, Seocho-gu	Seoul	So. Korea	
Diploma/Degree obtained, if any			
High School			

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
09/10-07/21	[redacted] Mountain Run	Boonton	NJ	07005
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 JC

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)
Noven Pharmaceuticals, Inc.			01/16-07/21
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2637	Vice President, Chief Financial Officer & Treasurer		
Description of Duties			
An executive in charge of functions of Finance and Information Technology			

Business Name			From - To (MM/YY – MM/YY)
Noven Pharmaceuticals, Inc.			04/10-12/15
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2637	Executive Director, Business Planning and Analysis		
Description of Duties			
Director in charge of financial analyses, budgeting and performance tracking			

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)

Date

Applicant's initials JC

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.

John Choi

Print Name (First, Last)

John S Choi — 6/30/2021

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 Bronx

I, John Choi, 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.

John S Choi — 7/7/2021

Original Signature — **Date**

Subscribed and Sworn to before me this 7 day of July 2021.

Maribel Berrios

Notary Public Signature

Maribel Berrios
Notary Public, State of New York
Qualified in Bronx County
Commission # 01BE6295473
Commission expires January 6, 2022

(Seal)

Applicant's initials JC

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: Noven Therapeutics, L.L.C., dba Grove Pharmaceuticals

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-253-5099 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: Naruhito Middle: Last: Higo

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

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

Mailing Address: Same as above

City: State: Zip:

Telephone: [redacted] Email: NHigo@noven.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: N H-H

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)	
Konan high school		4/1985-3/1988	
Address	**City**	**State**	**Zip**
Kaminosano-cho	Kagoshima	Japan	890-0052
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Kumamoto University		4/1989-3/1985	
Address	**City**	**State**	**Zip**
Kurokami 2-39-1	Kumamoto	Japan	860-8555
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
7/2017-7/2021	[redacted] McFarlane Rd #1218	Coconut Grove	Florida	33133
5/2021-6/2017	Abiko 2-4	Abiko	Chiba Jap	270-1166

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)	
Noven Pharmaceuticals, Inc.			7/2017-7/2021	
Business Address		**City**	**State**	**Zip**
11960 SW 144th Street		Miami	FL	33186
Phone	**Title**			
305-964-3503	Chairman of the Board			
Description of Duties				
As a chairman and CEO, I lead the company by making important decisions for the sustainable growth meeting social compliance requirements.				

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.

Applicant's initials MH

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 NH

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.

Naruhito Higo

Print Name (First, Last)

Naruhito Higo

Original Signature (electronic, copies or stamps not accepted)

July 2, 2021

Date

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

State of Florida, ss. County of Miami-Dade

I, Naruhito Higo, 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.

Naruhito Higo

Original Signature

July 2, 2021

Date

Subscribed and Sworn to before me this 7th day of July 2021

Sheryll K Hahn

Notary Public Signature Sheryll K. Hahn

Notary Public State of Florida
Sheryll K Hahn
My Commission GG 128585
Expires 08/27/2021

(Seal)

Applicant's initials NH

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. SU1173569

Application/License No. _____

Noven Pharmaceuticals, Inc. and its wholly-owned subsidiary Noven Therapeutics, LLC, doing or intending
Applicant/Principal
to do business as a pharmaceutical wholesaler, whose address for purposes of service is
11960 SW 144th Street, Miami, FL 33186, as
Address of Applicant/Principal
PRINCIPAL, and Arch Insurance Company, a
Surety Company
corporation organized under the laws of the state of Missouri
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
Harborside 3, 210 Hudson Street, Jersey City, NJ 07311-1107 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 July 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 19th day of July, 20 21.

APPLICANT/PRINCIPAL

Noven Pharmaceuticals, Inc. and its wholly-owned subsidiary Noven Therapeutics, LLC

Authorized Representative

SURETY COMPANY

Arch Insurance Company

Surety Company's Representative

Anett Cardinale, 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:

Anett Cardinale
Neveda Licensed Non-Resident Agent

Inquiries (813) 320-0239

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Alexa Diaz, Anett Cardinale and Radha Jones of Tampa, FL (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding Ninety Million Dollars ($90,000,000.00).
This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on December 10, 2020, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:
"VOTED, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on December 10, 2020:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on December 10, 2020, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this 26th day of April, 2021.

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
MICHELE TRIPODI, Notary Public
City of Philadelphia, Phila. County
My Commission Expires July 31, 2021

Michele Tripodi, Notary Public
My commission expires 07/31/2021

CERTIFICATION
I, **Regan A. Shulman**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated** April 26, 2021 on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.
IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 19 day of July, 20 21.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com
Please refer to the above named Attorney-In-Fact and the details of the bond to which the power is attached.

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☐ Nevada ☑ Out-of-State
Is your facility a reverse distributor?	☐ Yes ☑ No

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 _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: North American Rescue, LLC

Physical Address: 35 Tedwall Court

City: Greer State: SC Zip: 29650

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 864-675-9800 Website: www.narescue.com

Name of Designated Representative (DR): Tony Horton

Licensing Company Email: mconley@narescue.com DR Email: thorton@narescue.com

Entities the Wholesaler will Serve	**Products to be Handled or Wholesaled**
☐ Pharmacies	☑ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	☐ Controlled Substances no legend drugs
☐ Hospitals	☐ Hypodermic Devices
☐ Wholesalers	☐ Veterinary Legend Pharmaceuticals
☑ Others: US Dept of Defense, law enforcement, emergency medical services	☑ Others: human nonprescription drugs medical supplies

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.

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: Henry Schein, Inc.
Address: 135 Duryea Road City: Melville State: NY Zip: 11747

Name: NAR MD
Address: 54 Tedwall Court City: Greer State: SC Zip: 29650

Name: Bound Tree Medical, LLC
Address: 481 Airport Industrial Dr City: Southaven State: MS Zip: 38671

Name: McKesson Medical Surgical, Inc.
Address: 6500 Adelaide Ct City: Groveport State: OH Zip: 43125

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): North American Rescue Holdings, LLC
Corporation/Organization Name: North American Rescue, LLC
Mailing Address: 35 Tedwall Court
City: Greer State: SC Zip: 29650
Telephone: 864-675-9800 Email: mconley@narescue.com
Contact Person Name: Mary Ellen Conley

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Andrew Goldy
Print Name of Authorized Person Submitting Application

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

11/29/21
Date

Board Use Only	Date Received: _____	Amount: 500 CC

PRC 1041731

PERMIT NO. 15692
DATE ISSUED: 04/15/2021

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Non-Dispensing Drug Outlet Permit

2021-2022

Expires 06/30/2022

J. Addison Livingston, Board Chair

Robert Hubbard, Vice Chair

NORTH AMERICAN RESCUE, LLC
Permit Holder: WILLIAM SLEVIN
35 TEDWALL CT
GREER SC 29650

The State of South Carolina

Office of Secretary of State Mark Hammond

Certificate of Authority

I, Mark Hammond, Secretary of State of South Carolina Hereby Certify that:

NORTH AMERICAN RESCUE, LLC, a limited liability company duly organized under the laws of the State of Delaware, and issued a certificate of authority to transact business in South Carolina on October 27th, 2009, with a duration that is at will, has as of this date filed all reports due this office, paid all fees, taxes and penalties owed to the State, that the Secretary of State has not mailed notice to the company that it is subject to being dissolved by administrative action pursuant to S.C. Code Ann. §33-44-1006, and that the company has not filed a certificate of cancellation as of the date hereof.

Given under my Hand and the Great Seal of the State of South Carolina this 21st day of October, 2021.

Mark Hammond

Mark Hammond, Secretary of State

Establishment Registration & Device Listing

Establishment:
NORTH AMERICAN RESCUE, LLC.
35 TEDWALL COURT
Greer, SC 29650
Registration Number: 3005034064
FEI Number*: 3005034064
Status: Active
Date Of Registration Status: 2022

Owner/Operator:
NORTH AMERICAN RESCUE, LLC.
35 TEDWALL COURT
Greer, SC US 29650
Owner/Operator Number: 9070484

Official Correspondent:
William Slevin
35 TEDWALL COURT
Greer, SC 29650
Phone: 864-6759800

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified MS
11/12/22

Page Last Updated: 12/13/2021
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

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 Limited Partnership for American Outcomes Management, LP (file number 13653210), a Domestic Limited Partnership (LP), was filed in this office on July 03, 2000.

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 November 18, 2021.

John B. Scott
Secretary of State

NORTH AMERICAN RESCUE, LLC

ORGANIZED AS:	North American Rescue, LLC
EIN:	27-1024029
STATE OF ORGANIZATION:	Delaware
ADDRESS:	35 Tedwall Court, Greer, Greenville County, SC 29650
OFFICERS:	Andrew Goldy, Chief Operating Officer/President James Carino, Vice President
OWNER/MEMBER:	North American Rescue Holdings, LLC 35 Tedwall Court, Greer, SC 29650 100% ownership Andrew Goldy, Chief Operating Officer

NORTH AMERICAN RESCUE, LLC

ORGANIZED AS:	North American Rescue, LLC
EIN:	27-1024029
STATE OF ORGANIZATION:	Delaware
ADDRESS:	35 Tedwall Court, Greer, Greenville County, SC 29650
MEMBER/OWNER:	North American Rescue Holdings, LLC 35 Tedwall Court, Greer, SC 29650 100% ownership Andrew Goldy, Chief Operating Officer (no ownership)

NORTH AMERICAN RESCUE, LLC

Employees

Bautista	Martha
Baxter	Kimberly
Biggerstaff	Marianne
Bilger	Corina
Bogardus	Sam
Bolin	Chuck
Bond	Tom
Bresette	Lauren
Briggs	Mike
Brock	Keith
Bronson	Brent
Brown	Brandon
Butler	Tamara
Carino	Jim
Carruth	Reba
Coates	Stephanie
Colon	Mario
Conley	Mary
Crouch	Erik
Cupelli	Matt
Darnell	Russell
Davenport	James
Davis	James
Dominguez	John
Dooley	Paula
Doughty	Marybeth
Dunbar	Ian
Durbin	Austin
Earnhardt	Carson
Ferguson	Alfreda
Fields	Jamie
Gentile	Diana
Goldy	Andy
Griggs	Tameika
Grissett	Vario
Hall	Stephen
Hampton	Larry
Hanschke	Megan
Harris	Anna
Holupka	Garrison
Horton	Anthony
Horton	Jennifer
Horton	Anthony E.
Hoyne	Chris
Inabinet	Michael
Jamison	Will
Jenkins	Jessica
Johnson	Lonnie
King	Andrew
Koller	Tara
Krainas	Rick
Ling	Noreen
Lockey	Kmauri
McCall	Rob
McCallum	Bryan
McCarty	Matthew
McCue	Martin
Medlock	Jennifer
Miller	Robert
Miller	Lee
Miller	Dan
Mitchell	Jonathan
Moore	Brandon
Morris	Michelle
Nesbit	Chris
Nichols	Andraya
Nobles	William
Pearce	Mitch
Perez	Yanina
Pless	Devon
Porch	Holly
Powers	Mike
Prus	John
Pryor	Micah
Rice	David
Rogers	Natalie
Schmidt	Christian
Seidel	Shannon
Slevin	William
Smith	Ana
Spires	Susan
Stewart	JD
Struntz	DJ
Teixeira	Janice
Tucker	Tara
Turner	Brenda
Turner	Kelli
Valentine	Teresa
Varlack	Asia
Vecchio	Paul
Velez	Marleny
Ward	Kala
Westra	Matt
Williams	Blake
Wolff	Kayla

NORTH AMERICAN RESCUE, LLC

Independent Contractors
McKay, Sean
Miles, Ethan
Pangalangan, Don

North American Rescue has no agent, consultant, guardian, personal representative, lender or holder of indebtedness to report.

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. 015215493

Application/License No. _____

NORTH AMERICAN RESCUE, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 35 Tedwall Court Greer, SC 29650 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (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 December 2, 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 2nd day of December, 2021.

APPLICANT/PRINCIPAL
NORTH AMERICAN RESCUE, LLC

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Grace Laterza

Witness Anne Potter

Countersigned by:

Nevada Resident Agent Frances A. Rodriguez, NV Non-Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8205735-015009

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aklima Noorhassan; Anne Potter; Cynthia Farrell; Debra A. Deming; Frances Rodriguez; Francesca Kazmierczak; Jennifer L. Jakaitis; Kemal Brkanovic; Nancy Schnee; Pablo Garcia Horcajo; Peter Healy; Sandra Diaz; Susan A. Welsh; Valorie Spates

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 11th day of June, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 11th day of June, 2021 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute 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 have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 2nd day of December, 2021.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT — DECEMBER 31, 2020

Assets

Cash and Bank Deposits	$2,058,007,542
*Bonds — U.S Government	2,209,760,437
*Other Bonds	15,902,755,586
*Stocks	18,517,107,230
Real Estate	193,169,809
Agents' Balances or Uncollected Premiums	6,970,170,469
Accrued Interest and Rents	118,399,147
Other Admitted Assets	12,079,597,645
Total Admitted Assets	**$58,048,967,865**

Liabilities

Unearned Premiums		$8,448,706,991
Reserve for Claims and Claims Expense		23,879,216,613
Funds Held Under Reinsurance Treaties		343,068,613
Reserve for Dividends to Policyholders		1,192,716
Additional Statutory Reserve		77,397,000
Reserve for Commissions, Taxes and Other Liabilities		6,279,510,804
Total		**$39,029,092,737**
Special Surplus Funds	$178,155,102	
Capital Stock	10,000,075	
Paid in Surplus	10,945,045,214	
Unassigned Surplus	7,886,674,737	
Surplus to Policyholders		**19,019,875,128**
Total Liabilities and Surplus		**$58,048,967,865**

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the state of Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2020, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 25th day of March, 2021.

T A Mikolajewski

Assistant Secretary

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 North American Rescue, LLC

Physical Address 35 Tedwall Court

City Greer State SC Zip 29650

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 864-675-9800 Website www.narescue.com

Licensing Company Email mconley@narescue.com

Section 2: Personal Information

First Anthony Middle Earl Last Horton

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

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

Mailing Address [redacted] Hardin Road

City Chesnee State SC Zip 29323

Telephone [redacted] Email thorton@narescue.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 AEH

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)	
Spartanburg Community College		08/01 - 05/03	
Address	**City**	**State**	**Zip**
107 Community College Drive	Spartanburg	SC	29303
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Broome High School		08/97 - 05/01	
Address	**City**	**State**	**Zip**
381 Cherry Hill Road	Spartanburg	SC	29307
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
01/20 - present	[redacted] Hardin Road	Chesnee	SC	29323
05/07 - 01/20	111 Emory Road	Cowpens	SC	29330

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)
NAR Medical Depot, LLC dba NAR MD (fka TQM, LLC dba Two Rivers Medical)			06/16 - 05/20
Business Address	**City**	**State**	**Zip**
54 Tedwall Court	Greer	SC	29650
Phone	**Title**		**Number of Employed Hours**
800-291-0329 ext 571	Warehouse Manager		7360
Description of Duties Working under warehouse Director of Operations, supervised warehouse team in receiving, storing, packing, shipping, record-keeping for distribution of medical supplies including prescription drugs, in compliance with regulations governing pharmaceutical distribution per state and federal and company policies, observing facility security, safety, and environmental requirements for all product. Collaborated with company regulatory team for internal audits and for external audits such as NABP accreditation, DEA, and SC Board of Pharmacy.			

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			

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?		✓

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. N/A

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

Applicant's initials AEH

I, Anthony Earl Horton, **certify that as the designated representative for**

North American Rescue, 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

Anthony Earl Horton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/21
Date

Applicant's initials AEH

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.

Anthony Earl Horton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/21
Date

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

State of South Carolina, ss. County of Greenville

I, Anthony Earl Horton, 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

11/22/21
Date

Subscribed and Sworn to before me this 22nd day of November, 2021

Mary Ellen Carley
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 (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler North American Rescue, LLC

Physical Address 35 Tedwall Court

City Greer State SC Zip 29650

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 864-675-9800 Website www.narescue.com

Licensing Company Email mconley@narescue.com

Section 2: Personal Information

First Andrew Middle Paul Last Goldy

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] Tedwall Court

City Greer State SC Zip 29650

Telephone [redacted] Email agoldy@narescue.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: 1995 to: 2003

Military Occupation/Specialty Legal administration/Fire direction control

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 APG

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)	
Wright State University			08/98 - 05/02	
Address		**City**	**State**	**Zip**
3640 Colonel Glenn Highway		Dayton	OH	45435
Diploma/Degree obtained, if any				
Bachelor of Arts				
School Name			**From - To (MM/YY – MM/YY)**	
Grove City High School			09/91 - 06/95	
Address		**City**	**State**	**Zip**
4665 Hoover Road		Grove City	OH	43123
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)**	
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
11/16 - present	[redacted]Woodbridge Way	Simpsonville	SC	29681
08/14 - 11/16	6445 Oldbarn Court	Cincinnati	OH	45243
10/09- 08/14	6571 Kenview Drive	Cincinnati	OH	45243

Applicant's initials ARG

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)
North American Rescue, LLC			03/19 - present
Business Address	**City**	**State**	**Zip**
35 Tedwall Court	Greer	SC	29650
Phone	**Title**		
864-675-9800	Chief Operations Officer		

Description of Duties

Oversight of operating functions and strategy

Business Name			From - To (MM/YY – MM/YY)
Henry Schein Medical			11/16 - 03/19
Business Address	**City**	**State**	**Zip**
526 Congaree Road	Greenville	SC	29607
Phone	**Title**		
864-297-3680	General Manager, EMS Division		

Description of Duties

Responsible for sales, operations, and financial oversight of EMS Division

Business Name			From - To (MM/YY – MM/YY)
Henry Schein Medical			01/11 - 11/16
Business Address	**City**	**State**	**Zip**
9472 Meridian Way	West Chester Township	OH	45069
Phone	**Title**		
513-870-9635	Field Sales Consultant; Strategic Account Manager		

Description of Duties

Respsible for sales growth and business relationships Cincinnati region; e-rep for 2-state region
Coordination of sales and support services; responsible for integrated delivery network in four-state region

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

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			
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?		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:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials ARG

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 Goldy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/21
Date

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

State of South Carolina, ss. County of Greenville

I, Andrew Goldy, 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

11/29/21
Date

Subscribed and Sworn to before me this 29th day of November.

Mary Ellen Conley
Notary Public Signature

(Seal)

Applicant's initials APG

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 North American Rescue, LLC

Physical Address 35 Tedwall Court

City Greer State SC Zip 29650

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 864-675-9800 Website www.narescue.com

Licensing Company Email mconley@narescue.com

Section 2: Personal Information

First James Middle Edward Last Carino

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address 35 Tedwall Court

City Greer State SC Zip 29650

Telephone 864-675-9800 Email jcarino@narescue.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: N/A to: _____

Military Occupation/Specialty N/A

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 _____

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 Pennsylvania State University		09/74 - 11/78	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Elk County Catholic High School			
Address	**City**	**State**	**Zip**
600 Maurus Street	St. Marys	PA	15857
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
01/98 - present	[redacted]Bentford Court	Simpsonville	SC	29681
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
North American Rescue, LLC			01/05 - present
Business Address	**City**	**State**	**Zip**
35 Tedwall Court	Greer	SC	29650
Phone	**Title**		
864-675-9800	Vice President		
Description of Duties			
Oversight of facilities, warehouse operations, quality management			

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 N/A			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 _____

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 _____

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:

N/A

Original Signature (electronic, copies or stamps not accepted)

December 21, 2021
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.

James Carino

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

December 21, 2021

Date

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

State of South Carolina, ss. County of Greenville

I, James Carino, 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

December 21, 2021

Date

Subscribed and Sworn to before me this 21st day of December, 2021

Mary Ellen Conley

Notary Public Signature

(Seal)

Applicant's initials

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 North American Rescue, LLC

Physical Address 35 Tedwall Court

City Greer State SC Zip 29650

Mailing Address (if different from physical address) same

City State Zip

Telephone 864-675-9800 Website www.narescue.com

Licensing Company Email mconley@narescue.com

Section 2: Personal Information

First Andrew Middle Paul Last Goldy

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address 35 Tedwall Court

City Greer State SC Zip 29650

Telephone 864-675-9800 Email agoldy@narescue.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: 1995 to: 2003

Military Occupation/Specialty Legal administration/Fire direction control

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 APG

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)	
Wright State University			08/98 - 05/02	
Address		**City**	**State**	**Zip**
3640 Colonel Glenn Highway		Dayton	OH	45435
Diploma/Degree obtained, if any				
Bachelor of Arts				
School Name			**From - To (MM/YY – MM/YY)**	
Grove City High School			09/91 - 06/95	
Address		**City**	**State**	**Zip**
4665 Hoover Road		Grove City	OH	43123
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)**	
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
11/16 - present	[redacted]Woodbridge Way	Simpsonville	SC	29681
08/14 - 11/16	6445 Oldbarn Court	Cincinnati	OH	45243
10/09- 08/14	6571 Kenview Drive	Cincinnati	OH	45243

Applicant's initials ARG

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)
North American Rescue, LLC			03/19 - present
Business Address	**City**	**State**	**Zip**
35 Tedwall Court	Greer	SC	29650
Phone	**Title**		
864-675-9800	Chief Operations Officer		
Description of Duties			
Oversight of operating functions and strategy			

Business Name			From - To (MM/YY – MM/YY)
Henry Schein Medical			11/16 - 03/19
Business Address	**City**	**State**	**Zip**
526 Congaree Road	Greenville	SC	29607
Phone	**Title**		
864-297-3680	General Manager, EMS Division		
Description of Duties			
Responsible for sales, operations, and financial oversight of EMS Division			

Business Name			From - To (MM/YY – MM/YY)
Henry Schein Medical			01/11 - 11/16
Business Address	**City**	**State**	**Zip**
9472 Meridian Way	West Chester Township	OH	45069
Phone	**Title**		
513-870-9635	Field Sales Consultant; Strategic Account Manager		
Description of Duties			
Respsible for sales growth and business relationships Cincinnati region; e-rep for 2-state region Coordination of sales and support services; responsible for integrated delivery network in four-state region			

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			

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			
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?		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 ARG

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:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials ARG

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 Goldy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/21
Date

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

State of South Carolina, ss. County of Greenville

I, Andrew Goldy, 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

11/29/21
Date

Subscribed and Sworn to before me this 29th day of November.

Mary Ellen Conley
Notary Public Signature

(Seal)

Applicant's Initials APG

41

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler (Manufacturer)		☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	■ 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)

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Noven Pharmaceuticals, Inc.

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 305-964-3323 Website: www.noven.com

Name of Designated Representative (DR): Jose Almodovar

Licensing Company Email: Permits@noven.com DR Email: JAlmodovarTorres@noven.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.

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: Aspen API INC
Address: 2136 SOUTH WOLF ROAD City: DES PLAINES State: IL Zip: 60018

Name: CHATTEM CHEMICALS INC
Address: 3708 ST ELMO AVENUE City: CHATTANOOGA State: TN Zip: 37409

Name: SpecGx LLC
Address: 385 MARSHALL AVENUE City: WEBSTER GROVES State: MD Zip: 63119

Name: DUPONT
Address: 486 COLEMAN ROAD City: CHESHIRE State: CT Zip: 06410

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

State of Incorporation: Delaware
Parent Company (if any): Hisamitsu Pharmaceutical Co., Inc.
Corporation Name: Noven Pharmaceuticals, Inc.
Mailing Address: 1960 SW 144th Street
City: Miami State: FL Zip: 33186
Telephone: 305- 964-3323 Email: Permits@noven.com
Contact Person Name: Arlette Azua

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 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 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**	✓			
• **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.

Arlette Azua

Print Name of Authorized Person Submitting Application

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

07/22/21

Date

Processed 9/1/21

Board Use Only	Date Received: _____	Amount: $500 Check #034305

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS (850) 487-1395
2601 BLAIR STONE ROAD
TALLAHASSEE FL 32399-1047

NOVEN PHARMACEUTICALS, INC.
11960 SW 144TH STREET
MIAMI FL 33186

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

20260 ISSUED: 09/27/2021

PRESCRIPTION DRUG MANUFACTURER
NOVEN PHARMACEUTICALS, INC.

HAS REGISTERED under the provisions of Ch.499 FS.
Expiration date: OCT 31, 2023 L2109270000173

DETACH HERE

RON DESANTIS, GOVERNOR JULIE I. BROWN, SECRETARY

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

LICENSE NUMBER
20260

The PRESCRIPTION DRUG MANUFACTURER
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: OCT 31, 2023

NOVEN PHARMACEUTICALS, INC.
11960 SW 144TH ST &
14500 & 14530 SW 119TH AVE
MIAMI FL 33186

ISSUED: 09/27/2021 DISPLAY AS REQUIRED BY LAW SEQ # L2109270000173

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NOVEN 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 THIRTIETH DAY OF AUGUST, A.D. 2021.

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

2116094 8300

SR# 20213117266

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

Authentication: 204041092

Date: 08-30-21

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

Welcome, NOVEN PHARMACEUTICALS, INC. | Logout ALL Sessions (/webforms2/spring/logout) Need Help? Email Us: DEA.Registration.Help@usdoj.gov
Call Us Toll Free: 1-800-882-9539

CSA Registration Online Mgmt Tools: CSA Registration Validation Tool

DEA Number to be validated	RN0392136 Validate

DEA Number:	RN0392136
This DEA Number is ACTIVE	
Name(Last, First)	NOVEN PHARMACEUTICALS, INC.
Business Activity	MANUFACTURER
Registered Address:	11960 SW 144TH ST
City	MIAMI
State	FL
Zip	33186
Schedules	2 2N 3 3N 4
Fee Status:	Paid
Drug Codes:	1105 9143 9740 1615 9150 1100 9652 9801 4000 9220 1724
Expire Date:	10/31/2022

Download Registrant Validation **Please download a copy of your Registrant Validation Report for your records.**

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0392136	10-31-2021	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4	MANUFACTURER	10-08-2020

NOVEN PHARMACEUTICALS, INC.
11960 SW 144TH ST
MIAMI, FL 331866109

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
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Form DEA-223 (9/2016)

List of Directors, Noven Pharmaceuticals, Inc.

1) Naruhito Higo (Director 1)

Chairman of the Board, Noven Pharmaceuticals, Inc.

2) Toshiaki Tsuruda (Director 2)

Vice Chairman of the Board, Hisamitsu Pharmaceutical Co. Inc.

2-4-1 MARUNOUCHI

TOKYO, CHIYODA-KU 100-6330 Japan

3) Joel Lippman (Director 3)

Director, Noven Pharmaceuticals, Inc.

List of Officers, Noven Pharmaceuticals, Inc.

1) Naruhito Higo

Chairman & Chief Executive Officer

2) Joel Lippman

Chief Operating Officer & Chief Medical Officer

3) John Choi

Vice President, Chief Financial Officer & Treasurer

4) Takehito Kiuchi

Vice President, Hisamitsu Group Strategy & Planning

Drug Establishments Current Registration Site

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Noven**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Noven Pharmaceuticals, Inc.	1000222037	148585441	ANALYSIS; MANUFACTURE;	11960 SW 144 Street, Miami, Florida (FL) 33186, United States (USA)	12/31/2021

Showing 1 to 3 of 3 entries

Previous1Next

Data Current through: Tuesday, Apr 20, 2021

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified 10/7/21 MS

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Noven**

CSVExcel

Filter: 11

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Noven Pharmaceuticals, Inc.	1000222037	148585441	ANALYSIS; MANUFACTURE;	11960 SW 144 Street, Miami, Florida (FL) 33186, United States (USA)	12/31/2022

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Sunday, Jan 9, 2022

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Employee List - Noven Companies

Last Name	First Name
Abello	Teresa
Abou Baker	Cecilia
Acosta	Evelyn
Aguilar	Martha
Aikens	Clement
Almodovar Torres	Jose
Alvarez	Lucia
Alvarez	Oscar
Alvarez	Ybel
Andrade	Natalie
Andriuoli	Julio
Arenas	Diana
Ares	Marcos
Arias	Jessica
Avino	Salvatore
Aybar	Jose
Azua	Arlette
Balakrishnan	Kanan
Balliram	Jamie
Batson	Josanne
Benavides	Brian
Benitez	Julio
Bermudez	Roger
Berrios	Maribel
Bilbao	Maria
Bishaw	Mireille
Bonne	Somi
Bou	Judith
Bouzas	Lourdes
Bowers	Carrie
Bravo	Carlos
Brutus	Hans
Buckley	Devin
Byreddy	Sandeep
Caballero	Rossana
Cabrales	Brian
Cacioppo-Sorvill	Celeste
Calderon Correa	Damarys
Calderon Cruz	Sharlim
Calero	Edgardo
Campbell	Brendan
Capera	Lisa
Cardenas	Ludys
Cardona	Elizabeth
Cardona	Maria
Carrasquillo	Denelisse
Cartas	Delia
Casellas	Christian
Castelli	Mariacristina

Castrillon	Yudi
Castro	Benjamin
Castro	Osmar
Cata	Mixilexi
Chacin	David
Chin	Marilisa
Chinea	Tahamara
Choi	John
Cid	Ana
Cinnante	Dennis
Clavijo	Raisa
Comin	Raul
Conde	Denise
Contreras	Nathan
Corneille	Stephenson
Couso	Delsy
Cuevas	Eduardo
Curtis	Taryn
Desai	Saloni
Diaz	Alexis
Diaz	Armando
Diaz	Myra
Doddapaneni	Jagadeesh
Dominguez	Leslie
Donayre	Maria
Duncan	Cari
Escobar	Monica
Evans	Akeem
Felipe	Emily
Fernandez	Juan
Fernandez	Omar
Fonseca	Ana
Fonseca	Jose
Fonvil	Sam
Fornos	Mivis
Fraga	Allana
Francis	Martha
Francois	Jesula
Franqui	Olga
Freire	Santiago
Fuentes	Gualberto
Fundora Arza	Angel
Galeano	John
Galeano	Maria
Galeano	Yasna
Galy	Michael
Garces	Nicolas
Garcia Diaz	Nuria
Garcia Giraldelli	Marcio
Garriga	Nilda
Gatti	Cynthia
Gavrilas	Cristian

Gibson	Eric
Gilzean	Shanice
Gomez	Efrain
Gomez	Harley
Gonzalez	Griselvia
Gonzalez	Ismary
Gonzalez	Sueheith
Gonzalez	Susana
Gonzalez	Vanessa
Gonzalez Perez	Pedro
Goytia Cruz	Provimar
Guerra	Evelyn
Hahn	Sheryll
Haj-Ibrahim	Houda
Harrison	Patricia
Herbert	Andrew
Hernandez	Daylin
Hernandez	Diana
Hernandez	Hector
Heximer	Anuradha
Higo	Naruhito
Jarvis	Brenda
Jean	Adeline
Jean-Baptiste	Farah
Jefferson	Travis
Jimenez	Catalina
Jimenez	Diana
Jimenez	Juan
Jimenez	Luis
Jinete	Christian
Julian	Carmen
Kadiwar	Gautam
Katayama	Ken
Kaufman	Astrid
Kelly	Matthew
Khan	Mahwish
Khodadadi	Farzan
Kibria	Farhana
Kiuchi	Takehito
Klauss	Gunnar
Komaroff	Marina
Kulakofsky	Joshua
Lacayo	Promise
Lacotera	Verda
Lagomasino Carreras	Jose
Lambert	Robert
Lamenta	Stephanie
Lanzas	Jorge
Lara Flores	Joarce
Laurence	Samantha
Lawson	Raphael
Lebron	Carlos

Lee	Kenneth
Lippman	Joel
Lopez	Mercedes
Loyola Otero	Norberto
Lozano	Oscar
Luis Barrios	Osmany
Machuca Perez	Keysa
Macias Vazquez	Erika
Maestri	Johan
Manikonda	Prithvi Chandh
Marrero Cruz	Evy
Martinez	Cesar
Martinez	Jorge
Martinez	Jorge
Martinez	Jose
Martinez	Ricardo
Martinez	Wallie
Martinez-Ortiz	Ferdinand
Mathews	Reena
Meeves	Suzanne
Merida	Adam
Mohammed	Abdul Gaffar
Molina	Bresnier
Mondal	Deboprosad
Montalvo	Elena
Montoya	Angelica
Motamedi	Sahar
Munoz	Carlos
Murphy	Dennis
Navarrete	Erick
Negron	Che-Aufier
Nguyen	Viet
Noa Lima	Elizabeth
Noriega	Jose
Noyola	Carlos
Nunez	Marta
Obando	Johanna
Ocampo	Germanico
Orizondo	Matilde
Ortiz	Ben
Osorio	Mario
Osunde	Eseohen
Pastrana	Dennis
Pau	Leslie
Pavon Blanchet	Alexey
Pena	Alejandro
Perez	Elsa
Perez	Humberto
Perez	Marvin
Perez	Violetta
Perez Campana	Edelmira
Pernas	Enrique

Pierre	Patricia
Pire	Geidy
Purcell	Andrew
Ramirez	Luis
Ramon	Maritza
Ramos	David
Redd	Michael
Reynaldo	Marilyn
Richemond	Philoria
Richemond	Rose
Rios	Gerardo
Rivera	Alicia
Rivera	Roxana
Rivera Cordero	Marielis
Rivera Gonzalez	Lemuel
Rivera Sepulveda	Laymarie
Rivero	Yeniser
Rodrigues	Claudio
Rodriguez	Arnaldo
Rodriguez	Carlos
Rodriguez	Daniel
Rodriguez	Ivan
Rodriguez	Loreli
Rodriguez	Miguel
Rodriguez	Reyna
Rodriguez	Rolando
Rodriguez Gonzalez	Maydel
Rojas	Lissette
Romero	Dina
Romero	Lazara
Romero	Valeria
Roque	Jandro
Rosario	Maria
Sakhdari	Setareh
Salas	Jackeline
Salcedo	Joan
Saltos	Karina
Sanabria	Cassandra
Sandoval	Kathia
Santana Fuentes	Mabel
Sautie Castellanos	Beatriz
Sevilla	Belen
Shankar	Gayathri
Shao	Fei
Sharp	James
Shelley	Josie
Sintas	Jose
Soberats	Luis
Solivan	Armando
Sonobe	Atsushi
Sorbara	Matthew
Soto	Jessica

Space	Ryan
St. Elien	Sheila
Stade	David
Stamler	Ella
Starling	Brittney
Sterling	Chris
Stewart	Winn
Suarez	Margarita
Suzuki	Satoshi
Tanaka	Hiroyuki
Taylor	Iran
Thomas	Brent
Thomas	Candace
Tong	Suk
Trajtman	Angel
Valls	Ana
Vargas	Edgardo
Vargas	Luis
Vasquez	Jackson
Vellon Jr.	Bernardo
Vergel	Rodrigo
Villacres	Yamile
Villatoro	Alma
Vivero	Yanira
Wascura	Joseph
Wasserman	Patricia
Waters	Robert
Williams	Anthony
Yano	Toru
Yoshioka	Kazuki
Zayas	Eleodoro
Zequeira	Consuelo
Zuniga	Teresa

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. SU1173569

Application/License No. _____

Noven Pharmaceuticals, Inc. and its wholly-owned subsidiary Noven Therapeutics, LLC, doing or intending
Applicant/Principal
to do business as a pharmaceutical wholesaler, whose address for purposes of service is
11960 SW 144th Street, Miami, FL 33186, as
Address of Applicant/Principal
PRINCIPAL, and Arch Insurance Company, a
Surety Company
corporation organized under the laws of the state of Missouri
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
Harborside 3, 210 Hudson Street, Jersey City, NJ 07311-1107 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 July 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 19th day of July, 20 21.

APPLICANT/PRINCIPAL

Noven Pharmaceuticals, Inc. and its wholly-owned subsidiary Noven Therapeutics, LLC

Authorized Representative

SURETY COMPANY

Arch Insurance Company

Surety Company's Representative

Anett Cardinale, 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:

Anett Cardinale
Neveda Licensed Non-Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Alexa Diaz, Anett Cardinale and Radha Jones of Tampa, FL (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding Ninety Million Dollars ($90,000,000.00).
This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on December 10, 2020, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:
"**VOTED**, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on December 10, 2020:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on December 10, 2020, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **26th day of April, 2021**.

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
MICHELE TRIPODI, Notary Public
City of Philadelphia, Phila. County
My Commission Expires July 31, 2021

Michele Tripodi, Notary Public
My commission expires 07/31/2021

CERTIFICATION
I, **Regan A. Shulman**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated April 26, 2021** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.
IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 19 **day of** July, **20** 21.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com
Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

Arch | Insurance

Commercial Surety Application and Indemnity Agreement

Applicant's Full Name (name that will appear on bond): [redacted]	Bond Amount: $25,000
Business Address 11960 SW 144th Street, Miami, FL 33186	Year Started Business: 1987
Obligee Name and Address: Nevada State Board of Pharmacy	Type of Bond/Bond Title: Surety bond
Name and Address of Owner/Indemnitor:	SSN: % of Ownership: Email:
Name and Address of Owner/Indemnitor:	SSN: % of Ownership: Email:
Name and Address of Owner/Indemnitor:	SSN: % of Ownership: Email:

Has the applicant or any partners been bankrupt or insolvent? ☐ Yes, ☒ No
Are there any lawsuits, judgments, or liens outstanding against the Applicant? ☒ Yes, ☐ No
Has the Applicant for this bond been declined by another Surety? ☐ Yes, ☒ No
Please Explain all "yes" answers:

Noven is occasionally party to lawsuits, primarily for patent litigation, which is not unusual in the pharmaceutical industry.

Prior Surety: ☐ Yes, ☒ No If "Yes", give name and reason of change.

LOST INSTRUMENT BOND

Type of security and registration number: _____
Date of Instrument: _____
Payable to Applicant only? ☐ Yes ☐ No, to whom is it payable? _____
Are securities endorsed? ☐ Yes, how? _____ ☐ No
Has notice of loss been given? ☐ Yes, when and to whom? _____ ☐ No
Describe manner of loss _____
If registered, in whose name? _____
If a check, has payment been stopped? ☐ Yes, when? _____ ☐ No
If deed of trust or note, has either been involved in a lawsuit? ☐ Yes ☐ No Was judgment obtained? ☐ Yes ☐ No
If a bond, please provide:
Face Amount $_____ Interest %_____
Maturity Date: _____ Interest Paid: $_____
How and when is the interest paid? _____
If a stock certificate, please provide:
Number of Shares: _____ Current Market Value: $_____
Ticker Symbol: _____
Is the instrument negotiable? ☐ Yes ☐ No
Has any Power of Attorney been executed that would enable another person to transfer said instruments? ☐ Yes ☐ No

COURT BOND AND RECEIVER/TRUSTEE BOND
(Attach copy of initial pleadings and other relevant documents)

Explain Bond purpose: _____
Case number, Court and Docket Number: _____
Name and Address of Principal's Attorney: _____
If an injunction or restraining order, does the applicant anticipate foreclosure or collection against him/her? ☐ Yes ☐ No
Name and Address of bankrupt (debtor): _____
Name of debtor's business: _____
Do you carry Fidelity coverage? ☐ Yes, Amount: $_____ Carrier: _____ ☐ No
Do you carry Professional Liability or E&O coverage? ☐ Yes, Amount: $_____ Carrier: _____ ☐ No

Agency Name: _____

Recommendation: _____

Arch | Insurance

INDEMNITY AGREEMENT

The undersigned Applicant and Indemnitor(s) represent that all statements made in this Application are true and made to induce Arch Insurance Company and/or Arch Reinsurance Company and/or any other affiliate or subsidiary of Arch Insurance Company or Arch Reinsurance Company, severally not jointly and/or any other company for which surety business is underwritten by Arch Insurance Company and/or Arch Reinsurance Company, severally not jointly (Surety) to extend surety credit including but not limited to providing or having provided requested bond(s), and increase of the same or any bond or undertaking of similar nature given in substitution or renewal thereof, in reliance upon the provisions of Indemnitor(s)' indemnity and with regard to such surety credit, the undersigned Indemnitor(s) hereby agree to pay the premiums and renewal premiums for each bond period, until Surety has received written legal evidence, satisfactory to Surety, in its sole discretion, of the discharge from all such bonds and all liability related thereto. Indemnitor(s) agree to exonerate, indemnity and keep indemnified, the Surety and save it harmless from and against any and all liability for loss and expense of whatsoever kind of nature, including, but not limited to pre- and post judgment interest, court costs, attorney fees, and from and against any and all such losses and/or expenses incurred by Surety in connection with or by reason of furnishing any bond(s) hereunder. The Indemnitor(s) hereby agree to deposit upon demand with Surety an amount sufficient to discharge any claim of any such bond, which deposit may be held by Surety as collateral security against any loss, cost or expense on this bond. Indemnitor(s) authorize Surety to access its credit records and to make relevant inquiries as may be necessary from third party sources for the following purposes: (1) to verify information provided to Surety; (2) for underwriting purposes; and (3) upon receipt of a notice of claim or potential claim, for debt collection. Surety may furnish copies of any and all statements, agreements and financial statements and any information, which it now or may hereinafter obtain concerning each of the Indemnitor(s) to any companies or persons for the purpose of obtaining co-surety or reinsurance. Indemnitor(s) agree that Surety may decline the bond applied for, or may cancel or terminate such without incurring liability whatsoever to Indemnitor(s). Surety may exercise its remedies with respect to collateral security in the event of (1) Indemnitors' failure to fulfill any covenant, condition or obligation whatsoever: (a) for which Bond(s) are provided; (b) contained in any Bond(s) regardless of the Surety; or (c) contained within any Indemnity Agreement or other Agreement with the Surety and (2) any assignment by Indemnitor(s) for the benefit of creditors or any agreement or proceeding of liquidation, receivership or bankruptcy whatsoever. In the event of any payment by the Surety, the Indemnitor(s) agree that the Surety shall be entitled to charge for any and all disbursements made by it in and about the matters herein contemplated by this Agreement under the belief that it is or was liable for the sums and amounts so disbursed or that it was necessary or expedient to make such disbursements, whether or not such liability, necessity or expediency existed; and that the vouchers or other evidence of any such payments made by the Surety shall be *prima facie* evidence of the fact and amount of the liability to the Surety.

With respect to Court Bonds and Receiver/Trustee Bonds: INDEMNITORS ACKNOWLEDGE AND AGREE THAT: FIRST YEAR PREMIUM IS FULLY EARNED WHEN THE BOND IS ISSUED EVEN IF THE BOND IS SUBSEQUENTLY REDUCED OR TERMINATED DURING THE FIRST YEAR. IF THE BOND IS REDUCED OR TERMINATED DURING THE SECOND OR SUBSEQUENT YEAR, A RENEWAL PREMIUM SHALL BE ADJUSTED PRO-RATA UPON REDUCTION OR TERMINATION.

A DUPLICATE OR FACSIMILE COPY OR ELECTRONIC REPRODUTION OF THE GENERAL COMMERCIAL SURETY APPLICATION AND INDEMNITY AGREEMENT SHALL HAVE THE SAME FORCE AND EFFECT AS THE ORIGINAL.

Attention: *Any person who knowingly and with intent to defraud a surety company or other person files an application for a surety bond containing any materially false information, or conceals, for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent act and may be subject to civil and/or criminal penalties.*

Signed and dated this 16 day of July, 20 21

Individual/Sole Proprietorship Name: _____ SSN: _____

Individual Name: _____ SSN: _____

By: _____ (Seal) Witness: _____
, Individual/Proprietor

By: _____ (Seal) Witness: _____
, Individual

Partnership/Limited Partnership: _____ FEIN: _____

By: _____ (Seal) Witness: _____
, Individual & Partner

By: _____ (Seal) Witness: _____
, Individual & Partner

Corporation Name: Noven Pharmaceuticals, Inc and its wholly-owned subsidiary Noven Therapeutics, LLC FEIN: 59-2787832

By: [signature] (Seal) Attest: [signature]
, President , Secretary

Limited Liability Company Name: _____ FEIN: _____

By: _____ (Seal) Attest: _____
, Member, Manager or Managing Member , Secretary

USI UNDERSTAND. SERVICE. INNOVATE.

USI Insurance Services
2502 N. Rocky Point Drive, #400
Tampa, FL 33607
www.usi.com
Phone: (813) 320-0239

July 19, 2021

Ms. Alexis Diaz
Noven Pharmaceuticals, Inc.
11960 SW 2144th Street
Miami, FL 33186

RE: State of Nevada Bond SU1173569
Bond Amount $25,000.00

Dear Alexis,

Per your request, enclosed please find the captioned bond for the state of Nevada; the invoice will follow via email.

If you should have any questions, please reach out to me at (813) 610-4588 or anett.cardinale@usi.com

We appreciate your confidence in USI and look forward to serving you again.

Sincerely,

Anett Cardinale

Anett Cardinale
Surety Account Manager

Enclosure

Maria Herrera

From: Permits <Permits@noven.com>
Sent: Wednesday, August 18, 2021 8:50 AM
To: Maria Herrera; Permits
Cc: Campbell, Teresa
Subject: [Unverified Sender] RE: Nevada Wholesaler Application-Noven Therapeutics, LLC dba Grove Pharmaceuticals & Noven Pharmaceuticals

Hello Maria,

One license is the manufacturer, Noven Pharmaceuticals Inc. and the other is the distributor, Noven Therapeutics LLC. They are both located at the same address since Noven Therapeutics is a virtual company that is only used as a distributor. Do we need both licenses? Or just for one company?

I appreciate the help, thank you in advance,

Arlette Azua (アレット アズーア) **BS, MS, MBA**
Manager, Regulatory Affairs CMC
Noven Pharmaceuticals, Inc.
11960 SW 144th Street
Miami, Florida 33186
Direct: 305-964-3323
aazua@noven.com

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, August 17, 2021 5:01 PM
To: Permits <Permits@noven.com>
Subject: [EXTERNAL EMAIL] Nevada Wholesaler Application-Noven Therapeutics, LLC dba Grove Pharmaceuticals & Noven Pharmaceuticals

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. If you received a link to access a shared file, please contact the person first before clicking on it.

Hello,

We received 2 applications for the same location, just wanted to confirm that each license will be distributing for only one manufacture?

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206

Maria Herrera

From: Permits <Permits@noven.com>
Sent: Wednesday, August 18, 2021 11:09 AM
To: Maria Herrera
Cc: Campbell, Teresa; Escobar, Monica; Gonzalez, Vanessa; Casellas, Christian; Bouzas, Lourdes
Subject: [Unverified Sender] RE: Nevada Wholesaler Application-Noven Therapeutics, LLC dba Grove Pharmaceuticals & Noven Pharmaceuticals

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Waiting for Mark

Hello Maria,

We use a 3PL company to distribute our products, therefore we do not ship to Nevada directly from our Miami location. We also have a third party contractor for our sales representative, none of which are employed by either company, Noven Pharmaceuticals or Noven Therapeutics. Here is a summary description of our operations:

- Noven Pharmaceutical is the manufacturer of drug products
- Noven Therapeutics dba Grove Pharmaceutical is the distributor
- We use a 3PL to distribute nationwide
- Neither company has a sales force, we use a third party company

I hope that helps, please feel free to reach back with any other questions. I'll do my best to answer them.

Arlette

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, August 18, 2021 12:24 PM
To: Permits <Permits@noven.com>
Subject: [EXTERNAL EMAIL] RE: Nevada Wholesaler Application-Noven Therapeutics, LLC dba Grove Pharmaceuticals & Noven Pharmaceuticals

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. If you received a link to access a shared file, please contact the person first before clicking on it.

Good Morning Arlett,

1)Do either of the entities ship directly to the state of Nevada? 2)And do either have any sales reps in Nevada?

Regards,

Maria H.

IMS Health & Quintiles are now
IQVIA™

State Services
1025 Boulders Parkway
Suite 301
North Chesterfield, VA 23225
iqvia.com

Via Federal Express

July 22, 2021

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

Dear Ladies and Gentlemen:

Enclosed, you will find an initial application along with Check in the amount of $1000.00 (covering 2 applications) and required attachments on behalf of Noven Pharmaceuticals, Inc., located at 11960 SW 144th Street, Miami, FL 33186 who is applying for licensure in your state as an Out-of-State Wholesaler.

If you have any questions, please call me toll-free at (888) 590-9954 ext. 5079 or email me at Teresa.campbell1@iqvia.com.

Thank you for your time and assistance in this matter.

Sincerely,

Teresa Campbell

Teresa Campbell
State Services

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 Noven Pharmaceuticals, Inc.

Physical Address 11960 SW 144th Street

City Miami State FL Zip 33186

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 305-964-3323 Website www.noven.com

Licensing Company Email Permits@noven.com

Section 2: Personal Information

First Jose Middle _____ Last Almodovar

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

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

Mailing Address Same as above

City _____ State _____ Zip _____

Telephone [redacted] Email jalmodovar@torrepharma.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 JAT

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 Puerto Rico, Mayaguez Campus		08/1982 – 12/1987	
Address	**City**	**State**	**Zip**
PO Box 9000 Calle Post	Mayaguez	PR	00681-9000
Diploma/Degree obtained, if any			
Bachelors Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Blanca Malaret High School		08/1979 – 05/1982	
Address	**City**	**State**	**Zip**
96 C/1 Pedro Rodriguez Acosta	Sabana Grande	PR	00637
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
01/2017 – Present	[redacted] EL MAR DR. 302	Lauderdale by the Sea	FL	33308
05/2006 – 12/2016	3856 E Hibiscus ST	Weston	FL	33332

Applicant's initials JAT

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: Noven Pharmaceutical, Inc.			From - To (MM/YY – MM/YY): 05/2017 - Present
Business Address: 1960 SW 144th Street	City: Miami	State: FL	Zip: 33186
Phone: 305- 964-3323	Title: Executive Director Plant Manager		Number of Employed Hours: 8,000
Description of Duties:			

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

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

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

Applicant's initials JAT

I, Jose Almodovar, **certify that as the designated representative for** Noven 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

Jose Almodovar
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 25, 2021
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.

Jose Almodovar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/25/2021

Date

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

State of FLORIDA, ss. County of DADE

I, Jose Almodovar, 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

Jun 29, 2021

Date

Subscribed and Sworn to before me this 29th day of June 2021

Sheryll K Hahn

Notary Public Signature

Notary Public State of Florida
Sheryll K Hahn
My Commission GG 128585
Expires 06/29/2021

(Seal)

Applicant's initials JAT

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: Noven Pharmaceuticals, Inc.

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-253-5099 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: Naruhito Middle: Last: Higo

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

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

Mailing Address: Same as above

City: State: Zip:

Telephone: [redacted] Email: NHigo@noven.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: NH

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)	
Konan high school		4/1985-3/1988	
Address	**City**	**State**	**Zip**
Kaminosano-cho 23-1	Kagoshima	Kagoshim	890-0052
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Kumamoto University		4/1989-3/1985	
Address	**City**	**State**	**Zip**
Kurokami 2-39-1	Kumamoto	Kumamotc	860-8555
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
7/2017-7/2021	[redacted] McFarlane Rd #1218	Coconut Grove	Florida	33133
5/2010-6/2017	Abiko2-4	Abiko	Chiba	270-1166

Applicant's initials MH

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)
Noven Pharmaceuticals, Inc.			7/2017-7/2021
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
305-964-3503	Chairman of the Board		
Description of Duties			
As a Chairman and CEO, I lead the company by making important decisions for the sustainable growth meeting social compliance requirements.			

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) 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.

Naruhito Higo

Print Name (First, Last)

Naruhito Higo

Original Signature (electronic, copies or stamps not accepted)

July 2, 2021

Date

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

State of Florida, ss. County of Miami-Dade

I, Naruhito Higo, 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.

Naruhito Higo

Original Signature

July 2, 2021

Date

Subscribed and Sworn to before me this 7th day of July 2021

Sheryll K. Hahn

Notary Public Signature Sheryll K. Hahn

Notary Public State of Florida
Sheryll K Hahn
My Commission GG 128585
Expires 08/27/2021

(Seal)

Applicant's initials NH

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: Noven Pharmaceuticals, Inc.

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-964-3323 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: Takehito Middle: Last: Kiuchi

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

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

Mailing Address: [redacted] S Le Jeune Rd. [redacted]

City: Coral Gables State: FL Zip: 33134

Telephone: [redacted] Email: TKiuchi@noven.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: T.K.

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)
Nagano Yoshida High School			04/89-03/92
Address	**City**	**State**	**Zip**
2-12-9, Yoshida, Nagano-city, Nagano, Japan			381-8570
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Showa University, School of Pharmacy			04/92-03/95
Address	**City**	**State**	**Zip**
1-5-8, Hatanodai, Shinagawa-ku, Tokyo, Japan			142-8555
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Showa University, Graduate School of Pharmaceutical Sciences			04/95-03/97
Address	**City**	**State**	**Zip**
1-5-8, Hatanodai, Shinagawa-ku, Tokyo, Japan			142-8555
Diploma/Degree obtained, if any			
Master of Pharmaceutical Sciences			

School Name			From - To (MM/YY – MM/YY)
Keio University, Management Development Program of Keio Business School			09/11-11/11
Address	**City**	**State**	**Zip**
4-1-1 Hiyoshi Kohoku-ku, Yokohama, Kanagawa, Japan			223-8526
Diploma/Degree obtained, if any			
Completed Management Development Program			

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
07/09-03/21	1-23-22-506 Chidori, Ota-ku, Tokyo, Japan			146-0083
04/21-04/21	8250 SW 72nd Court #517	Miami	FL	33143
05/21-	[redacted] S Le Jeune Rd. [redacted]	Coral Gables	FL	33134

Applicant's initials T. K.

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)
Noven Pharmaceuticals, Inc.			03/21-
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
305-964-4601	Vice President, Hisamitsu Group Strategy & Planning		

Description of Duties

It is to act as intermediary between Hisamitsu Pharmaceutical Co., Inc. and Noven management to lead Hisamitsu's strategic objective successfully and expand the business to the United States.

Business Name			From - To (MM/YY – MM/YY)
Hisamitsu Pharmaceutical Co., Inc.			03/18-02/21
Business Address	City	State	Zip
2-4-1 Marunouchi, Chiyoda-Ku, Tokyo, Japan			100-6330
Phone	Title		
+81-3-5293-1713	Department General Manager of Business Development Department		

Description of Duties

It is to oversee the department activities and directs conducting feasibility study on all the products under development by Hisamitsu and Noven.

Business Name			From - To (MM/YY – MM/YY)
Hisamitsu Pharmaceutical Co., Inc.			03/13-02/18
Business Address	City	State	Zip
2-4-1 Marunouchi, Chiyoda-Ku, Tokyo, Japan			
Phone	Title		
+81-3-5293-1713	Section Manager of Business Development Department		

Description of Duties

It is to oversee the section activities and to conduct feasibility study on all the products under development by Hisamitsu.

Business Name			From - To (MM/YY – MM/YY)
Hisamitsu Pharmaceutical Co., Inc.			03/08-02/13
Business Address	City	State	Zip
2-4-1 Marunouchi, Chiyoda-Ku, Tokyo, Japan			
Phone	Title		
+81-3-5293-1713	Licensing Department		

Description of Duties

It is to engage in licensing-in activities for other companies' products and to manage business alliances with partners.

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 T.K.

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 T.K.

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.

Takehito Kiuchi

Print Name (First, Last)

Takehito Kiuchi — 07/01/2021

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 Miami-Dade

I, Takehito Kiuchi, 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.

Takehito Kiuchi — 07/01/2021

Original Signature — **Date**

Subscribed and Sworn to before me this 1st day of July 2021.

Sheryll K. Hahn

Notary Public Signature Sheryll K. Hahn

Notary Public State of Florida
Sheryll K Hahn
My Commission GG 128585
Expires 08/27/2021
(Seal)

Applicant's initials T.K.

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: Noven Pharmaceuticals, Inc.

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-253-5099 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: John Middle: S Last: Choi

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

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

Mailing Address: [redacted] Mountain Run

City: Boonton State: NJ Zip: 07005

Telephone: [redacted] Email: JChoi@noven.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 JC

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 Utah		09/90-06/92	
Address	City	State	Zip
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Master of Business Administration (MBA)			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		01/86-06/90	
Address	City	State	Zip
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Bachelor of Arts Accounting (BAA)			

School Name		From - To (MM/YY – MM/YY)	
Hankuk University of Foreign Studies		03/83-06/85	
Address	City	State	Zip
107 Imun-ro, Imun-dong, Dongdaemun-gu	Seoul	So. Korea	
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Seoul High School		03/80-02/83	
Address	City	State	Zip
197 Hyoryeong-ro, Seocho 3(sam)-dong, Seocho-gu	Seoul	So. Korea	
Diploma/Degree obtained, if any			
High School			

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
09/10-07/21	[redacted]Mountain Run	Boonton	NJ	07005
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 +C

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)
Noven Pharmaceuticals, Inc.			01/16-07/21
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2637	Vice President, Chief Financial Officer & Treasurer		
Description of Duties			
An executive in charge of functions of Finance and Information Technology			

Business Name			From - To (MM/YY – MM/YY)
Noven Pharmaceuticals, Inc.			04/10-12/15
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2637	Executive Director, Business Planning and Analysis		
Description of Duties			
Director in charge of financial analyses, budgeting and performance tracking			

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.

Applicant's initials JC

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 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.

John Choi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/30/2021

Date

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

State of New York, ss. County of Bronx

I, John Choi, 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

7/7/2021

Date

Subscribed and Sworn to before me this 7 day of July 2021

Notary Public Signature

Maribel Berrios
Notary Public, State of New York
Qualified in Bronx County
Commission # 01BE6295473
Commission expires January 6, 2022

(Seal)

Applicant's initials JC

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: Noven Pharmaceuticals, Inc.

Physical Address: 11960 SW 144th Street

City: Miami State: FL Zip: 33186

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 305-964-3323 Website: www.noven.com

Licensing Company Email: Permits@noven.com

Section 2: Personal Information

First: Joel Middle: S Last: Lippman

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

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

Mailing Address: Same as above

City: State: Zip:

Telephone: [redacted] Email: JLippman@noven.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: N/A to: N/A

Military Occupation/Specialty: N/A

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: J L

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)	
Harvard University School of Public Health		1987 - 1988	
Address	City	State	Zip
677 Huntington Avenue	Boston	MA	02115
Diploma/Degree obtained, if any			
Graduate School - M.P.H.			
School Name		From - To (MM/YY – MM/YY)	
University of Connecticut Affiliated Hospitals		1979-1983	
Address	City	State	Zip
200 Academic Way	Farmington	CT	06032
Diploma/Degree obtained, if any			
Internship and Residency - OB-GYN			
School Name		From - To (MM/YY – MM/YY)	
New York Medical College		1975 - 1979	
Address	City	State	Zip
40 Sunshine Cottage Rd	Valhalla	NY	10595
Diploma/Degree obtained, if any			
M.D.			
School Name		From - To (MM/YY – MM/YY)	
New York University		1971-1975	
Address	City	State	Zip
70 Washington Square South	New York	NY	10012
Diploma/Degree obtained, if any			
B.A. Biology			
School Name		From - To (MM/YY – MM/YY	
Canarsie High School		1968-1971	
Address	City	State	Zip
1600 Rockaway Pkwy	Brooklyn	NY	11236
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
2003-2021	[redacted]Raspberry Trail	Warren	NJ	07059
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)
Noven Pharmaceuticals, Inc.			12/2019 - Present
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2647	Chief Operating Officer & Chief Medical Officer		

Description of Duties

Providing leadership throughout the organization as needed. This includes leadership and supervision of clinical pharmacology,clinical research/operations, med affairs, regulatory affairs/PV, legal, business development, marketing

Business Name			From - To (MM/YY – MM/YY)
Independent Consultant			01/2017 - 11/2019
Business Address	**City**	**State**	**Zip**
14 Raspberry Trail	Warren	NJ	07059
Phone	**Title**		
908-229-1504	Consultant		

Description of Duties

Clinical diligence, clinical research and regulatory advice to venture capital and other firms to assist in valuating opportunities and initiating development plans.

Business Name			From - To (MM/YY – MM/YY)
Noven Pharmaceuticals, Inc.			09/2008 - 12/2016
Business Address	**City**	**State**	**Zip**
11960 SW 144th Street	Miami	FL	33186
Phone	**Title**		
551-233-2647	Executive Vice President, Product Development & Chief Medical Officer		

Description of Duties

Responsible for product development from concept through FDA approval, including formulation development, preclinical testing, clinical development, regulatory affairs, medical affairs and drug safety and surveillance. Member of Executive Team.

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 # _____. 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:

Joel S Tippmar

Original Signature (electronic, copies or stamps not accepted)

7/06/21

Date

Applicant's initials JSL

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 S Lippman, MD

Print Name (First, Last)

Joel S Lippman — 7/06/21

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 Bronx

I, Joel S. Lippman, 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.

Joel S Lippman — 7/06/21

Original Signature — **Date**

Subscribed and Sworn to before me this 6 day of July 2021.

Maribel Berrios

Notary Public Signature

Maribel Berrios
Notary Public, State of New York
Qualified in Bronx County
Commission # 01BE6295473
Commission expires January 6, 2022

(Seal)

Applicant's initials JSL

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☐ Nevada ■ Out-of-State
Is your facility a reverse distributor?	☐ Yes ■ No

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*	WH 01728	■ 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)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Padagis US LLC

Physical Address: 3940 Quebec Ave N

City: Minneapolis State: MN Zip: 55427

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-775-2054 Website: www.padagis.com

Name of Designated Representative (DR): Deborah Sullivan

Licensing Company Email: Stephanie.FitzSimmons@padagis. DR Email: Deborah.Sullivan@padagis.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.

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: This site only ships to the Padagis South Carolina LLC Distribution Center

Address: 110 Hidden Lake Circle, STE A City: Duncan State: SC Zip: 29334

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):

Corporation/Organization Name: Padagis US LLC

Mailing Address: 3940 Quebec Ave N

City: Minneapolis State: MN Zip: 55427

Telephone: 800-775-2054 Email: Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@

Contact Person Name: Stephanie FitzSimmons; Trisha Nguyen

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 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 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 **6 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**	✔			
• **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)**	✔	✔	✔	✔
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.

Colter Van Stedum

Print Name of Authorized Person Submitting Application

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

11/4/21

Date

Board Use Only	Date Received: _____	Amount: 500 check # 644144

Maria Herrera

From: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Sent: Wednesday, January 12, 2022 3:41 PM
To: Maria Herrera
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Maria,

Yes, that is correct. Padagis US LLC only ships directly to the distribution center in South Carolina currently. It's set up as a wholesaler as back up in case of a catastrophic event.

Thanks,
Steph

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, January 12, 2022 6:27 PM
To: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

Hi Steph,

One quick question, on the attached page it states that Padagis US, LLC only ships to Padagis South Carolina, LLC distribution Center? Is this Correct?

Regards,
Maria H.

From: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Sent: Wednesday, January 12, 2022 1:33 PM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Maria,

Let's try this again. See attached 😊

Thanks,

Steph

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, January 12, 2022 1:17 PM
To: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

Hi Steph,

Thank you for the quick response, however what you sent me is the certificate for the name change? We would need the one that has the updated name, dated within 6 months and states "in good standing".

Regards,
Maria H.

From: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Sent: Wednesday, January 12, 2022 10:13 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Maria,

Happy New Year to you as well!

Please find attached the Delaware Certificate of Good Standing for Padagis US LLC.

Please feel free to reach out if anything additional is needed.

Thank you!
Steph

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, January 12, 2022 1:07 PM
To: Stephanie FitzSimmons <Stephanie.FitzSimmons@padagis.com>
Subject: RE: Deficiency Response: Nevada Wholesaler License Application-Padagis South Carolina LLC CHOW WH01728 & WH01862

Hello Steph,

Happy New Year!

State of Minnesota

BOARD OF PHARMACY
2829 UNIVERSITY AVE SE #530
MINNEAPOLIS, MN 55414-3251

HAS ISSUED

MANUFACTURER LICENSE NUMBER: 460544 (ACTIVE)

To:

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS MN 55427

EFFECTIVE DATE	EXPIRATION DATE
05/03/2021	05/31/2022

State of Minnesota

BOARD OF PHARMACY
2829 UNIVERSITY AVE SE #530
MINNEAPOLIS, MN 55414-3251

HAS ISSUED

MANUFACTURER LICENSE
NUMBER: 460544 (ACTIVE)

To: PADAGIS US LLC

EFFECTIVE DATE	EXPIRATION DATE
05/03/2021	05/31/2022

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PADAGIS US 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 TWELFTH DAY OF JANUARY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PADAGIS US LLC" WAS FORMED ON THE THIRTY-FIRST DAY OF JANUARY, A.D. 2011.

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

Jeffrey W. Bullock, Secretary of State

4934238 8300

SR# 20220108267

Authentication: 202383541

Date: 01-12-22

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 September 27, 2021

Name	Padagis US LLC
Address	3940 Quebec Ave N Minneapolis, MN 55427

License/Registration Information

Type	Manufacturer License
Category	
Number	460544
Status	Active
Original Issue Date	03/04/2011
Date	05/03/2021
Expiration Date	05/31/2022
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.

10000871 2/001804-1/1-0

1: 5 218/525
PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0417382	03-31-2022	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2, 3,3N,4,5,L1	MANUFACTURER	02-24-2021

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

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
RP0417382	03-31-2022	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2, 3,3N,4,5,L1	MANUFACTURER	02-24-2021

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

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)

10000871. 2/001800-1/1-0

214/525 1: 5

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0417407	03-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	DISTRIBUTOR	02-24-2021

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

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
RP0417407	03-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	DISTRIBUTOR	02-24-2021

PADAGIS US LLC
3940 QUEBEC AVE N
MINNEAPOLIS, MN 55427-1244

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)

Business Record Details »

Minnesota Business Name
Padagis US LLC

Business Type
Limited Liability Company (Foreign)

File Number
4390509-5

Filing Date
07/26/2011

Renewal Due Date
12/31/2021

Registered Agent(s)
Corporation Service Company

Manager
Perrigo Company
515 Eastern Avenue
Allegan, MI 49010
USA

Home Office Address
2711 Centerville Rd #400
Wilmington, DE 19808
USA

MN Statute
322C

Home Jurisdiction
Delaware

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street, Suite 230
Roseville, MN 55113
USA

Home Business Name
Padagis US LLC

Principal Executive Office Address
515 Eastern Avenue
Allegan, MI 49010
USA

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	07/26/2011	Original Filing - Limited Liability Company (Foreign) (Business Name: Paddock Laboratories, LLC)	
☐	2/5/2015	Registered Office and/or Agent - Limited Liability Company (Foreign)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Foreign)	
☐	6/23/2021	Amendment - Limited Liability Company (Foreign) (Business Name: Padagis US LLC)	

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Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Padagis**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Padagis US LLC	2127022	967694121	ANALYSIS; LABEL; MANUFACTURE; PACK;	3940 Quebec Ave N, Minneapolis, Minnesota (MN) 55427, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries

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Data Current through: Thursday, Jul 15, 2021

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified MS 1/12/22

Padagis

Padagis Entities – Officer Listing

Entity	Officers	Officer Contact:
Padagis US LLC (Delaware)	Executive Vice President – Chief Commercial Officer - John Wesolowski Executive Vice President – Chief Growth Officer - Colter Van Stedum Tax Officer – William DeGood	1251 Lincoln Rd. Allegan, MI 49010 (800)-775-2054
Padagis South Carolina LLC (Michigan)	Executive Vice President – Chief Commercial Officer - John Wesolowski Executive Vice President – Chief Growth Officer - Colter Van Stedum Tax Officer – William DeGood	

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. 107490962

Application/License No. _____

Padagis US LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3490 Quebec Avenue N, Minneapolis, MN 55427 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (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 Tower Square , Hartford, CT 06183 (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 August 25, 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 25th day of August, 2021.

APPLICANT/PRINCIPAL

Padagis US LLC

PADAGIS US LLC LIMITED LIABILITY SEAL 2021 DELAWARE COMPANY

Authorized Representative

SURETY COMPANY

Travelers Casualty and Surety Company of America

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA HARTFORD, CONN.

By: Donna M Planeta
Surety Company's Representative

Donna M Planeta, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Bethany Stevenson

Witness

Countersigned by:

Nevada Resident / Non-Resident Agent Aimee Perondine
License No. 3134182

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty 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 Donna M Planeta of Chicago , IL , their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge the following bond:

Surety Bond No.: 107490962
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Padagis US LLC
Obligee: Nevada State Board of Pharmacy

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 25th day of August , 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.

Site Leads (Indebtedness to the applicant)
Padagis US LLC
3940 Quebec Ave N
Minneapolis, MN 55427

1.) Ofir Seva, Chief Operating Officer
2.) Deborah Sullivan, Vice President Operations, MN

Padagis US LLC - 3940 Quebec Ave North, Minneapolis, MN 55427
Controlled Substance Authorized Access List

Abdufatah Warsame
Akorn Sitthimongkohl
Amanda Beck
Amanda Hixon
Amber Hemberger
Amy Lewis
Angie Peterson
Annette Robinson
Anthony Hopponen
Ashley LaCayo
Bee Xiong
Ben Myers
Bill Mink
Brian Fliehr
Brian Gammelgaard
Bryan Vang
Casey Lantz
Cathy Lockwood
Charlie Cheng
Cheng Moua
Chris Anderson
Claire Haskin
Connie Frahm
Corey Casper
Courtney Taylor
Dalton Hershey
Dan Pearsall
Dana Harren
Dave Jagdeo
David Lien
Dominque Attoro
Doua Yang
Emily Dummann
Emily Meyer
Florence Bradley
Gonzalo Hernandez
Grant Kregness
Greg Hyrkas
Hans Olson
Hawera Butta
James Bonner
James May
Jay Grimm
Jeanne Glover
Jeff Hiedeman
Jeff Moskalik
Jeremiah Fossie
Jim Kuebelbeck
Joe Kurpierz
John Davis
Jonna Kolmer
Joseph Simonson
Joyce Heinz
Kaitlyn Yang
Kay Goetsch
Kelsey Lindsay
Kevin Her
Kevin Merkling
Kheng Xiong
Kim Hudyma
Kristine Theis
Kyle Skildon
Linda Moll
Lloyd Bihon
Lorenzo Hampton
Lydia Kostuch
Maria Vigstol
Matt Xiong
Mauricio Cordova
Max Smith
Meera Patel
Michelle Campeau
Mike Vahlsing
Nick Van Veldhuizen
Noah Valen
Pablo Samaniego
Pao Xiong
Paul Olson
Paul Sparby
Phang Vang
Philip Mayer
Ramon Escano
Randy Dostal
Randy Eiden
Robert Kelley
Roger Stigen
Roscoe Van Pelt
Ryan Emmons
Sarah Matson
Scott Stephan
Shawn Garling
Shelley Scott
Sherri Machler
Soutta Sengthong
Stacy Spates
Stephanie Strohbeen
Steve Krone
Sue Carlstrom
Susan Olson
Tamar Meyers
Tammy Atchison
Tan Nguyen
Tatyana Maksinova
Teresa Johnson
Terri Imig
Thuy Ha Nguyen
Tilahun Mersha
Tim Rogers
Tony Lee
Trent Hanson
Valerie Pygman
Victoria Bolton
Xeng Yang

Drug Establishments Current Registration Site

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

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EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Padagis US**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Padagis US LLC	2127022	967694121	ANALYSIS; LABEL; MANUFACTURE; PACK;	3940 Quebec Ave N, Minneapolis, Minnesota (MN) 55427, United States (USA)	12/31/2022

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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 Padagis US LLC

Physical Address 3940 Quebec Ave N

City Minneapolis State MN Zip 55427

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First Deborah Middle _____ Last Sullivan

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

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

Mailing Address [redacted] Quebec Ave N

City Minneapolis State MN Zip 55427

Telephone [redacted] Email Deborah.Sullivan@padagis.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 DS

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. Cloud State University		9/1984 - 5/1989	
Address	**City**	**State**	**Zip**
720 4th Avenue South	St. Cloud	MN	56301
Diploma/Degree obtained, if any			
Bachelor of Science - Accounting			

School Name		From - To (MM/YY – MM/YY)	
Anoka High School		8/1981 - 5/1984	
Address	**City**	**State**	**Zip**
7th Avenue	Anoka	MN	55303
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
12/2002- Present	[redacted] Sandy Point Road	Eden Prairie	MN	55347
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DS

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)	
Padagis US LLC			July/2021 - Present	
Business Address		**City**	**State**	**Zip**
3940 Quebec Ave N		Minneapolis	MN	55427
Phone	**Title**		**Number of Employed Hours**	
800-775-2054	Vice President, Operations		~ See below	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Perrigo Pharmaceuticals Company/Paddock Laboratories			01/2012 - July 2021	
Business Address		**City**	**State**	**Zip**
3940 Quebec Ave N		Minneapolis	MN	55427
Phone	**Title**		**Number of Employed Hours**	
	Vice President, Operations		~17,000	
Description of Duties				

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

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

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?		✔

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

Applicant's initials _____

I, Deborah Sullivan, **certify that as the designated representative for** Padagis US 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

Deborah Sullivan

Print Name (First, Last)

Deborah Sullivan

Original Signature (electronic, copies or stamps not accepted)

11/8/2021

Date

Applicant's initials DS

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.

Deborah Sullivan

Print Name (First, Last)

Deborah Sullivan — 11/9/2021

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

---

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

State of Minnesota, ss. County of Hennepin

I, Tamara 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.

Tamara Paul — Nov. 9, 2021

Original Signature — **Date**

Subscribed and Sworn to before me this 9th day of Nov.

Tamara Paul

Notary Public Signature

TAMARA LYNN PAUL
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2025

(Seal)

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 Padagis US LLC

Physical Address 3940 Quebec Ave N

City Minneapolis State MN Zip 55427

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First Colter Middle _____ Last VanStedum

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

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

Mailing Address [redacted] Lincoln Road

City Allegan State MI Zip 49010

Telephone [redacted] Email Colter.VanStedum@padagis.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 CVS

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)	
Grand Valley State University			08/08 - 05/10	
Address		City	State	Zip
1 Campus Dr		Allendale	MI	49401
Diploma/Degree obtained, if any				
MBA				
School Name			From - To (MM/YY – MM/YY)	
Central Michigan University			08/01 - 05/05	
Address		City	State	Zip
1200 S. Franklin Street		Mt. Pleasant	MI	48859
Diploma/Degree obtained, if any				
BSBA				
School Name			From - To (MM/YY – MM/YY)	
Hudsonville High School			08/97 - 06/01	
Address		City	State	Zip
5037 32nd Ave		Hudsonville	MI	49426
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
10/14 - Present	[redacted] W Bay Ct.	Hudsonville	MI	49426
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/14 - 10/14	4886 Faringdom Grove Dr	Hudsonville	MI	49426
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/13 - 06/14	6084 16th Ave	Hudsonville	MI	49426
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/06 - 06/13	6202 Sheldon Dr	Hudsonville	MI	49426
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 CVB

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)
Padagis			07/2021 - Present
Business Address	**City**	**State**	**Zip**
1251 Lincoln Road	Allegan	MI	49010
Phone	**Title**		
800-775-2054	Executive Vice President		

Description of Duties

Reporting to the CEO, I am responsible for growth of the business and have functional reporting responsibility for R&D, Regulatory, Project Management, Pipeline and Business Development.

Business Name			From - To (MM/YY – MM/YY)
Perrigo Pharmaceuticals Company			07/06 - 07/21
Business Address	**City**	**State**	**Zip**
515 E Avenue	Allegan	MI	49010
Phone	**Title**		
	Vice President		

Description of Duties

Reporting to the President of Perrigo Pharmaceuticals, I was responsible for Project Management, Pipeline and Business Development.

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)

10/5/2021

Date

Applicant's Initials CVB

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.

Colter VanStedum

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/5/2021

Date

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

State of Michigan, ss. County of Kent

I, Colter Van Stedum, 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

11/5/2021

Date

Subscribed and Sworn to before me this 5th day of NOV, 2021.

Notary Public Signature

Eden Pikaert, Notary Public
State of Michigan, County of Kent
My Commission Expires 3/22/2027
Acting in the County of Ottawa

EDEN PIKAERT NOTARY PUBLIC KENT COUNTY, MI

(Seal)

Applicant's initials CVS

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: Padagis US LLC

Physical Address: 3940 Quebec Ave N

City: Minneapolis State: MN Zip: 55427

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-775-2054 Website: www.padagis.com

Licensing Company Email: Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First: William Middle: James Last: DeGood

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

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

Mailing Address: [redacted] Lincoln Road

City: Allegan State: MI Zip: 49010

Telephone: [redacted] Email: William.DeGood@padagis.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: WJD

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)	
Michigan State University		08/92 - 12/96	
Address	**City**	**State**	**Zip**
426 Auditorium Road	East Lansing	MI	48824
Diploma/Degree obtained, if any			
BA Accounting			

School Name		From - To (MM/YY – MM/YY)	
South Christian High School		08/89 - 06/92	
Address	**City**	**State**	**Zip**
7979 Kalamazoo Avenue SE	Byron Center	MI	49315
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
09/09 - current	[redacted] Sandy Ridge Dr.	Dorr	MI	49323
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 MJ

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)
Padagis			07/21 - Present
Business Address	**City**	**State**	**Zip**
1251 Lincoln Road	Allegan	MI	49010
Phone	**Title**		
800-775-2054	Tax Officer		

Description of Duties

Responsible for all U.S. tax matters of the company and coordination with the Israel local team, also responsible for establishing and monitoring the company's worldwide transfer pricing ensuring we have the appropriate documentation.

Business Name			From - To (MM/YY – MM/YY)
Perrigo Company plc			07/05 - 07/21
Business Address	**City**	**State**	**Zip**
515 Eastern Ave	Allegan	MI	49010
Phone	**Title**		
	Director, International Tax		

Description of Duties

Responsible for dealing with Perrigo's international locations and their tax matters, both local country and U.S. tax impacts. Also responsible for transfer pricing and certain aspects of financial reporting related to tax.

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

William J. DeGroot
Original Signature (electronic, copies or stamps not accepted)

11-09-21
Date

Applicant's initials WJD

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.

William DeGood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-09-21

Date

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

State of Michigan, ss. County of Allegan

I, William J. DeGood, 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

11-09-21

Date

Subscribed and Sworn to before me this 9 day of NOVEMBER, 2021

Notary Public Signature

(Seal)

Applicant's initials WJD

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 Padagis US LLC

Physical Address 3940 Quebec Ave N

City Minneapolis State MN Zip 55427

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First John Middle Edgard Last Wesolowski

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

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

Mailing Address [redacted] Lincoln Road

City Allegan State MI Zip 49010

Telephone [redacted] Email John.Wesolowski@padagis.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 _____

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)	
Hackett Central Prep		9/81 – 6/85	
Address	City	State	Zip
~~6767~~ 1000 W. Kilgore	Kalamazoo	MI	49008
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
KVCC		9/85 - 6/87	
Address	City	State	Zip
6767 W Q Ave	Kalamazoo	MI	49009
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Western Michigan University		9/87 – 4/91	
Address	City	State	Zip
~~1~~ 1903 W. Michigan Ave	Kalamazoo	MI	49008
Diploma/Degree obtained, if any			
BS - Aviation			

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
10/04 - Present	[redacted] Harrington Road	Delton	MI	49046
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 MW

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)
Padagis			July/2021 - Present
Business Address	**City**	**State**	**Zip**
1251 Lincoln Road	Allegan	MI	49010
Phone	**Title**		
800-775-2054	Executive Vice President		
Description of Duties			
EVP - Sales, Marketing, Distribution, Contracting			

Business Name			From - To (MM/YY – MM/YY)
Perrigo Company plc			Feb 2012 - July 2021
Business Address	**City**	**State**	**Zip**
515 Eastern Ave	Allegan	MI	49010
Phone	**Title**		
1-800-719-9260	Sr. Vice President, Commercial Operations		
Description of Duties			
SVP - Sales, Marketing, Contracting			

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.

Applicant's initials JW

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)

11/11/2024
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.

John Wesolowski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 11/11/2024

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

State of Michigan, ss. County of Barry

I, John Wesolowski, 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:** 11/11/2021

Subscribed and Sworn to before me this 11th day of November 2021

Notary Public Signature

Jody J May

Notary Public, Barry County, MI
My Commission Expires July 20, 2025
Acting in the County of Barry

(Seal)

Applicant's initials

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Is your facility a reverse distributor? ☐ Yes ☒ No

☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Facility Name: RVL Pharmaceuticals, Inc.

Physical Address: 400 Crossing Blvd, 1st Floor

City: Bridgewater State: NJ Zip: 08807

Mailing Address (if different from physical address): 400 Crossing Boulevard, 1st Floor

City: Bridgewater State: NJ Zip: 08807

Telephone: (908) 809-1300 Website: _____

Name of Designated Representative (DR): Benjamin Markison

Licensing Company Email: statelicenses@rvlpharma.com DR Email: bmarkison@rvlpharma.com

☐ Pharmacies	☒ Legend Pharmaceuticals, Supplies or Devices
☒ Practitioners	☐ Controlled Substances
☐ Hospitals	☐ Hypodermic Devices
☐ Wholesalers	☐ Veterinary Legend Pharmaceuticals
☐ Others:	☐ 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

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.

[illegible] your company has been associated with in regards to pharmaceuticals [illegible] 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:** _____

[illegible]

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:

[illegible] Corporation of Company

State of Incorporation/Organization: DE

Parent Company (if any): Osmotica Pharmaceutical Corp.

Corporation/Organization Name: RVL Pharmaceuticals, Inc.

Mailing Address: 400 Crossing Boulevard, 1st Floor

City: Bridgewater State: NJ Zip: 08807

Telephone: (908) 809-1300 Email: statelicenses@rvlpharma.com

Contact Person Name: Chris Klein

[illegible]

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

[illegible]

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Christopher Klein
Print Name of Authorized Person Submitting Application

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

11/16/2024
Date

Board Use Only	Date Received: _____	Amount: $500 check # 14808 ✓

Processed 1/24/22

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RVL 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 TWENTY-FOURTH DAY OF JANUARY, 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 "RVL PHARMACEUTICALS, INC." WAS INCORPORATED ON THE NINTH DAY OF AUGUST, A.D. 2011.

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

Jeffrey W. Bullock, Secretary of State

5022283 8300

SR# 20220223121

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

Authentication: 202467828

Date: 01-24-22

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0746066

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:

400 CROSSING BLVD, 1ST FL BRIDGEWATER, NJ 08807-

Reg. No.
5005820

RVL PHARMACEUTICALS, INC.
400 CROSSING BLVD, 1ST FL
BRIDGEWATER, NJ 08807-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2023

Establishment Copy

RVL
PHARMACEUTICALS, INC.

Ownership Information

Osmotica Pharmaceutical Corp.
400 Crossing Blvd.
Bridgewater, NJ 08807

Owns 100% of RVL Pharmaceuticals, Inc.

Corporate Officers

Brian Markison, CEO 400 Crossing Blvd. Bridgewater, NJ 08807 Phone: (908) 809-1300	**Andrew Einhorn, CFO** 400 Crossing Blvd. Bridgewater, NJ 08807 Phone: (908) 809-1300
James Schaub, Vice President 400 Crossing Blvd. Bridgewater, NJ 08807 Phone: (908) 809-1300	**Chris Klein, General Counsel and Secretary** 400 Crossing Blvd. Bridgewater, NJ 08807 Phone: (908) 809-1300

RVL
PHARMACEUTICALS, INC.

Description of Operations

RVL Pharmaceuticals, Inc. ("RVL") is wholly owned by Osmotica Pharmaceutical Corp., which is a privately held corporation. RVL's products are manufactured and packaged by a contract manufacturer and will be distributed by Eversana Life Science Services, who is licensed to ship pharmaceutical products into your state.

RVL Labeler Code: 73687

Contract Manufacturer:
We are using the following contract manufacturer to produce our product:

Nephron Pharmaceuticals Corporation
4500 12th Street Extension
West Columbia, SC 29172
FEIN: 3011158388

Nephron Pharmaceuticals Corporation manufactures RVL's product and packages finished product. At no time do they own the product, contract with RVL's customers, invoice, nor sell an RVL product. RVL's products are not Controlled Substances.

Third Party Logistics:
For distribution into commercial supply channels, Eversana acts as RVL's Third Party Logistics (3PL) provider to manage the storage and distribution of RVL's product to physicians throughout the United States.

Eversana Life Science Services, LLC
4580 Mendenhall Road
Memphis, TN 38141

RVL's hours of operation are 8:00 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through January 21, 2022

You have searched Finished drug products

Search Results '73687'

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	Market Category	Package Description
UPNEEQ	73687-062-45	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/2020	N/A	NDA	45 AMPULE in 1 CARTON (73687-062-45) > 3 mL in 1 AMPULE (73687-062-70)
UPNEEQ	73687-062-25	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A	NDA	15 AMPULE in 1 CARTON (73687-062-25) > 3 mL in 1 AMPULE (73687-062-80)
UPNEEQ	73687-062-32	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A	NDA	30 AMPULE in 1 CARTON (73687-062-32) > 3 mL in 1 AMPULE (73687-062-70)
UPNEEQ	73687-062-	1 mg/mL	SOLUTION/	OPHTHALMIC	NDA212520	RVL	73687-062	Oxymetazoline	OXYMETAZOLINE	HUMAN	08/21/2020	N/A	NDA	30 AMPULE in 1

Verified
MH 1/21/2022

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PIN IT (HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

+

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

PRINT

Current through December 21, 2021

You have searched Finished drug products

Search Results: *'73687'*

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
UPNEEQ	73687-062-45	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/2020	N/A
UPNEEQ	73687-062-25	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A
UPNEEQ	73687-062-32	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A
UPNEEQ	73687-062-34	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A
UPNEEQ	73687-062-68	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	10/19/2020	N/A

Showing 1 to 5 of 5 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 1/21/22

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 RVL Pharmaceuticals, Inc.

Physical Address 400 Crossing Blvd, 1st Floor

City Bridgewater State NJ Zip 08807

Mailing Address (if different from physical address) 400 Crossing Boulevard, 1st Floor

City Bridgewater State NJ Zip 08807

Telephone (908) 809-1300 Website

Licensing Company Email statelicenses@rvlpharma.com

Section 2: Personal Information

First Benjamin Middle Last Markison

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] Crossing Blvd., 1st Floor

City Bridgewater State NJ Zip 08807

Telephone [redacted] Email bmarkison@rvlpharma.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?		X

Applicant's initials BJM

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 Miami		Completed 2014	
Address	**City**	**State**	**Zip**
1320 S Dixie Hwy	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelor's degree			

School Name		From - To (MM/YY – MM/YY)	
The Pennington School		2006 - 2010	
Address	**City**	**State**	**Zip**
112 W Delaware Ave	Pennington	NJ	08534
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
10/20 - present	[redacted]Ocean Avenue	Mantoloking	NJ	08738
01/11 - 10/20	[redacted]Stuart Road W	Princeton	NJ	08540
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)	
RVL Pharmaceuticals, Inc.			06/21 - present	
Business Address		**City**	**State**	**Zip**
400 Crossing Blvd, 1st Floor		Bridgewater	NJ New	08807
Phone	**Title**		**Number of Employed Hours**	
(908) 809-1300	Sr. Manager, RVL Supply Chain Operations		800+	
Description of Duties				
See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
Trigen Laboratories, LLC			06/17 - 06/21	
Business Address		**City**	**State**	**Zip**
2500 Main Street Extension, Suite 6		Sayreville	NJ	08872
Phone	**Title**		**Number of Employed Hours**	
(770) 509-5954	Manager of Warehouse Operations		8,000+	
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				

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:

Ben Mock

Original Signature (electronic, copies or stamps not accepted)

11/22/2021

Date

Applicant's initials BJM

I, Benjamin Markison, **certify that as the designated representative for**

RVL 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

Benjamin Markison

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/12/2021

Date

Applicant's initials BJM

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.

Benjamin Markison
Print Name (First, Last)

Ben Markison
Original Signature (electronic, copies or stamps not accepted)

11/22/2021
Date

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

State of NJ, ss. County of Somerset

I, Benjamin Markison, 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.

Ben Markison
Original Signature

11/22/2021
Date

Subscribed and Sworn to before me this 22 day of NOV 2021

Notary Public Signature

GOPIBEN PATEL
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES April 3, 2022

(Seal)

Applicant's initials BM

Benjamin J. Markison
[redacted]Ocean Ave.
Mantoloking, NJ 08738
[redacted]@aol.com

Education

University of Miami, December 2014
Coral Gables, FL
Major: Communications
Minor: Sports Administration

Experience:

Osmotica Pharmaceuticals
RVL Pharmaceuticals, INC.

Sr. Manager, RVL Supply Chain Operations (June 2021 – Present)

- Manage production and inventory based upon input from commercial team
- Coordinate and communicate forecast requirement updates to Suppliers and Contract Manufacturing Organizations (CMOs)
- Work closely with Internal/External Manufacturing organizations to ensure that the production plans are achievable using capacity planning, level loading, materials availability planning, etc.
- Manage inventory levels to ensure order fulfillment
- Responsible for monitoring CMO's inventories to ensure commercial production and clinical supply production are not interrupted due to material or component shortages or expiry dating
- Responsible for analyzing monthly inventory levels for finished goods, semi-finished goods and API, to ensure adherence to safety stock requirements
- Manage product output as supplied to third party logistics (3PL) distribution
- Monitoring of Bill of Materials and Component Specifications at CMO's and Suppliers
- Manage product serialization activities as required
- Developed policies and procedures to run an efficient and complaint department
- Manage inventory through establishment of control of inventory, regular cycle counts, and year-end physical counts for accuracy.
- Maintain inventory control of finished product and samples to include proper storage, stock rotation, replenishment, cycle counting, availability, release status, and related activities.
- Interface with appropriate personnel to oversee the effective implementation and maintenance of logistics systems, such as Microsoft Dynamics AX, Serialization, Small Parcel Integrated Shipping Solutions, etc. as they relate to the operations of the DC
- Work with internal departments to ensure operations are compliant with all applicable government agencies, including, but not limited to, FDA, OSHA, State of New Jersey, etc.
- Designated representative on all State distribution licenses
- Lead delegate from Distribution Operations during third-party as well as internal audits or inspections.
- Manage all aspects of traffic activities for inbound and outbound freight to optimize service and cost, including negotiating rates and arrangements, scheduling individual shipments, selecting the most effective mode of transportation, monitoring service and working with carriers on improvements, negotiating settlement of damage claims, and communicating RVL's approved/preferred carrier information to internal departments, vendors, and customers.

Vertical Pharmaceuticals, LLC
Trigen Laboratories, LLC

Manager of Warehouse Operations, Sayreville NJ (June 2017 – June 2021)

- Lead and direct the work of Warehouse Associates
- Act as designated representative for all Federal and State licenses
- Manage the Distribution staff in the processes of order fulfillment to include product receipt, picking, confirmation, checking, packing and shipment.
- Monitor floor operations and adjust assignments as appropriate to meet deadlines and overall corporate objectives
- Maintain inventory control of finished product and samples to include proper storage, stock rotation, replenishment, cycle counting, availability, release status, and related activities
- Maintain a safe working environment through education, training and continuous improvement of material handling functions
- Maintain a fully trained staff through identification, pursuit, and implementation of training programs to assure compliance with GMPs, DEA and OSHA regulations, and corporate requirements
- Interface with internal departments to ensure the facility and operations are compliant with all applicable government agencies, including, but not limited to, FDA, DEA, OSHA, State of New Jersey, etc.
- Lead delegate from Distribution Operations during third-party as well as internal audits or inspections.
- Author SOPs when required and execute training for all affected Distribution staff.
- Manage all aspects of traffic activities for inbound and outbound freight to optimize service and cost, including negotiating rates and arrangements, scheduling individual shipments, selecting the most effective mode of transportation, monitoring service and working with carriers on improvements, negotiating settlement of damage claims, and communicating Vertical's approved/preferred carrier information to internal departments, vendors, and customers.
- Harmonized multiple standard operating procedures (SOPs), between two companies
- Successfully implemented ERP system, Microsoft Dynamics AX 2012. Worked with individuals from IT, and third party integration Company (RSM), to ensure the system was running at a functional level.

Supply Chain Analyst, Marietta, GA, and Sayreville NJ (July 2016- June 2017)

- Process backorder reports & provide to customers weekly
- Manage backorder status & coordinate shipment/order processing once released
- Develop internal backorder report and distribute weekly.
- Issue & maintain all Trigen & Vertical Return Goods Authorizations including Return Authorizations for destruction shipments and complaints
- Respond to customer inquiries as it relates to returns, credits, overages/shortages, inventory research for Trigen & Vertical
- Perform customer service functions, support sales & customer inquiries, PO research & provide tracking information
- Responsible for Returns & Customer Service/Sales support
- Support Warehouse Manager:
- Develop and track distribution metrics.

Pharmaceutical Sales Representative, Monmouth County, NJ (February 2015- July 2016)

- Accomplished 100% Quota Attainment
- Generated prescriptions through developing and maintaining relationships with doctors and offices within territory

Marketing/Sales Internship, Sayreville, NJ (May 2014 – August 2014)

- Assisted Marketing department in developing detail aids
- Reviewed weekly reports for accuracy for the field sales force
- Supported inside sales representatives with data entry
- Strategically organized warehouse for more efficient pick, pack, and shipping
- Contributed to construction professional sales representative sample kits

Comcast Spectacor - Marketing Internship, Philadelphia, PA (May 2013-August 2013)

- Contributed to client and sales development for professional lacrosse team
- Created content and developed administrative pages for WingsLAX.com
- Assisted in the execution of marketing programs and events
- Brainstormed new marketing and game entertainment ideas
- Contributed to client and sales development

The Rehabilitation Center – Physical Therapy Associate, Princeton, NJ (June 2012 – August 2012)

- Reported to the Head of Physical Therapy
- Assisted with prepping patients for physical and exercise therapy
- Provided administrative support, including scheduling and outpatient instruction follow-up

True North Lacrosse - Sales and Website Design, Pennington, NJ (September 2010 –August 2011)

- Scheduled camps and activities for players
- Ran clinics specializing in team defense and proper player alignment
- Overlooked the store part-time
- Managed sales, inventory and scheduling

References available upon request.

RVL Pharmaceuticals, Inc. - Employee List

Barnes, Nancy
Biggiani, Timothy
Bonante, Jo Ann
Cherichello, Anthony
Chester, Claude
Confalone, Deana
Daly, Gregory
De Los Santos, Yuraima
Desilva, Paul
deVries, Tina
Doyle, Thomas
Ducey-Munde, Joan
Einhorn, Andrew
Fee, Nicholas
Galvin, Paul
Gembarski, Katerina
Giordano, Kathleen
Green, James Aaron
Haig, Brian
Hoefele, Pamela
Kee, Nickee
Klein, Christopher
Malieckal, Sanjay
Markison, Benjamin
Markison, Brian A.
Miller, Jarret
Napoliello, Veronica
Ortiz, Xiomara
Owens, Eifwa Pollyann
Rivera, Javier
Schaub, James
Stavole, Joann
Supetran, Myralyn
Thieme, Brittany
Tinescu, Ada
Velasco, Meredith
Wagner, George
Weissman, Craig
Wozniak, Teresa

GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: Pharmaceutical Wholesalers Surety Bond

Bond No. : BLY1020177

Dated effective: 7/24/2020
(MONTH, DAY, YEAR)

executed by: RVL Pharmaceuticals, Inc. , **as Principal,**
(PRINCIPAL)

and by: The Hanover Insurance Company , **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 Address	2500 Main Street Extension, Suite 6	400 Crossing Boulevard
Principal City	Sayreville	Bridgewater
Principal Zip	08871	08807

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 7/24/2021
(MONTH, DAY, YEAR)

Signed and Sealed 8/6/2021
(MONTH, DAY, YEAR)

RVL PHARMACEUTICALS, INC CORPORATE SEAL EST 2011 DELAWARE

RVL Pharmaceuticals, Inc.
PRINCIPAL

BY: _____ General Counsel & Secretary
TITLE

The Hanover Insurance Company
SURETY

BY: _____
Wendy Lee Wadkins, ATTORNEY-IN-FACT

The Hanover Insurance Group

The Hanover Insurance Company, Bedford, New Hampshire
Assets and Liabilities as of December 31, 2020

ASSETS		2020
Cash in Banks (Including Short-Term Investments)		$ (57,030,013)
Bonds and Stocks		$6,691,401,588
Other Admitted Assets		$2,339,121,590
Total Admitted Assets		$8,973,493,165

LIABILITIES, CAPITAL AND SURPLUS

Reserve for Unearned Premiums		$1,893,941,039
Reserve for Loss and Loss Expense		$3,991,508,445
Reserve for Taxes		$ 10,515,546
Funds held under reinsurance treaties		$ 2,233,892
Reserve for all other liabilities		$ 492,418,556
Capital Stock - $1.00 par	$ 5,000,000	
Net Surplus	$2,577,875,687	
Policyholders' Surplus		$2,582,875,687
Total Liabilities, Capital and Surplus		$8,973,493,165

COMMONWEALTH OF MASSACHUSETTS

COUNTY OF WORCESTER

I, Jeffrey Farber, Assistant Treasurer of The Hanover Insurance Company, being duly sworn deposes and says that he is the above described officer of said Company, and certifies that the forgoing statement is a true statement of the condition and affairs of the said Company on December 31, 2020.

J. Farber

Jeffrey Farber
Assistant Treasurer

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Wendy Lee Wadkins, Christopher F. Mulvaney, Charles N. Parsons, Vincent J. Mancini and/or Pablo Rios, Jr.

Of **Willis of Pennsylvania, Inc. of Radnor, PA** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Twenty Five Million and No/100 ($25,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this **14th** day of **February, 2018.**

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this **14th** day of **February, 2018** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do heraby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 6thday of August 2021

CERTIFIED COPY

Theodore G. Martinez, Vice President

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. BLY2020177

Application/License No. _____

RVL Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2500 Main Street Extension, Suite 6, Sayreville, New Jersey 08871 (Address of Applicant/Principal), as PRINCIPAL, and The Hanover Insurance Company (Surety Company), a corporation organized under the laws of the state of New Hampshire (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 440 Lincoln Street, Worcester, Massachusetts 01653-0002 (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 July 24, 2020 (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 24th day of July, 20 20.

APPLICANT/PRINCIPAL
RVL PHARMACEUTICALS, INC.

Authorized Representative

SURETY COMPANY
THE HANOVER INSURANCE COMPANY

Surety Company's Representative

Wendy Lee Wadkins, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Pablo Rios, Jr.

Witness Danielle M. Bechard

Countersigned by:

Non- Nevada Resident Agent License #3091632
Wendy Lee Wadkins

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Wendy Lee Wadkins, Christopher F. Mulvaney, Charles N. Parsons, Vincent J. Mancini and/or Pablo Rios, Jr.

Of **Willis of Pennsylvania, Inc. of Radnor, PA** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Twenty Five Million and No/100 ($25,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this **14th** day of **February, 2018.**

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this **14th** day of **February, 2018** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 24thday of July 2020

CERTIFIED COPY

Theodore G. Martinez, Vice President

4L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Waylis Therapeutics LLC

Physical Address: 47220 Cartier Drive, Suite B

City: Wixom State: MI Zip: 48393

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (248) 313-9675 Website: -

Name of Designated Representative (DR): David Risk

Licensing Company Email: compliance.waylis@gmail.com DR Email: compliance.waylis@gmail.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: OTC

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.

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. N/A

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 N/A

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: Michigan

Parent Company (if any): Future Pak, LTD.

Corporation Name: Waylis Therapeutics LLC

Mailing Address: 47220 Cartier Drive, Suite B

City: Wixom State: MI Zip: 48393

Telephone: (248) 313-9675 Email: compliance.waylis@gmail.com

Contact Person Name: David Risk

Section 6: Partnership N/A

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner N/A

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 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 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**	✓			
• **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.

David Risk

Print Name of Authorized Person Submitting Application

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

5/18/21

Date

Board Use Only	Date Received: _____	Amount: 500 Check #15589

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

WAYLIS THERAPEUTICS LLC

was validly authorized on August 28 , 2020, as a Michigan DOMESTIC LIMITED LIABILITY COMPANY. and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 28th day of December , 2021.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 21120832805

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Registrant Verification For

RXCROSSROADS 3PL LLC

DEA Number:	RR0577241
Expiration Date:	04/30/2022
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:	04/07/2021

Department of Justice
Drug Enforcement Administration
Diversion Control Division

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

5306006621APP20

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

WAYLIS THERAPEUTICS LLC
47220 CARTIER DRIVE
SUITE B
WIXOM, MI 48393

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

P676553

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

WAYLIS THERAPEUTICS LLC
47220 CARTIER DRIVE
SUITE B
WIXOM, MI 48393

LICENSE NO.
5306006621

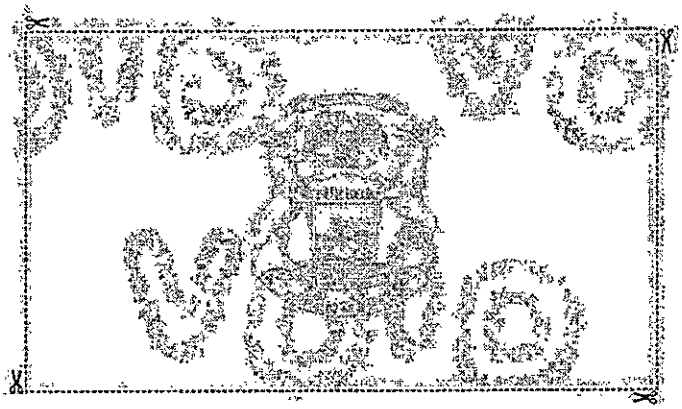
EXPIRATION DATE
1/5/2023

21006070130

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

5315221946APP20

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909



WAYLIS THERAPEUTICS LLC
47220 CARTIER DRIVE
SUITE B
WIXOM, MI 48393

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

P677082

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
CONTROLLED SUBSTANCE LICENSE

*THIS LICENSE IS ONLY VALID IF PROFESSIONAL LICENSE IS ACTIVE

WAYLIS THERAPEUTICS LLC
47220 CARTIER DRIVE, SUITE B
WIXOM, MICHIGAN 48393

LICENSE NO.
5315221946

EXPIRATION DATE
1/5/2023

216070117

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

ORLENE HAWKS
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE
MICHIGAN BOARD OF PHARMACY
VERIFICATION OF LICENSURE AS OF 02/25/2021

NAME: **Waylis Therapeutics LLC**
ADDRESS: 47220 Cartier Drive
Suite B
Wixom, MI 48393

STATUS: Active

LICENSE TYPE: Wholesale Distributor License

LICENSE NUMBER: 5306006621

ORIGINAL DATE: 01/05/2021
EXPIRATION DATE: 01/05/2023
SPECIALTY: None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
None		

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

Waylis Therapeutics LLC
47220 Cartier Drive, Suite B, Wixom, MI 48393
Tel (248) 313-9675 Fax (248) 480-0153
www.waylistherapeutics.com

THERAPEUTICS

Licensing details

Applicant:

Waylis Therapeutics LLC
47220 Cartier Drive, Suite B
Oakland County
Wixom, MI 48393
Phone: 248-313-9675
Fax: 248-480-0153
EIN: 85-2942824

Michigan Limited Liability Company incorporated on August 28, 2020

Parent Company:

Future Pak, LTD 100% Ownership
28115 Lakeview Drive
Wixom, MI 48393
EIN: 38-2174754

Corporate Officers:

David Risk, CEO
[redacted] Ellwood Avenue
Berkley, MI 48072
SS# [redacted] DOB: [redacted]
E-mail: [redacted]@woodwardpharma.com

Designated Representative:

David Risk

Method of Distribution: Third Party Logistics Provider

RxCrossroads 3PL LLC
4200 Binion Way, Suite 200
Mason, OH 45036 DEA# RM0535546

Contracted CMO:

Avet Pharmaceuticals Inc.
21B Cotters Ln
East Brunswick, NJ 08816, USA FDA# 3005139373

Nature of Business:

Waylis Therapeutics LLC (Waylis) is a virtual manufacturer that intends to sell legend prescription drugs. Waylis will utilize contract manufacturers to produce its products and a licensed third-party logistics provider to warehouse and distribute. Waylis will never physically manufacture or distribute any products. Waylis is not required by the Drug Enforcement Administration to obtain registration, as there are no controlled substances on its premises. The state of Michigan does not inspect Virtual Manufacturers.

FDA Labeler Code: 80725

List of Products to be manufactured:

Humatin (Paromomycin Sulfate Capsules)	80725-250-01	250 mg/1

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)
TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM) ±
EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through January 12, 2022

You have searched Finished drug products

Search Results: *'80725'*

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	Market Category	Package Description
⊕ Humatin	80725-250-01	250 mg/1	CAPSULE	ORAL	ANDA065173	Waylis Therapeutics LLC	80725-250	PAROMOMYCIN SULFATE	PAROMOMYCIN SULFATE	HUMAN PRESCRIPTION DRUG	04/08/2021	N/A	ANDA	100 CAPSULE in 1 BOTTLE (80725-250-01)

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
MS
1/12/22

Waylis Therapeutics LLC

List of Officers/Owners:

Name	Title	Address	D.O.B.	SSN/FEIN	% Owned
David Risk	President & CEO	[redacted] Ellwood Avenue, Berkley, MI 48072	[redacted]	[redacted]	N/A
Future Pak, LTD.	N/A	28115 Lakeview Drive, Wixom, MI 48393	N/A	38-2174754	100%

Full list of employees pertaining to Waylis Therapeutics LLC:

1. David Risk - President & CEO
2. Olivia Kaye - Senior Manager, Commercial Operations

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 Waylis Therapeutics LLC

Physical Address 47220 Cartier Drive, Suite B

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) -

City - State - Zip -

Telephone (248) 313-9675 Website -

Licensing Company Email compliance.waylis@gmail.com

Section 2: Personal Information

First David Middle - Last Risk

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

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

Mailing Address [redacted]Cartier Drive, Suite B

City Wixom State MI Zip 48393

Telephone [redacted] Email compliance.waylis@gmail.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 DR

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)	
Dartmouth College		08/96 - 05/99	
Address	**City**	**State**	**Zip**
6016 McNutt Hall	Hanover	NH	03755
Diploma/Degree obtained, if any			
English			
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
01/20 - Present	[redacted] Ellwood Avenue	Berkley	MI	48072
03/15 - 01/20	[redacted] S Bates Street	Birmingham	MI	48009
02/13 - 03/15	[redacted] N Main Street	New Hope	PA	18938
08/12 - 01/13	[redacted] S West Street	Royal Oak	MI	48067
01/10 - 07/12	[redacted] Top Avenue	Green Brook	NJ	08812
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)	
Waylis Therapeutics LLC			
Business Address	**City**	**State**	**Zip**
47220 Cartier Drive, Suite B	Wixom	MI	48393
Phone	**Title**	**Number of Employed Hours**	
(248) 313-9675	President & CEO	6000 + hours	
Description of Duties			
please see attached - David Risk 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.)		✔
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.

N/A

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 DR

I, David Risk, **certify that as the designated representative for** Waylis Therapeutics 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

David Risk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/21

Date

Applicant's initials DR

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 Risk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/21

Date

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

State of Michigan, ss. County of Oakland

I, DAVID RISK, 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

9/27/21

Date

Subscribed and Sworn to before me this 27th day of September, 2021

Notary Public Signature

ELLADA AZARIAH
NOTARY PUBLIC - STATE OF MICHIGAN
OAKLAND COUNTY
My Commission Expires July 14, 2027
Acting in the County of Oakland

(Seal)

Applicant's initials DR

DAVID M. RISK

[redacted]S Bates Street, Birmingham, MI 48009

[redacted] (cell) [redacted]@gmail.com

Experience

Woodward Pharma Services LLC
Chief Executive Officer. Birmingham, MI — *March 2015 – Present*

- Founded a new company focused on providing outsourced commercial services to pharmaceutical manufacturers
- Responsible for all start up activities to establish Woodward Pharma Services as an operating company

Amedra Pharmaceuticals LLC
President. Horsham, PA — *October 2012 – March 2015*

- Led spin out from CorePharma including start up activities to establish Amedra Pharmaceuticals as an operating company
- Responsible for all business development activities and related interaction with RoundTable Healthcare Partners
- Departmental reports include Finance, Supply Chain, Sales, Managed Markets, Marketing, and Human Resources
- Amedra and CorePharma were sold to Impax Laboratories in March 2015

CorePharma LLC
Vice President, Business Development. Middlesex, NJ — *December 2009 – October 2012*

- Led all M&A activities focusing on marketed product acquisitions to generate Net Sales and EBITDA growth. Partnered with CEO and the Board of Directors on key strategic decisions
- Managed cross-functional teams during transactions consisting of internal diligence team members, external consultants, M&A and regulatory attorneys, lenders, and transaction team members from RoundTable Healthcare Partners, the majority owner of CorePharma
- Responsible for product in-licensing, third party development, alliance management, new product selection, portfolio management, and intellectual property
- Designed and completed a major restructuring of internal Research & Development
- Responsible for quarterly presentations to the Board of Directors and the company's lenders

Caraco Pharmaceutical Laboratories, Ltd.
Director, Business Development. Detroit, MI — *May 2006 – October 2009*

- Identified, structured and negotiated new business deals with strategic partners (e.g., Product licensing, contract development, strategic partnerships, M&A) through collaboration with CEO and SVP of Business Strategies. Successfully balanced competing priorities between R&D, sales, and finance organizations resulting in the execution of new business development agreements
- Utilized analytical skills and market knowledge to perform valuations and structure financial terms for licensing transactions and potential acquisitions. Presented findings and recommendations to CEO, SVP of Business Strategies and the Chairman of Caraco's Board of Directors
- Led team to complete financial due diligence on product and company acquisition opportunities. Interacted with investment bankers and outside legal counsel on key elements of potential transactions
- Extensive experience in India and Europe, including numerous site visits
- Completed macro analysis and presented strategic recommendations to senior management on the following new market opportunities: biosimilars, OTC products, and veterinary pharmaceuticals
- Presented at BioPharm Asia 2009 (Singapore) conference on biosimilars licensing and M&A strategy

Halpern Capital, Inc.
Vice President, Investment Banking/Equity Research. Aventura, FL — *December 2004 – April 2006*

- Joined Healthcare investment banking team in January 2006 after bolding the position of senior Healthcare analyst on the equity research team
- Interacted with institutional investors on a daily basis to present opportunities and discuss industry/company fundamentals; this includes proprietary research publications, phone updates, and providing access to company management
- Senior research analyst responsible for publication of industry reports and companies under coverage in generics and specialty pharma

Sterling Financial Investment Group Inc. — *July 2003 – October 2004*
Research Analyst/Institutional Sales. Boca Raton, FL — *October 2000 – October 2002*

- Conducted fundamental research focused on pharmaceuticals and biotechnology
- Executed financial and valuation analysis to generate proprietary equity research publications for distribution to institutional investor client base

DMR Capital
Consultant. New York, NY — *December 2002 – July 2003*

- Sole-proprietor of consulting business providing equity research to institutional clients to supplement their in-house research
- Built complex product and financial models using prescription trends, patient population data, surveys, and channel checks
- Developed client base of hedge funds and mutual funds ($50 million - $6 billion AUM)

DAVID M. RISK

Charlotte Checkers/Trenton Titans
Professional Hockey Player. Charlotte, NC/Trenton, NJ *March 1999 – July 2000*

- Under contract in the New York Rangers' developmental organization (Charlotte Checkers) and following a trade, the Philadelphia Flyers' developmental organization (Trenton Titans)
- Selected as the Charlotte Checkers' Humanitarian of the Year for community involvement

Education

Dartmouth College
Hanover, NH *Class of 1999*

- Major – English
- Men's Ice Hockey – Captain, four year varsity starter

License – Organizational Membership

- Twin Brooks Country Club Board of Governors (2010-2012)

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 Waylis Therapeutics LLC

Physical Address 47220 Cartier Drive, Suite B

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone (248) 313-9675 Website _____

Licensing Company Email compliance.waylis@gmail.com

Section 2: Personal Information

First David Middle _____ Last Risk

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

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

Mailing Address [redacted] Ellwood Avenue

City Berkley State MI Zip 48072

Telephone [redacted] Email compliance.waylis@gmail.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 DR

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)	
Dartmouth College		08/96 - 05/99	
Address	**City**	**State**	**Zip**
6016 McNutt Hall	Hanover	NH	03755
Diploma/Degree obtained, if any			
English			
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
01/20 - Present	[redacted] Ellwood Avenue	Berkley	MI	48072
03/15 - 01/20	[redacted]S Bates Street	Birmingham	MI	48009
02/13 - 03/15	[redacted] N Main Street	New Hope	PA	18938
08/12 - 01/13	[redacted]S West Street	Royal Oak	MI	48067
01/10 - 07/12	[redacted] Top Avenue	Green Brook	NJ	08812
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DR

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)
Woodward Pharma Services LLC			03/2015 - Present
Business Address	**City**	**State**	**Zip**
47220 Cartier Drive, Suite A	Wixom	MI	48393
Phone	**Title**		
248.308.1120	Chief Executice Officer		
Description of Duties			
please see attached - David Risk Resume			

Business Name			From - To (MM/YY – MM/YY)
Amedra Pharmaceuticals LLC			10/2012 - 03/2015
Business Address	**City**	**State**	**Zip**
2 Walnut Grove Dr # 190	Horsham	PA	19044
Phone	**Title**		
(888) 894-6528	President		
Description of Duties			
please see attached - David Risk Resume			

Business Name			From - To (MM/YY – MM/YY)
CorePharma LLC			12/2009 - 10/2012
Business Address	**City**	**State**	**Zip**
215 Wood Ave	Middlesex	NJ	08846
Phone	**Title**		
(732) 893-5942	Vice President, Business Development.		
Description of Duties			
please see attached - David Risk Resume			

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 DR

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.

N/A

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 DR

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 Risk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/21

Date

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

State of Michigan, ss. County of Oakland

I, DAVID RISK, 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

9/27/21

Date

Subscribed and Sworn to before me this 27th day of September, 2021

Notary Public Signature

ELLADA AZARIAH
NOTARY PUBLIC - STATE OF MICHIGAN
OAKLAND COUNTY
My Commission Expires July 14, 2027
Acting in the County of Oakland

(Seal)

Applicant's initials DR

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. 45BSBIS0685

Application/License No. _____

Waylis Therapeutics LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 47220 Cartier Drive, Suite B, Wixom, MI 48393 (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 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 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 7/14/21 (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 14th day of July August, 20 21.

APPLICANT/PRINCIPAL COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Kristie A. Pudvan, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Connor Bardo

Witness

JENNIFER HENNINGS
Notary Public - State of Michigan
County of Livingston
My Commission Expires Jun 15, 2027
Acting in the County of Oakland

SIGNED and SEALED in the presence of:

Witness

Susan E. Hurd
Witness

Countersigned by:

n/a
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
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: HYLANT GROUP INC
Agency Code(s): 35-351588, 35-350851, 81-151273

- [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:***

Susan E. Hurd, Vicki S. Duncan, Michael M. Hylant, Jamie Laurencelle, Kristie A. Pudvan, Lisa M. Wilmot,Judy K. Wilson, Kathy S Zack, Terri Mahakian

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 13th day of February, 2020, before me personally came Joelle L. 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

Jessica Noelle Ciccone
My Commission #GG077453
Expires June 20, 2021

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 July 14, 2021.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

HARTFORD FIRE INSURANCE COMPANY

Hartford, Connecticut

Financial Statement, December 31, 2020

Statutory Basis

ASSETS

U.S. Government Bonds	$	822,048,138
Bonds of Other Governments		145,404,785
State, County Municipal		
Miscellaneous Bonds		7,673,274,628
Stocks		5,813,449,034
Short Term Investments		371,408,387
	$	**14,825,584,972**
Real Estate	$	316,014,806
Cash		56,518,067
Agents' Balances (Under 90 Day)		2,844,035,257
Other Invested Assets		3,879,799,822
Miscellaneous		2,898,213,113
Total Admitted Assets	$	**24,820,166,037**

LIABILITIES

Reserve for Claims and Claim Expense		$	9,568,594,695
Reserve for Unearned Premiums			2,080,982,281
Reserve for Taxes, License and Fees			39,764,817
Miscellaneous Liabilities			1,883,565,726
Total Liabilities		$	**13,572,907,518**
Capital Paid In	$ 55,320,000		
Surplus	11,191,938,518		
Surplus as regards Policyholders		$	**11,247,258,518**
Total Liabilities, Capital and Surplus		$	**24,820,166,037**

STATE OF FLORIDA
SEMINOLE COUNTY } SS.
CITY OF LAKE MARY

Joelle L. LaPierre, Assistant Vice President and Shelby Wiggins, Assistant Secretary of the Hartford Fire Insurance Company, being duly sworn, each deposes and say that the foregoing is a true and correct statement of the said company's financial condition as of December 31, 2020.

Subscribed and sworn to before me this
22nd day of March, 2021.

Jessica Ciccone
Notary Public

JESSICA CICCONE
MY COMMISSION # GG077453
EXPIRES June 20, 2021

Joelle L. LaPierre
Assistant Vice President

Shelby Wiggins
Assistant Secretary

4M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☐ Nevada ☑ Out-of-State
Is your facility a reverse distributor?	☐ Yes ☑ No

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* See Attachment A ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02571	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Xeris Pharmaceuticals, Inc.

Physical Address: 180 N. LaSalle Street, Suite 1600

City: Chicago State: IL Zip: 60601

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 844-445-5704 Website: www.xerispharma.com

Name of Designated Representative (DR): Mark E. Zyrkowski

Licensing Company Email: mzyrkowski@xerispharma.com DR Email: mzyrkowski@xerispharma.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)?		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

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.

Name: See Attachment B

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): Xeris Biopharma Holdings, Inc.

Corporation/Organization Name: Xeris Pharmaceuticals, Inc.

Mailing Address: 180 N. LaSalle Street, Suite 1600

City: Chicago State: IL Zip: 60601

Telephone: 844-445-5704 Email: mzyrkowski@xerispharma.com

Contact Person Name: Mark E. Zyrkowski

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 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/. N/A		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment C 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 D		

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 E	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment 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 **6 months.** See Attachment F	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment G		✓	✓	✓
• **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 - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** N/A	✓			
• **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)** See Attachment H	✓	✓	✓	✓
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. N/A - See Attachment C		✓	✓	✓
• **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 - See Attachment C		✓	✓	✓

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 E. Zyrkowski

Print Name of Authorized Person Submitting Application

MZ

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

12/7/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc Received 12/7/21

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "XERIS 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 FIFTEENTH DAY OF SEPTEMBER, A.D. 2021.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "XERIS PHARMACEUTICALS, INC." WAS INCORPORATED ON THE TWENTY-NINTH DAY OF JULY, A.D. 2005.

Jeffrey W. Bullock, Secretary of State

4000705 8300

SR# 20213248768

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

Authentication: 204160523

Date: 09-15-21

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005138

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:
12/31/2022

LICENSED WHOLESALE DRUG DISTRIBUTOR

XERIS PHARMACEUTICALS INC
MARK E ZYRKOWSKI
180 N LA SALLE ST STE 1600
ROOM 1640
CHICAGO, IL 60601-2603

MARIO TRETO, JR.
ACTING SECRETARY

CECILIA ABUNDIS
ACTING DIRECTOR

The official status of this license can be verified at www.idfpr.com

16200991

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: 4492747

Attachment A

Regarding the Ownership Change

Effective October 5, 2021, Xeris Pharmaceuticals, Inc. (Xeris) ceased being a publicly-traded company. Xeris became wholly-owned by **Xeris Biopharma Holdings, Inc.**, a publicly-traded company. Please note that the Federal Tax Identification # did not change. Enclosed please find the ownership change documentation. Provided below is the new parent company information.

Parent Company Information:

Xeris Biopharma Holdings, Inc. - 100% owner
Address: 180 N. LaSalle Street, Suite 1600, Chicago, IL 60601
FEIN #: 87-1082097

XERIS PHARMACEUTICALS COMPLETES ACQUISITION OF STRONGBRIDGE BIOPHARMA

Xeris Pharmaceuticals, Inc. and Strongbridge Biopharma plc are now subsidiaries of Xeris Biopharma Holdings, Inc. (Nasdaq: XERS)

CHICAGO, IL, October 5, 2021 – Xeris Pharmaceuticals, Inc. ("Xeris"), a pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable drug formulations, today announced that it has successfully completed the previously announced acquisition of Strongbridge Biopharma plc (Nasdaq: SBBP) ("Strongbridge"). Under the terms of the acquisition agreement, the businesses of Xeris and Strongbridge are now combined under Xeris Biopharma Holdings, Inc. ("Xeris Biopharma Holdings"). Strongbridge shares and Xeris shares ceased trading on the Nasdaq Global Select Market ("Nasdaq") at the close of business today. Shares of Xeris Biopharma Holdings are expected to begin trading on the Nasdaq under the ticker symbol "XERS" on October 6, 2021.

"We remain very enthusiastic about the combination. The new Xeris BioPharma will have two marketed products showing very positive growth, another potential commercial asset currently in front of the FDA that could launch in early 2022 and additional assets under development. With the close of the acquisition, we are ready to execute our integration plan and begin to realize the compelling strategic and financial benefits of the combination. In addition to highly differentiated products with multiple value inflection points, our pipeline, drug development talent and commercial infrastructure will enable us to accelerate product launches and drive further growth in the future as well," said Paul R. Edick, Chairman and CEO of Xeris BioPharma Holdings, Inc. "I want to thank the Xeris team who have worked diligently to get us to this point in our growth as a company and welcome the Strongbridge team to help drive our next phase of growth. I am extremely excited about what the future potential of Xeris Biopharma brings for all of us, our shareholders, and ultimately the patient communities we serve."

The stock and contingent value rights ("CVRs") consideration payable in the transaction, when including the maximum aggregate amount payable under the CVRs, values Strongbridge at approximately $267 million based on the closing price of Xeris common stock of $[3.47] on May 21, 2021 and Strongbridge's fully diluted share capital. Under the terms of the transaction, each ordinary share of Strongbridge outstanding as of the close of the transaction has been converted into the right to receive a fixed exchange ratio of 0.7840 shares of Xeris Biopharma Holdings common stock and 1 non-tradeable CVR, worth up to an additional $1.00 payable in cash or Xeris Biopharma Holdings common stock (at Xeris Biopharma Holdings' election) upon achievement of the following triggering events: (i) the listing of at least one issued patent for KEVEYIS® in the U.S. Food & Drug Administration's Orange Book by the end of 2023 or at least $40 million in KEVEYIS® annual net sales in 2023 ($0.25 per ordinary share), (ii) achievement of at least $40 million in RECORLEV® annual net sales in 2023 ($0.25 per ordinary share), and (iii) achievement of at least $80 million in RECORLEV® annual net sales in 2024 ($0.50 per ordinary share). The minimum payment on the CVR per Strongbridge ordinary share is zero and the maximum payment is $1.00 in cash or Xeris Biopharma Holdings common stock, at Xeris Biopharma Holdings' election.

Following the close of the transaction, former Xeris shareholders own approximately 60% of Xeris Biopharma Holdings, while former Strongbridge shareholders own approximately 40%.

In conjunction with the close of the transaction, John H. Johnson, Strongbridge's former CEO, and Garheng Kong, M.D., PhD, MBA, Strongbridge's former Chairman of the board of directors of Strongbridge, will join the Board of Directors of Xeris Biopharma Holdings as new independent directors, increasing the size of the Board to eight members.

"On behalf of our Board of Directors, we welcome John and Garheng and their wealth of insights and experiences from across the industry, and specifically their intimate knowledge of Strongbridge Biopharma," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Biopharma Holdings. "As Xeris Biopharma continues to grow and evolve as a commercial company, we look forward to collaborating with them to shape our strategic plans and advance our mission."

SVB Leerink LLC is acting as financial advisor to Xeris, and Goodwin Procter LLP and A&L Goodbody LLP are serving as legal counsel. MTS Health Partners, LP is acting as financial advisor to Strongbridge, and Skadden, Arps, Slate, Meagher & Flom, LLP and Arthur Cox LLP are serving as legal counsel.

About Xeris Biopharma Holdings

Xeris (Nasdaq: XERS), is a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology, and gastroenterology. Xeris has two commercially available products, Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia and Keveyis®, the first and only FDA-approved therapy for primary periodic paralysis. Xeris also has a robust pipeline of development programs to extend the current marketed products into important new indications and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect™, supporting long-term product development and commercial success.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on Twitter, LinkedIn, or Instagram.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc. including statements regarding the market and therapeutic potential of its products and product candidates, expectations regarding clinical data or results from planned clinical trials, estimates and projections about the potential benefits of the Strongbridge Biopharma acquisition, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, the timing or likelihood of identifying potential development and commercialization partnerships, the potential utility of its formulation platforms and other statements containing the words "will," "would," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits of the possible acquisition, failure to promptly and effectively integrate Strongbridge's businesses, general economic and business conditions that affect the combined companies following the consummation of the possible acquisition,

the impact of the COVID-19 pandemic on the combined businesses following the consummation of the transaction, changes in global, political, economic, business, competitive, market and regulatory forces, future exchange and interest rates, changes in tax laws, regulations, rates and policies, future business acquisitions or disposals and competitive developments. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris' experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this communication could cause Xeris' plans with respect to Strongbridge, Xeris' actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Although it is believed that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this communication are therefore cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this communication. Additional information about economic, competitive, governmental, technological, and other factors that may affect Xeris is set forth in Item 1A, "Risk Factors," in Xeris' 2020 Annual Report on Form 10-K, which has been filed with the SEC and other important factors in Xeris' subsequent filings with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Additional information about economic, competitive, governmental, technological, and other factors that may affect Strongbridge is set forth in Item 1A, "Risk Factors," in Strongbridge's 2020 Annual Report on Form 10-K, which has been filed with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Any forward-looking statements in this communication are based upon information available to Xeris, as of the date of this communication and, while believed to be true when made, may ultimately prove to be incorrect. Subject to any obligations under applicable law, Xeris does not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations. All subsequent written and oral forward-looking statements attributable to Xeris or any person acting on behalf of any of them are expressly qualified in their entirety by this paragraph.

Investor Contact

Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com
312-736-1237

Attachment B

Nature of Business

Xeris Pharmaceuticals, Inc. (Xeris) is a virtual manufacturer of human prescription non-controlled drugs. Xeris utilizes third parties to produce, manufacture, and distribute its products to wholesalers. **At no time does this facility handle, store, produce or distribute its own products.** Provided below is the information for the contract manufacturer and third party logistics provider:

Contract Manufacturer:

Pyramid Laboratories, Inc.
3598 Cadillac Ave., Costa Mesa, CA 92626
FDA Registration #: 1000160734

Third Party Logistics Provider:

Cardinal Health 105, Inc. dba Specialty Pharmaceutical Services
501 Mason Road, Suite 200, LaVergne, TN 37086

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)
TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)
EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through September 28, 2021

You have searched Finished drug products

Search Results: *'xeris'*

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
Gvoke HypoPen	72065-120-11	.5 mg/.1mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-120	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke HypoPen	72065-120-12	.5 mg/.1mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-120	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke HypoPen	72065-121-11	1 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-121	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke HypoPen	72065-121-12	1 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-121	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG

verified
M.T 12/17/21

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Gvoke PFS	72065-130-11	.5 mg/.1mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-130	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke PFS	72065-130-12	.5 mg/.1mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-130	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke PFS	72065-130-99	.5 mg/.1mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-130	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke PFS	72065-131-11	1 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-131	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke PFS	72065-131-12	1 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-131	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG
Gvoke PFS	72065-131-99	1 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA212097	Xeris Pharmaceuticals, Inc.	72065-131	glucagon injection, solution	GLUCAGON	HUMAN PRESCRIPTION DRUG

Showing 1 to 10 of 10 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)

510

Xeris Pharmaceuticals, Inc.
NDC/NHRIC LABELER CODE REQUEST

Labeler - Xeris Pharmaceuticals, Inc. (609377135) **NDC Labeler Code:** 72065

Contact	Address	Telephone Number	Email Address
Kenneth Johnson	Address: 180 N. LaSalle Street, Suite 180 City, State, Zip: Chicago, IL, 60601 Country: USA	+1-312-517-1387	kjohnson@xerispharma.com

Revised: 1/2018

Xeris Pharmaceuticals, Inc.

Attachment E

Personnel Information

Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1600
Chicago, IL 60601

Corporate Officers:

Paul Edick
Chairman & CEO

John Shannon
COO

Steve M. Pieper
CFO

Beth Hecht
Corporate Secretary and General Counsel

Allison Wey
SVP of Investor Relations and Corporate Communications

Steve Prestrelski
Founder and Chief Science Officer

Kenneth Johnson
SVP of Medical Affairs, Clinical Development, Regulatory and Quality Assurance

Directors:

John Schmid
BJ Bormann Kennedy
Jeffrey Sherman
Dawn Halkuff
Marla Persky
Jonathan Rigby

Designated Representative:

Mark E. Zyrkowski
Associate Director, Supply Chain Operations

Xeris Pharmaceuticals, Inc. Employee List

First Name	Last Name	Location Description
Nana	Agyapong	Chicago-180
Ana	Aldape Sanchez	Chicago-180
Rebecca	Andrade	Chicago-180
Sonnie	Arakawa	Chicago-180
Michael	Athey	Chicago-180
Christine	August	Chicago-180
Ashley	Banach	Chicago-180
Adam	Barrett	Chicago-180
Natalie	Bean	Chicago-180
Rebeca	Bechily	Chicago-180
Andrea	Becker	Chicago-180
Ruta	Bera	Chicago-180
Katy	Bergeron	Chicago-180
Thomas	Best	Chicago-180
David	Birnbaum	Chicago-180
Alexandria	Bley	Chicago-180
Alan	Bloomfield	Chicago-180
Corey	Boeh	Chicago-180
Olivia	Bordenet	Chicago-180
Chelsea	Boundy	Chicago-180
Shawntiana	Boyd	Chicago-180
Julia	Burton	Chicago-180
Richard	Cabildo	Chicago-180
Conner	Castleberry	Chicago-180
Reece	Chadima	Chicago-180
Kathleen	Chavanu	Chicago-180
Diana	Cisneros	Chicago-180
Griffin	Cleary	Chicago-180
Krista	Coleman	Chicago-180
Jack	Coney	Chicago-180
Valentina	Conoscenti	Chicago-180
Vincent	Curta	Chicago-180
Matthew	Davi	Chicago-180
Elza	Demiri	Chicago-180
Carolyn	DeVivo	Chicago-180
Mary	Devona	Chicago-180
Sandra	Dide	Chicago-180
August	Edick	Chicago-180
Paul	Edick	Chicago-180
Ariane	Estepa	Chicago-180
Gino	Fasso	Chicago-180
James	Fisher	Chicago-180
William	Fleming III	Chicago-180
Luke	Fortuna	Chicago-180

Nicolette	Geddeis	Chicago-180
Regina	Gelhaus	Chicago-180
Mark	George	Chicago-180
Jazmin	Gomez	Chicago-180
Theodora	Grant-Acquah	Chicago-180
Forest	Grefe	Chicago-180
Jacob	Gross	Chicago-180
John	Hall	Chicago-180
Kyler	Haupt	Chicago-180
Julie	Healy	Chicago-180
Tyrone	Horton	Chicago-180
Nadia	Jaeger	Chicago-180
Kenneth	Johnson	Chicago-180
Mohammed	Junaidi	Chicago-180
Sherryl	King	Chicago-180
Heather	King	Chicago-180
Christina	Kline	Chicago-180
Thomas	Kohs	Chicago-180
Kendal	Korte	Chicago-180
Matthew	Krecic	Chicago-180
Christian	Leon	Chicago-180
Eric	Lewis	Chicago-180
Amy	Liesemeyer	Chicago-180
Daniel	Lutsch	Chicago-180
David	Maciag	Chicago-180
Rogelio	Martinez	Chicago-180
Kristin	Marvin	Chicago-180
Kevin	McCulloch	Chicago-180
Mary Beth	McNerney	Chicago-180
James	Meyer	Chicago-180
Matthew	Mick	Chicago-180
Francis	Micor	Chicago-180
James	Moore	Chicago-180
Sheila	Moran	Chicago-180
Przemyslaw	Nalaskowski	Chicago-180
Radha	Nath	Chicago-180
Wilson	Noriega	Chicago-180
Jeffrey	Norris	Chicago-180
Paijit	Ostrowski	Chicago-180
Aubrey	Papaeliou	Chicago-180
Peter	Pappas	Chicago-180
Vivek	Pavle	Chicago-180
David	Paz	Chicago-180
Shinita	Pettiford	Chicago-180
Steve	Pieper	Chicago-180
Brandon	Ranberger	Chicago-180
Blake	Randolph	Chicago-180

Amy	Reece	Chicago-180
Gigi	Relic	Chicago-180
Jack	Ricobene	Chicago-180
Curtis	Robinson	Chicago-180
Blaine	Roeder	Chicago-180
Neysharie	Sanchez Torres	Chicago-180
Thomas	Savage	Chicago-180
John	Shannon	Chicago-180
Marsha	Shetsky	Chicago-180
Eva	Shuman	Chicago-180
Robyn	Silverman	Chicago-180
Cathlyn	Sison	Chicago-180
Courtney	Sommer	Chicago-180
Nikola	Spegar	Chicago-180
Emily	Sulik	Chicago-180
Donna	Townsend	Chicago-180
Kiryl	Tsukerman	Chicago-180
Elizabeth	Urbas	Chicago-180
Vladislav	Volfson	Chicago-180
Lucy	Wangunyu	Chicago-180
Carissa	Werlinger	Chicago-180
Jackson	Wilcox	Chicago-180
Jeffrey	Wittah	Chicago-180
Kimberly	Woods	Chicago-180
Matthew	Wuchter	Chicago-180
Qin	Zhao	Chicago-180
Mark	Zyrkowski	Chicago-180

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 Xeris Pharmaceuticals, Inc.

Physical Address 180 N. LaSalle Street, Suite 1600

City Chicago State IL Zip 60601

Mailing Address (if different from physical address) Same as physical address.

City _____ State _____ Zip _____

Telephone 844-445-5704 Website www.xerispharma.com

Licensing Company Email mzyrkowski@xerispharma.com

Section 2: Personal Information

First Mark Middle Ernest Last Zyrkowski

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address 180 N. LaSalle Street, Suite 1600

City Chicago State IL Zip 60601

Telephone [redacted] Email mzyrkowski@xerispharma.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 639.139)	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	

Applicant's initials [illegible]

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

School Name		From - To (MM/YY – MM/YY)	
North Central College		08/05-05/08	
Address	**City**	**State**	**Zip**
30 North Brainard Street	Naperville	IL	60540
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Millikin University		08/99-12/03	
Address	**City**	**State**	**Zip**
1184 West Main Street	Decatur	IL	62522
Diploma/Degree obtained, if any			
BS in Accounting			

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
05/14 – Present	[redacted] Vance Ct.	Lake Barrington	IL	60010
08/09 – 05/14	15210 W. Belle Plaine Ave., Unit 2	Chicago	IL	60613
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 KNZ

Section 7: Additional Employment Provide details of all jobs held during the last 10 years. Start with your most recent employer. Include part-time, temporary, and self-employment. Explain any gaps in employment. Indicate if you were employed by a pharmacy, wholesaler, manufacturer, or other entity licensed by the state. Include contact information for each employer listed.

Business Name		From - To (MM/YY – MM/YY)
Xeris Pharmaceuticals, Inc.		04/18 - Present
Business Address	**City**	**State / Zip**
180 N. LaSalle Street, Suite 1600	Chicago	IL 60601
Phone	**Title**	**Number of Employed Hours**
312-517-1995	Associate Director, Supply Chain Operations	~25,416

Description of Duties
Responsible for inventory planning, procurement and distribution.

Business Name		From - To (MM/YY – MM/YY)
Lundbeck / Ovation Pharmaceuticals		11/07 - 04/18
Business Address	**City**	**State / Zip**
4 Parkway North	Deerfield	IL 60015
Phone	**Title**	**Number of Employed Hours**
847-282-1000	Associate Director, Supply Chain Management	~90,000

Description of Duties
Supervise a Senior Manager of Supply Chain and a Senior Distribution Manager; Supply Chain lead for DSCSA implementation; Designated representative for state licensing.

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

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 B: 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

Applicant's initials _____

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:

MZ

Original Signature (electronic, copies or stamps not accepted)

12/7/2021

Date

Applicant's initials MZ

I, Mark E. Zyrkowski **, certify that as the designated representative for**

Xeris 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

Mark Zyrkowski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/7/2021

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.

Mark Zyrkowski
Print Name (First, Last)

MZ
Original Signature (electronic, copies or stamps not accepted)

11/30/2021
Date

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

State of ILLINOIS, ss. County of COOK

I, Mark E. Zyrkowski, 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.

MZ
Original Signature

11/30/2021
Date

Subscribed and Sworn to before me this 30th day of November.

Notary Public Signature

(Seal)

ROBYN SILVERMAN
Official Seal
Notary Public - State of Illinois
My Commission Expires Dec 1, 2024

Applicant's initials MZ

svb
Silicon Valley Bank

IRREVOCABLE STANDBY LETTER OF CREDIT NO. SVBFS000137

DATE: DECEMBER 16, 2021

ISSUING BANK:
SILICON VALLEY BANK
3003 TASMAN DRIVE
2ND FLOOR, MAIL SORT HF210
SANTA CLARA, CALIFORNIA 95054

BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NEVADA 89521
ATTN: DAVE WUEST

APPLICANT:
XERIS PHARMACEUTICALS, INC.
180 N. LASALLE, SUITE 1810
CHICAGO, IL 60601

AMOUNT: US$25,000.00 (TWENTY-FIVE THOUSAND AND 00/100 U.S. DOLLARS)

EXPIRATION DATE: DECEMBER 16, 2022

PLACE OF EXPIRATION: ISSUING BANK'S COUNTERS AT ITS ABOVE ADDRESS

LADIES AND GENTLEMEN:

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. SVBFS000137 IN YOUR FAVOR AVAILABLE BY PAYMENT AGAINST YOUR PRESENTATION TO US OF THE FOLLOWING DOCUMENTS:

1. THE ORIGINAL OF THIS LETTER OF CREDIT AND ORIGINALS OR COPIES OF ALL AMENDMENTS, IF ANY, TO THIS LETTER OF CREDIT.

2. BENEFICIARY'S SIGNED AND DATED STATEMENT STATING AS FOLLOWS:

"THE APPLICANT HAS FAILED TO PAY AS PER THAT CERTAIN AGREEMENT DATED (INSERT DATE). THE AMOUNT HEREBY DRAWN UNDER THE LETTER OF CREDIT NO. SVBFS000137 IS US$_____, WITH PAYMENT TO BE MADE TO THE FOLLOWING ACCOUNT: [INSERT WIRE INSTRUCTIONS (TO INCLUDE NAME AND ACCOUNT NUMBER OF THE BENEFICIARY)]."

PARTIAL DRAWS AND MULTIPLE PRESENTATIONS ARE ALLOWED.

svb

Silicon Valley Bank

IRREVOCABLE STANDBY LETTER OF CREDIT NO. SVBFS000137

THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST 60 DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE SEND TO YOU A NOTICE BY REGISTERED OR CERTIFIED MAIL OR OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESS THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE THEN CURRENT EXPIRATION DATE. IN THE EVENT WE SEND SUCH NOTICE OF NON-EXTENSION, YOU MAY DRAW HEREUNDER BY YOUR PRESENTATION TO US OF (1) THE ORIGINAL LETTER OF CREDIT AND ORIGINALS OR COPIES OF ALL AMENDMENTS, IF ANY, TO THIS LETTER OF CREDIT AND (2) YOUR SIGNED AND DATED STATEMENT STATING THAT YOU HAVE RECEIVED A NON-EXTENSION NOTICE FROM SILICON VALLEY BANK IN RESPECT OF LETTER OF CREDIT NO. SVBFS000137, YOU ARE DRAWING ON SUCH LETTER OF CREDIT FOR US$_____, AND YOU HAVE NOT RECEIVED A REPLACEMENT LETTER OF CREDIT ACCEPTABLE TO YOU.

ALL DEMANDS FOR PAYMENT SHALL BE MADE BY PRESENTATION OF THE REQUIRED DOCUMENTS ON A BUSINESS DAY AT OUR OFFICE (THE "BANK'S OFFICE") AT: SILICON VALLEY BANK, 3003 TASMAN DRIVE, MAIL SORT HF 210, SANTA CLARA, CA 95054, ATTENTION: GLOBAL TRADE FINANCE.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO YOUR ACCOUNT WITH ANOTHER BANK, WE WILL ONLY EFFECT SUCH PAYMENT BY FED WIRE TO A U.S. REGULATED BANK, AND WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS EVEN IF THE NUMBER IDENTIFIES A PERSON OR ENTITY DIFFERENT FROM THE INTENDED PAYEE.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 590.

IF YOU HAVE ANY QUESTIONS REGARDING THIS TRANSACTION, PLEASE CONTACT FAUSTO OMNE AT TEL NO. 408-450-5073, ALWAYS QUOTING OUR LETTER OF CREDIT NO. SVBFS000137.

SILICON VALLEY BANK

_____

AUTHORIZED SIGNATURE

Fausto Omne

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svb

Silicon Valley Bank

Application and Agreement for Standby Letter of Credit

TO: SILICON VALLEY BANK

A. APPLICATION

DATE	FOR BANK USE ONLY	LETTER OF CREDIT NO.
12/9/2021		

APPLICANT HEREBY REQUESTS THAT SILICON VALLEY BANK ("SVB") ISSUE ITS IRREVOCABLE STANDBY LETTER OF CREDIT (THE "CREDIT") ON SUBSTANTIALLY THE TERMS BELOW AND, UNLESS OTHERWISE SPECIFIED BELOW IN SPECIAL INSTRUCTIONS, FORWARD THE CREDIT BY THE FOLLOWING MEANS TO BENEFICIARY DIRECTLY OR THROUGH A BANK OR BANKS SELECTED BY SVB:

☐ S.W.I.F.T. ☑ COURIER ☐ OTHER_____

Applicant: *(name & street address; P.O. Box not accepted)*
XERIS PHARMACEUTICALS, INC.
180 N. LASALLE STREET SUITE 1600
CHICAGO IL 60601

☐ **Applicant is requesting the Credit for account of Account Party** *(check only if the party to be named in the Credit as account party, customer, applicant or the like is different from Applicant or if the party whose obligation to be supported by the Credit is different from Applicant)*

☐ **Applicant and Account Party are jointly and severally obligated hereunder** *(check if applicable)*

Account Party: *(if applicable) (name & street address; P.O. Box not accepted)*

Beneficiary: *(name & street address; P.O. Box not accepted)*
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NEVADA 89521
ATTN: DAVE WUEST

Amount: *(in words)*
Twenty thousand exactly
(in figures)
$25,000.00

Advising Bank: *(used mostly for international beneficiaries; if left blank, SVB may select; else state "None" or specify name & street address)*

Currency: *(in U.S. Dollars unless otherwise specified)*

Foreign Exchange Contract No.: *(if applicable)*

Place of Expiration: Unless otherwise specified herein, the Credit is to expire at SVB's issuing office or, if confirmation is requested herein, at the confirming bank's office.

Expiration Date: 1 YEAR FROM ISSUE DATE *(MM/DD/YYYY)*. If the Expiration Date is more than one year after issuance, SVB may at its option include an annual automatic extension provision.

☑ Auto annual extension with at least 60 days' prior notice of non-extension and a final expiration date of Evergreen *(MM/DD/YYYY)*. *(check & complete if applicable)*

Drawing condition(s): *(check & complete only one of the following. Applicant must sign & approve SVB's draft Credit prior to issuance)*

☑ Issue the Credit substantially in the form and with the wording attached to this Application. The attached specimen is approved by Applicant. *(label the attached specimen as an attachment to this specific Application)*

☐ A statement worded as follows indicating it is signed by Beneficiary (if an individual) or its authorized officer: *(please quote below the exact wording of the drawing statement; attach additional signed sheet(s), if necessary, & label as attachments to this specific Application)*

Additional Requirements and/or Special Instructions: *(if any) (attach additional signed sheet(s), if necessary, and label as attachments to this specific Application)*

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svb

Silicon Valley Bank

Application and Agreement for Standby Letter of Credit

Purpose: *(insert brief description of the purpose for the Credit; for example: to support tenant obligations of Applicant to Beneficiary under a lease agreement)*

TO SUPPORT LICENSING REQUIREMENT FOR THE STATE OF NEVADA.

Transferability: *(if not checked, the Credit will not be transferable)*

☑ The Credit is to be transferable, with transfer charges for: ☐ Applicant's account ☐ Beneficiary's account

Agreement and Signature(s): The opening of the Credit is subject to the terms of the following Agreement, which are incorporated herein by reference. By executing this Application, Applicant (and the above named Account Party, if applicable) hereby acknowledges and agrees to the same and to the Schedule of Fees referred to in the following Agreement, as such Schedule may be amended by SVB from time to time.

Print or Type Name of Applicant:	**Print or Type Name of Account Party**: *(required only if Applicant & Account Party are designated as jointly & severally obligated hereunder)*
SAME AS ABOVE	
Authorized Applicant Signature: *(must be a signer on the latest borrowing certificate)* Steve Pieper DDB473AA2A134A8...	**Authorized Account Party Signature**:
Name: **Title**: CFO	**Name**: **Title**:
Authorized Applicant Signature: *(must be a signer on the latest borrowing certificate)*	**Authorized Account Party Signature**:
Name: **Title**:	**Name**: **Title**:

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Silicon Valley Bank

Application and Agreement for Standby Letter of Credit

B. AGREEMENT

In consideration of SVB in its discretion issuing the Credit, each of Applicant and, if Applicant and Account Party are designated as jointly and severally obligated hereunder, Account Party (in which case Applicant and Account Party are collectively referenced herein, jointly and severally, as "Applicant"), agrees as follows:

1. Applicant agrees to pay to SVB, on demand, the amount of each draw on the Credit, together with interest accrued on any such amount calculated for each day such amount remains outstanding at a variable rate equal to SVB's Prime Rate plus 5% per annum; provided that if the Credit provides for the acceptance of a time draft or incurrence of a deferred payment obligation and if SVB notifies Applicant of such acceptance or incurrence at least one Business Day in advance of the maturity of such time draft or deferred payment obligation, then reimbursement shall be due one Business Day in advance of its maturity. The term "Prime Rate" means the fluctuating per annum rate announced from time to time by SVB as its "Prime Rate," such rate to be adjusted from time to time by SVB; provided that if the Prime Rate shall at any time be less than zero it shall be treated as zero for purposes of this Agreement. In addition, Applicant agrees to pay to SVB, on demand, all commissions, charges, fees, taxes, costs and expenses (including reasonable attorneys' fees) assessed against or incurred by SVB or any of its correspondents in connection with the Credit, this Application and Agreement, the administration of the Credit (including any amendments, modifications and extensions thereof), and the enforcement by SVB of its rights hereunder, including such fees and expenses as may be set forth from time to time in SVB's then current "Schedule of Fees." All such amounts are non-refundable upon payment (including in the instance a related Credit is cancelled prior to its expiration date) and, if not paid when due, shall bear interest at the variable rate set forth in the first sentence of this Section. Unless otherwise specified in SVB's then current "Schedule of Fees," all accrual computations of any commissions, fees or interest under this Agreement shall be based on a 360-day year for the actual number of days elapsed (including the first day and the last day, in the case of commissions and fees, and including the first day but excluding the last day, in the case of interest). All computations of commissions and fees based upon the available or face amount of the Credit at any time shall be calculated by reference to the greatest amount for which SVB may be contingently liable under any circumstances under the Credit at such time or thereafter, including, if the Credit by its terms provides for scheduled increases in the amount of the Credit, the amount of each such increase that has not yet taken effect. Applicant irrevocably authorizes SVB to charge any accounts maintained by Applicant with SVB and to make advances against any lines of credit extended by SVB to Applicant for payment of all such amounts set forth in this Application and Agreement. Applicant acknowledges that SVB is not obligated to charge such accounts or to make any such advances and the failure for whatever reason of SVB to do so will not relieve Applicant of its obligation to pay such amounts, including interest.

2. All amounts payable hereunder are payable in U.S. Dollars and in immediately available funds. If the Credit is issued in a foreign currency, unless SVB agrees otherwise in writing in its sole discretion, Applicant will pay the U.S. Dollar equivalent of the foreign currency amounts paid by SVB under the Credit at the then-prevailing rate of exchange in San Francisco, California, for sales of the foreign currency for transfer to the country issuing such foreign currency, as determined by SVB.

3. Applicant will indemnify and hold SVB and its affiliates, officers, directors, employees, agents and correspondents (collectively, the "Indemnified Parties") harmless from and against any and all claims, losses, liabilities, costs (including reasonable attorneys' fees) and damages (collectively, "Losses") arising out of or relating to (i) the Credit, any demand for payment, other presentation or request under the Credit, or the transaction(s) supported by the Credit, (ii) this Application and Agreement, (iii) any action or inaction of any Indemnified Party with respect to any of the foregoing, (iv) any act or omission, whether rightful or wrongful, of any present or future de jure or de facto government or governmental authority or any other cause beyond SVB's control with respect to any of the foregoing or (v) any indemnity or other undertaking that Applicant requests or authorizes SVB to issue to induce any other financial institution (including any branch or affiliate of SVB) to issue its own letter of credit, demand guarantee, or other undertaking in connection with the Credit, in each case other than such as are found in a final, non-appealable judgment by a court of competent jurisdiction to result directly from the gross negligence or willful misconduct of such Indemnified Party. If the beneficiary of the Credit or any transferee thereof ("Beneficiary") is a financial institution which, in reliance upon the Credit, has issued or is to issue its own letter of credit, guarantee or similar undertaking to a third party at Applicant's request (whether such request is communicated directly by Applicant or through SVB to such Beneficiary), Applicant will (i) reimburse SVB for all amounts paid by SVB to such Beneficiary (whether or not the Credit has expired) and (ii) indemnify each Indemnified Party for any Losses (including fees paid to such Beneficiary) arising out of or in connection with the Credit and such letter of credit, guarantee or other undertaking. Applicant will remain liable under this Application and Agreement and in respect of the Credit until each such Beneficiary expressly releases SVB from its obligations under the Credit.

4. (a) If any law or regulation or the interpretation thereof by any court or administrative or governmental authority shall (i) impose any reserve or similar requirement against letters of credit issued or assets held by, or deposits in or for the account of, SVB or (ii) impose on SVB any insurance premium or other condition regarding the Credit, and the result shall be to increase the costs of issuing or maintaining the Credit over that which SVB assumed in determining its pricing relating to the Credit, then Applicant shall pay to SVB from time to time upon demand such additional amounts as are sufficient to compensate SVB for such increased cost.

(b) If SVB determines that the introduction or effectiveness of, or any change in, any treaty, international agreement, law, rule or regulation or compliance with any directive, guideline or request from any central bank or other governmental or quasi-governmental authority (whether or not having the force of law), or any change in the interpretation of any of the foregoing, in each case after the date hereof, affects the amount of capital, liquidity, insurance or reserves

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(including special deposits, deposit insurance or similar requirements) to be maintained by SVB or any corporation controlling SVB, or otherwise increases the costs of, or reduces the amount received or receivable by, SVB or any corporation controlling SVB, and SVB determines that the amount of such capital, liquidity, insurance or reserve or other increased cost or reduction, as the case may be, is increased or reduced by or based upon the existence of this Agreement or the Credit (excluding in each case any increased costs resulting from any taxes), then Applicant shall pay to SVB, promptly upon demand from time to time, such additional amounts as SVB may demand to compensate for the increase or reduction, as the case may be; provided that SVB computes all amounts due under this paragraph on a reasonable basis. (i) All requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States of America or foreign regulatory authorities, in each case pursuant to Basel III, and (ii) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith shall, in each case, be deemed to be a change in law for purposes of this Section, regardless of the date enacted, adopted or issued. Failure or delay on the part of SVB to demand compensation pursuant to this Section shall not constitute a waiver of SVB's right to demand such compensation; provided that the Applicant shall not be required to compensate SVB pursuant to this Section for any increased costs or reductions incurred more than 180 days prior to the date that SVB notifies the Applicant of the introduction, effectiveness or change, as the case may be, giving rise to such increased costs or reductions and of SVB's intention to claim compensation therefor; provided, further, that, if the introduction, effectiveness or change, as the case may be, giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof. As used herein, "Business Day" means any day that is not a Saturday, Sunday or other day on which commercial banks are authorized or required to close in San Francisco, California, or at such other place where SVB is obligated to honor a presentation or otherwise act under the Credit or this Agreement.

5. SVB may place a hold on any account pledged as collateral and may hold the collateral for up to 30 days following the expiration of the Credit and the payment by Applicant of its obligations hereunder.

6. (a) The obligation of Applicant hereunder to reimburse SVB for drawings under the Credit is absolute, irrevocable and unconditional under any and all circumstances and irrespective of any dispute, claim, set-off, counterclaim or defense which Applicant may have against SVB or any affiliated Person (as defined below), whether in connection with the Credit, this Application and Agreement or otherwise, including any of the same based upon or arising out of: (i) any lack of validity or enforceability of the Credit or any document issued or provided in connection with the Credit or this Application and Agreement; (ii) any allegation by Applicant or any other Person that any demand, statement or any other document presented under the Credit is forged, fraudulent, invalid or insufficient in any respect, or that any statement therein is inaccurate or incomplete in any respect or that variations in punctuation, capitalization, spelling or format were contained in the drafts or any statements presented in connection with any drawing; (iii) any amendment or waiver of or consent to departure from the terms of the Credit; (iv) the existence of any dispute, claim, set-off, counterclaim or defense or other right which Applicant or any other Person may have at any time against any Beneficiary (or any Person for whom any Beneficiary may be acting); (v) the presentation of a draft or other instrument by an assignee, transferee or successor-in-interest of the original or any subsequent Beneficiary; (vi) any exchange, release or non-perfection of any lien securing the obligations of Applicant hereunder or the release of any guarantor of such obligations; (vii) any delay, default or fraud in connection with the underlying transaction giving rise to the issuance of the Credit; (viii) any delay in giving or failure to give notice of any kind; (ix) any errors, omissions, neglect, default or delay in transmission of any messages by SVB, any affiliated Person or any advising bank in connection with the Credit; (x) the invalidity or insufficiency of any endorsements relating to the Credit; or (xi) any other circumstance that might, but for the provisions of this Section, constitute a legal or equitable discharge of or defense to the obligation of Applicant hereunder to reimburse SVB for drawings under the Credit. As used herein, "Person" means any natural person, corporation, limited liability company, trust, joint venture, association, company, partnership, government (including any subdivision, agency, court, central bank, or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including any supranational bodies such as the European Union or the European Central Bank)) or other entity.

(b) Nothing contained herein shall constitute a waiver by Applicant of any rights Applicant may have against SVB resulting from SVB's gross negligence or willful misconduct; provided that Applicant expressly agrees that (i) its right to exercise any such rights is conditioned upon Applicant having first made all payments required to be made by Applicant hereunder; (ii) it shall not constitute gross negligence or willful misconduct, and SVB in its discretion, (A) may honor any presentation that substantially or reasonably complies with the terms and conditions of the Credit even if the Credit requires strict or literal compliance by Beneficiary; (B) may honor a nonnegotiable or informal or unmarked demand or a demand by Beneficiary presented electronically even if the Credit requires that Beneficiary's demand be in the form of a draft and state that it is drawn under the Credit; (C) may honor a presentation without regard to any non-documentary conditions in the Credit; (D) may honor a presentation up to the amount available under the Credit against a draft or other documents claiming an amount in excess of the amount available; (E) may honor any presentation after the expiration date of the Credit (x) if presentation on or prior to such expiration date was prevented by an interruption of business or other cause beyond the control of SVB or strikes or lockouts, or (y) notwithstanding that a presentation was made on or prior to such expiration date and dishonored, if subsequently SVB or any court or other finder of fact determines such presentation should have been honored; (F) shall not be responsible for errors in interpretation of technical terms or in translation (and SVB may transmit Credit terms without translating them); (G) may replace a purportedly lost, stolen or destroyed original Credit with a replacement marked as such or waive a requirement for its presentation; (H) unless the Credit specifies the means of payment, may make any payment under the Credit by any means it chooses, including by wire transfer of immediately available funds, (I) may select SVB or any subsidiary, affiliate or branch thereof or any other bank to act as advising, transferring, confirming and/or nominated bank under the law and practice of the place where it is located (if the application for the Credit requested or authorized such advice,

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transfer, confirmation and/or nomination, as applicable); (J) may amend the Credit to reflect any change of address or other contact information of any Beneficiary; (K) shall not be obligated to examine, and may disregard for purposes of determining compliance of any presentation with the terms and conditions of the Credit, (x) any presented document not called for by the terms and conditions of the Credit and (y) that portion, if any, of any presented document called for by the terms and conditions of the Credit that contains data not called for by the terms and conditions of the Credit, regardless of whether such data conflicts with data in the Credit or any other presented document; (L) shall not be responsible for any other action or inaction taken or suffered by SVB under or in connection with the Credit, that is required or permitted under any applicable domestic or foreign law or letter of credit practice; and (M) may purchase or discount any accepted draft or deferred payment obligation incurred under the Credit without affecting the amount or timing of the reimbursement due from Applicant; and (iii) in no event shall SVB or any affiliated Person have any liability to Applicant or any other Person for any action taken, or any failure to act, with respect to the Credit or this Application and Agreement if done in good faith.

(c) Applicant will notify SVB in writing of any objection Applicant may have to SVB's issuance or amendment of the Credit, SVB's honor or dishonor of any presentation under the Credit, or any other action or inaction taken by SVB under or in connection with this Application and Agreement or the Credit. Applicant's notice of objection must be delivered to SVB within one week after Applicant receives notice of the action or inaction it objects to. Applicant's failure to give notice of objection within such period shall automatically waive Applicant's objection. Applicant's acceptance or retention beyond such period of any original documents presented under the Credit, or of any property for which title is conveyed by such documents or for which payment is made (in whole or in part) under such Credit, shall ratify SVB's honor of the applicable presentation(s).

(d) Applicant's ultimate responsibility for the final text of the Credit shall not be affected by any assistance SVB may provide such as drafting or recommending text, and Applicant assumes all risks that: (i) any non-documentary conditions stated in the Credit will be ignored when presentment is made, or may cause the Credit to be interpreted by a court as a dependent guarantee; (ii) any ambiguous or inconsistent provisions may be interpreted in a manner not intended by Applicant; (iii) any permitted payment or other action at a foreign location may invoke the application of foreign laws or rules; and (iv) the Credit does not satisfy Applicant's needs or intentions. SVB may, without incurring any liability to Applicant or impairing its entitlement to payment under this Application and Agreement, honor the Credit despite notice from Applicant of, and without any duty to inquire into, any purported defense to honor or any claim against any Beneficiary or any other Person.

(e) If the Credit is issued in transferable form, SVB shall have no duty to determine the identity of anyone appearing in any transfer request, draft or other document as transferee, or the validity or correctness of any transfer made pursuant to documents that appear on their face to be substantially in accordance with the terms and conditions of the Credit.

(f) Except as may be provided in the Credit or otherwise agreed to in writing by SVB in its sole discretion, SVB shall have no duty to (i) issue or refrain from issuing notice of (A) its election not to extend the Credit, (B) if the Credit by its terms permits it to do so, its election to terminate the Credit prior to its stated expiration date, or (C) its election not to reinstate the amount of any drawing under the Credit or (ii) otherwise amend or modify the Credit. If the Credit by its terms provides for automatic renewal or extension unless SVB notifies the Beneficiary of SVB's election not to renew or extend the Credit and if Applicant desires that SVB give such notice, then Applicant's request that SVB give such notice shall be given to SVB at least 30 days prior to the date that Applicant wishes that SVB give such notice (but SVB shall have no obligation to accede to such request).

(g) If Applicant or any other Person seeks to restrain any presentation under or honor of the Credit or takes any other action that has a similar effect or if any court shall do any of the foregoing or extend the term of the Credit, then, in each case, Applicant shall, at SVB's request, provide SVB with a bond or other collateral of a type and value reasonably satisfactory to SVB as security for all the Applicant's obligations (absolute or contingent) with respect to the Credit.

(h) SVB shall not be liable in contract, tort, or otherwise for any punitive, exemplary, consequential, indirect or special damages (including for any consequences of forgery or fraud by any Beneficiary or any other Person). Any claim by Applicant under or in connection with the Credit or this Application and Agreement shall be reduced by an amount equal to the sum of (i) the amount (if any) saved by Applicant as a result of the breach or other wrongful conduct complained of (such as where SVB's erroneous payment of the Credit results in Applicant's obtaining valuable property) and (ii) the amount (if any) of the loss that would have been avoided had Applicant taken reasonable steps to mitigate such loss.

7. Each Applicant waives: (i) any right at law or in equity to require SVB to (A) proceed against any Person, including any other Applicant or any guarantor, (B) proceed against or exhaust any collateral held for the obligations of Applicant hereunder, (C) pursue any other remedy in SVB's power or (D) make any presentment, demand for performance, or give any notice of nonperformance, protest, notice of protest or notice of dishonor in connection with such Applicant's obligations hereunder; and (ii) any defense arising by reason of (A) the incapacity, lack of authority, death or disability of, or other defense available to, Applicant or any other Person, including the insolvency or bankruptcy of any Applicant or any other Person, or any stay in connection with any such proceeding, or the failure of Beneficiary to file or enforce a claim against the estate (in administration, bankruptcy, or any other proceeding) of any Applicant or any other Person or (B) any act or omission by SVB which directly or indirectly results in or aids the discharge or release of any party obligated hereunder, any other Person, or any collateral. Each Applicant represents that each of the above waivers are made with full knowledge that events giving rise to any defense waived may adversely affect rights which Applicant otherwise may have against the other Applicant, SVB or other Persons or against any collateral.

8. Applicant represents and warrants to SVB that: (i) this Application and Agreement has been duly authorized, executed and delivered by Applicant and constitutes the valid and binding obligation of Applicant, enforceable against Applicant in accordance with its terms; (ii) Applicant's execution, delivery and performance of this Application and Agreement and its obtaining of

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the Credit do not contravene any charter provision, by-law, resolution, contract or other undertaking binding on or affecting Applicant or any of Applicant's properties, do not violate any applicable domestic or foreign law, rule or regulation (including any Anti-Corruption Law or Anti-Terrorism Law, each as defined below) or any order, writ, judgment, decree, award or permit of any arbitration tribunal, court or other governmental authority applicable to Applicant or any of Applicant's properties, and do not require any notice, filing or other action to or by any governmental authority (other than those that have been made or obtained and are in full force and effect); (iii) Applicant and the parties with whom Applicant conducts business are reputable and are not using SVB as a conduit for money laundering or other illicit purposes; (iv) none of Applicant's transactions supported by the Credit is prohibited by any applicable law, regulation, rule, order, or judgment; (v) neither Beneficiary, Applicant nor any of their respective employees is a national of a designated blocked country or "Specially Designated National," "Blocked entity," "Specially Designated Terrorist," "Specially Designated Narcotics Trafficker," or "Foreign Terrorist Organization," as defined by the United States Office of Foreign Assets Control or any successor; (vi) any and all necessary import, export or other licenses for the import, export or shipping of any and all goods shipped under or pursuant to or in connection with the Credit have been obtained and all foreign and domestic governmental regulations in regard to the shipment of any such property or the financing thereof have been and will be complied with; (vii) the financial statements received by SVB from Applicant or disclosed in Applicant's periodic and current reports filed with the U.S. Securities and Exchange Commission (or any successor thereto), if applicable, present fairly its financial condition as of the dates and for the periods therein indicated, in accordance with generally accepted accounting principles, consistently applied, and since the date of its most recent audited annual financial statements there has been no material adverse change in such financial condition or its business or assets; (viii) no other information furnished by it to SVB is or shall be materially false or misleading when furnished; (ix) there is no pending or threatened action or investigation which is reasonably likely to materially adversely affect Applicant's financial condition, business or assets or which purports to affect the validity or enforceability of this Application and Agreement, any other agreement supporting or securing this Application and Agreement, or the Credit; (x) under laws in effect on the date hereof, Applicant will not be required to make any deduction or offset from any payment it may make hereunder, and if it learns of any change requiring any such deduction or offset it will promptly notify SVB thereof; and (xi) Applicant is not an investment company within the meaning of the Investment Company Act of 1940 or, directly or indirectly, controlled by or acting on behalf of any party which is such an investment company. As used herein, (i) "Anti-Corruption Laws" mean, at any time, all laws, rules and regulations of any jurisdiction concerning or relating to bribery or corruption" and (ii) "Anti-Terrorism Laws" mean, at any time, all laws, rules and regulations of the United States of America relating to economic or trade sanctions, terrorism, narcotics trafficking or money laundering, including the Patriot Act, the Trading with the Enemy Act, the International Emergency Economic Powers Act, U.S. Executive Order No. 13224 of September 23, 2001 Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism, and the laws administered from time to time by the Office of Foreign Assets Control of the United States Department of the Treasury.

9. Applicant will (i) comply with all foreign and domestic laws, rules and regulations now or hereafter applicable to Applicant, its properties, the Credit or transactions related to the Credit, except where the failure to do so could not reasonably be expected to have a material adverse effect in the business, operations, or condition (financial or otherwise) of Applicant or a material impairment of the prospect of repayment of any portion of the obligations under this Application and Agreement, (ii) deliver to SVB, upon request from time to time, (x) unless Applicant is required to file, and timely files (without giving effect to any extension), regular annual and quarterly financial statements with the U.S. Securities and Exchange Commission (or any successor thereto) pursuant to the United States Securities Exchange Act of 1934, as amended, financial statements, and (y) such other information concerning Applicant's financial condition, business and prospects as SVB may reasonably request, (iii) permit SVB to inspect Applicant's books and records on reasonable notice during regular business hours, (iv) comply with all Anti-Corruption Laws and Anti-Terrorism Laws applicable to it, its subsidiaries and its and their respective directors, officers, employees and agents from time to time and not cause the Credit to be issued or used (x) to fund, finance or facilitate any activities, business or transaction of or with any Person that is the target of any Anti-Terrorism Law or in any country or territory that is the subject of any Anti-Terrorism Law or (y) in furtherance of an offer, payment or giving of money or anything else of value to any Person in violation of any Anti-Corruption Law, and (v) promptly upon obtaining knowledge of the occurrence of any Event of Default or any event which with notice or lapse of time or both would constitute an Event of Default, notify SVB thereof in writing, specifying the nature thereof and the action Applicant proposes to take with respect thereto.

10. Each of the following shall constitute an "Event of Default" under this Application and Agreement: (i) Applicant fails to pay or perform any of Applicant's obligations hereunder or there occurs a default under any other agreement between Applicant and SVB; (ii) there occurs a material impairment in the perfection or priority of SVB's lien on any collateral or if the value of such collateral falls below the aggregate amount of Applicant's obligations under this Agreement (including undrawn amounts under the Credit); (iii) there occurs a material adverse change in the business, operations, or condition (financial or otherwise) of Applicant or a material impairment of the prospect of repayment of any portion of the obligations under this Agreement; (iv) a petition is filed by or against Applicant for any relief under any bankruptcy or other law relating to the relief of debtors; (v) any governmental authority, receiver or court takes possession of or exercises control over any substantial part of the property of Applicant; (vi) any court order, injunction or other legal process is issued restraining or seeking to restrain any draw or payment under the Credit; (vii) Applicant's (A) merger or consolidation with any third party unless Applicant is the survivor, (B) division or sale, lease or other conveyance of all or substantially all of its assets or business, or (C) agreement to do any of the foregoing; (viii) the occurrence of a Change in Control. As used herein, "Change of Control" means (A) a "Change of Control" as defined in any outstanding loan or credit agreement between Applicant and SVB, or (B) if there is no such agreement, (1) if Applicant is a publicly held Person, that (x) any Person or two or more Persons acting in concert shall have acquired beneficial ownership (within the meaning of Rule 13d-3 under the United States Securities Exchange Act of 1934), directly or indirectly, of voting stock of Applicant (or other securities convertible into or exchangeable for such voting stock) representing 25% or more of

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the combined voting power of all voting stock of Applicant (on a fully diluted basis), (y) during any period of up to 24 consecutive months, commencing on or after the date of this Agreement, a majority of the members of the board of directors of Applicant shall not be continuing directors, or (z) any Person or two or more Persons acting in concert shall have acquired, by contract or otherwise, or shall have entered into a contract or arrangement that upon consummation will result in its or their acquisition of power to exercise, directly or indirectly, a controlling influence over the management or policies of Applicant; and (2) if Applicant is not an individual or a publicly held Person, (x) a sale (whether of stock or other assets), merger or other transaction involving Applicant shall have occurred (whether in one transaction or a series of related transactions), as a result of which those Persons who held 100% of the voting stock of Applicant immediately prior thereto do not hold (either directly or indirectly) more than 50% of the voting stock of Applicant (or the surviving or resulting entity thereof) after giving effect thereto, or (y) a division or sale of all or substantially all of the assets of Applicant shall have occurred (whether in one transaction or a series of related transactions); or (ix) Applicant's repudiation of, or assertion of the unenforceability of any provision of, this Application and Agreement or any separate security agreement or other agreement or undertaking supporting this Application and Agreement, or any court or other governmental authority shall issue any order, ruling or determination that this Application and Agreement or such other agreement or undertaking is not in full force and effect. Upon the occurrence of an Event of Default, unless SVB shall otherwise elect, any and all obligations and liabilities of Applicant to SVB, whether absolute or contingent (including the obligation to reimburse past or future drawings under the Credit), shall become due and payable without notice or demand and SVB may exercise all rights, powers and remedies available to it, at law, in equity or otherwise. In addition, if Applicant's obligations hereunder are not fully secured by cash deposited with SVB, then, upon the occurrence of an Event of Default, Applicant will deposit with SVB, as cash security for Applicant's obligations hereunder, an amount equal to the undrawn amount of the Credit, Applicant hereby being automatically deemed to have granted to SVB a first priority perfected security interest in such cash and to have irrevocably authorized SVB to debit such cash on account of any future drawings. All rights and remedies of SVB and all obligations of Applicant under or in connection with this Application and Agreement and any other documents delivered in connection herewith are cumulative and in addition to those provided or available at equity, by law or under any other agreement.

11. Applicant understands that the final form of the Credit may vary from the wording specified in the Application, and Applicant authorizes SVB to make such changes not materially inconsistent with the Application as SVB deems necessary or appropriate. If Applicant includes in the Application any language describing events or conditions that would not be possible for SVB to verify solely from the documents required to be presented under the Credit, Applicant acknowledges and agrees that SVB has no obligation to verify compliance with such requirements or conditions. Applicant acknowledges and agrees that (i) SVB and its affiliates offer a wide range of financial and related services, which may at any time include back-office processing services on behalf of financial institutions, letter of credit beneficiaries, and other customers; (ii) some of these customers may be Applicant's counter-parties or competitors; and (iii) SVB and its affiliates may perform more than one role in relation to the Credit.

12. (a) This Application and Agreement and all other agreements and instruments required by SVB in connection herewith shall be governed by, subject to and construed in accordance with (i) the law governing any outstanding loan or credit agreement between Applicant and SVB, or (ii) if there is no such agreement, the internal laws of the State of New York applicable to contracts made and to be performed in such State (including New York General Obligations Law Section 5-1401) and applicable federal laws of the United States of America. The Credit and the rights and duties of SVB thereunder and the obligations of Applicant with respect thereto shall, unless the Credit otherwise expressly so provides, be subject to the International Standby Practices 1998, International Chamber of Commerce Publication No. 590 – ISP98 (or such later revision thereof as may be published by the Institute of International Banking Law & Practice), and any rights and remedies granted to SVB therein shall be in addition to, and not in limitation of, those expressly provided herein. If the law of a state or country other than the State of New York has expressly been chosen to govern the Credit, Applicant shall be obligated to reimburse SVB for payments made under the Credit if such payment is justified under New York law or such other law.

(b) Applicant and SVB each submit to the exclusive jurisdiction of (i) the jurisdiction submitted to under any outstanding loan or credit agreement between Applicant and SVB, or (ii) if there is no such agreement, the State and Federal courts in the State of New York.

(c) This Application and Agreement shall be binding upon Applicant and its successors and assigns when executed and delivered by Applicant, and shall inure to the benefit of and be enforceable by SVB and its successors and assigns. Applicant shall not transfer or otherwise assign any of its rights or obligations under this Application and Agreement without SVB's prior written consent. SVB may transfer or otherwise assign its rights and obligations under this Application and Agreement, in whole or in part, without the consent of Applicant. SVB may grant participations in its rights and obligations under this Application and Agreement or the Credit, in whole or in part, without the consent of Applicant; provided that (i) SVB's obligations under this Application and Agreement shall remain unchanged, (ii) SVB shall remain solely responsible to Applicant for the performance of such obligations and (iii) Applicant shall continue to deal solely and directly with SVB in connection with SVB's rights and obligations under this Application and Agreement. Applicant acknowledges that information pertaining to Applicant as it relates to this Application and Agreement or the Credit may be disclosed to actual or prospective participants, transferees or assignees.

(d) None of the terms of this Application and Agreement may be waived, terminated or amended orally, by course of dealing, or otherwise, except in a writing signed by the party against whose interest the term is waived, terminated or amended; provided that the signature of Applicant shall also be binding upon each of its affiliates that at any time is bound by any of the provisions of this Application and Agreement. Forbearance, failure or delay by SVB in the exercise of a right or remedy shall not constitute a waiver, nor shall any exercise or partial exercise of any right or remedy preclude any further exercise of that or any other right or remedy. Any waiver or consent by SVB shall be effective only in the specific instance and for the specific purpose for which it is given.

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(e) This Application and Agreement constitutes the entire agreement between the parties hereto concerning the subject matter hereof and supersedes all prior or simultaneous agreements, written or oral, with respect to the subject matter hereof.

13. Applicant agrees that SVB may issue or amend the Credit or otherwise act on instructions received by facsimile transmission (a "Faxed Application") or scanned image transmitted by email (a "Scanned Application"). Applicant accepts all risks that any Faxed Application or Scanned Application is not genuine, accurate or authorized.

14. TO THE EXTENT PERMITTED BY LAW, APPLICANT AND SVB EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF THE CREDIT, THIS APPLICATION AND AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO OR RELY UPON THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' CHOICE OF LAW, SUBMISSION TO JURISDICTION OR AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable under the laws of the State of California (as finally determined by a court of competent jurisdiction in such State), the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery, which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge in such jurisdiction. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

15. The Applicant named on the face page of this Application and Agreement has the sole right to give instructions and make agreements and amendments with respect to this Application and Agreement and the Credit; provided that if Applicant and Account Party are designated as jointly and severally obligated hereunder, (i) such Applicant irrevocably agrees that Account Party has the sole right to give instructions and make agreements and amendments with respect to this Application and Agreement and the Credit and that such Applicant shall automatically be deemed to be in accord therewith and bound thereby and (ii) each Applicant and Account Party agrees that its obligations hereunder are primary, waives all discharge defenses available to a secondary obligor, and forgoes negotiation of a separate guaranty and security agreement providing for secondary liability to SVB.

16. Applicant and any other party hereto may execute this Application by electronic means and each party hereto recognizes and accepts the use of electronic signatures and records by any other party hereto in connection with the execution and storage hereof. Any references herein to "written" or "in writing" shall be deemed to include all modes of representing or reproducing words in visible form, including in the form of an "Electronic Record" as such term is defined in the Electronic Transactions Law (2003 Revision) of the Cayman Islands (the "Cayman Islands Electronic Transactions Law"). Any requirements herein as to delivery of any document include delivery in the form of an Electronic Record. Any requirements as to execution or signature can be satisfied in the form of an "Electronic Signature" as such term is defined in the Cayman Islands Electronic Transactions Law; provided, however, that Section 8 and 19(3) of such law shall not apply.

17. U.S. Federal laws require all financial institutions to obtain, verify and record information that identifies each Person who opens an account. Issuing the Credit is considered to be opening an account and will require compliance with these Federal laws. Applicant hereby acknowledges and agrees that it shall promptly submit documentation acceptable to SVB that complies with Customer Due Diligence Requirements for Financial Institutions (31 CFR 1010, 1020, 1023, 1024 and 1026) (the "CDD Attestation"), and provide SVB with prompt written notice of any changes to the information set out in the CDD Attestation. Applicant understands and acknowledges that SVB relies on such true, accurate and up-to-date beneficial ownership information to meet SVB's regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers. Applicant further agrees to provide SVB with any other documents requested by SVB if deemed necessary by SVB to enable SVB to comply with applicable law, including the Patriot Act, the Bank Secrecy Act and the rules and regulations promulgated thereunder.

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4N

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☐ Nevada ☒ Out-of-State
Is your facility a reverse distributor?	☐ Yes ☒ No

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 _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Agile Therapeutics, Inc.

Physical Address: 500 College Road East, Suite 310

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): 500 College Road East, Suite 310

City: Princeton State: NJ Zip: 08540-1941

Telephone: 609-683-1880 Website: https://agiletherapeutics.com/

Name of Designated Representative (DR): Robert Conway

Licensing Company Email: licensing@agiletherapeutics.com DR Email: licensing@agiletherapeutics.com

Entities the Wholesaler will Serve	**Products to be Furnished 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)?		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

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 the top four suppliers your company has been doing business with for products or 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: DE

Parent Company (if any): N/A

Corporation Name: Agile Therapeutics, Inc.

Mailing Address: 500 College Road East, Suite 310

City: Princeton State: NJ Zip: 08540-1941

Telephone: 609-683-1880 Email: licensing@agiletherapeutics.com

Contact Person Name: Alfred Altomari

Date of SEC Registration: 5/22/2014 | SEC Registration Number: CIK: 0001261249 | Stock Exchange Symbol: AGRX

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: _____

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Alfred Altomari

Print Name of Authorized Person Submitting Application

Alfred Altomari

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

12-17-21

Date

Board Use Only	Date Received: _____	Amount: 500 check # 15040 ✓ 1/26/22

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0745700

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:

101 POOR FARM RD PRINCETON, NJ 08540-
500 COLLEGE ROAD EAST, STE 310 PRINCETON,NJ 08540-

Reg. No.
5005304

AGILE THERAPEUTICS
101 POOR FARM RD
PRINCETON, NJ 08540-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2023

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 1/3/2022

Registration Number: 5005304 **Registered as:** Manufacturer and Wholesale

Name: AGILE THERAPEUTICS

DBA:

Address: 101 POOR FARM RD, PRINCETON, NJ 08540

Original Issue Date: 10/17/2017 **Expiration Date:** 01/31/2023

Current Issue Date: 12/17/2021

Disciplines: No

Additional Registered Addresses:
500 COLLEGE ROAD EAST, STE 310 , PRINCETON, NJ 08540

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AGILE THERAPEUTICS, 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 FIFTH DAY OF OCTOBER, A.D. 2021.

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

2829324 8300

SR# 20213428882

Authentication: 204328013

Date: 10-05-21

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

Ownership

Agile Therapeutics, Inc. is publicly traded on the NASDAQ stock market under the symbol "AGRX".

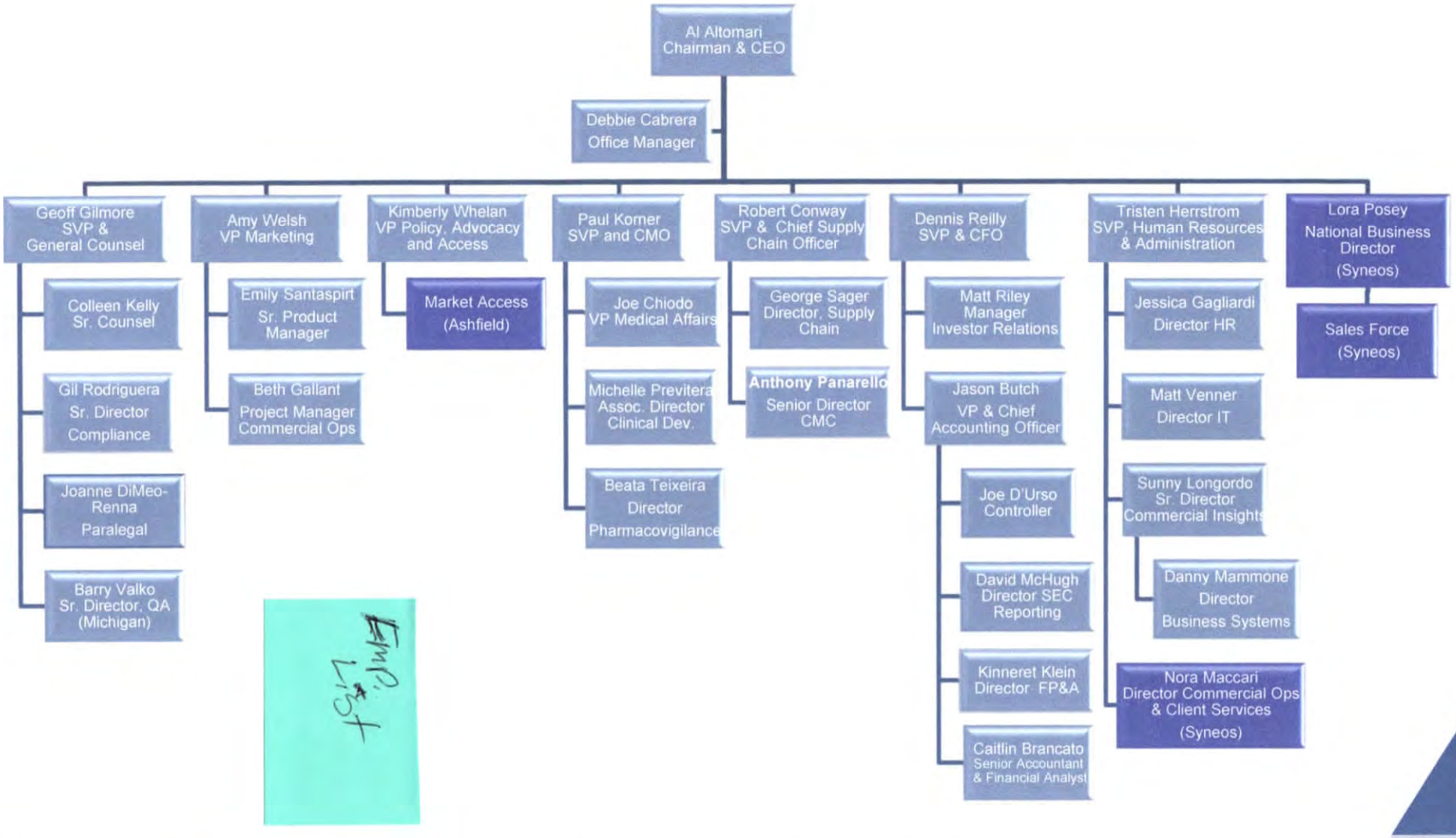
Company Info

Agile Therapeutics, Inc.
500 College Road East, Suite 310
Princeton, NJ 08540
(609) 683-1880

FEIN: 23-2936302

Corporate Officers

Alfred F. Altomari, Chairman and CEO 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: .33%	**Geoffrey Gilmore, Senior Vice President and General Counsel** 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: .08%
Dennis P. Reilly, SVP and Chief Financial Officer 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: .09%	**Robert Conway, SVP and Chief Supply Chain Officer** 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: .01%
Jason H. Butch, Chief Accounting Officer 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: N/A	**Paul Korner, Chief Medical Officer** 500 College Road East, Suite 310 Princeton, NJ 08540 (609) 683-1880 Ownership: N/A



Confidential – for internal planning and discussion purposes only. Do not distribute further.

Agile THER

Description of Operations

Agile Therapeutics, Inc. is a "virtual manufacturer of prescription drugs. Agile is a publicly traded company on the NASDAQ stock exchange under the symbol AGRX. Agile's products are manufactured by a contract manufacturer. Agile's products will be distributed by their third-party logistics provider, Cardinal Health "SPS," who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer
Corium International, Inc.
4558 50th St.
Grand Rapids, MI 49512
FDA Establishment No. 3003693105

Corium manufactures Agile Therapeutics, Inc. product and packages finished product. At no time does Corium own the product, contract with Agile Therapeutics, Inc. customers, invoice, nor sell an Agile Therapeutics, Inc. product.

Third Party Logistics Provider
501 Mason Road, Suite 200
La Vergne, TN 37086.
(615) 793-4400

Agile utilizes Cardinal "SPS" as the Third-Party Logistics provider to manage the storage and distribution of Agile Therapeutics, Inc. products.

Description of Facility

Agile Therapeutics, Inc. does not handle, store or ship commercial product from its headquarters in Princeton, NJ (it is used exclusively for office space). Agile Therapeutics, Inc. uses Cardinal "SPS" as its Third-Party Logistics provider to manage the storage and distribution of our products.

Our hours of operation are 8:00 a.m. – 5:00 p.m. EST, Monday through Friday.

National Drug Code Directory

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through November 11, 2021

You have searched Finished drug products

Search Results: *'71671'*

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
Twirla	71671-100-01	2.6 mg/1, 2.3 mg/1	PATCH	TRANSDERMAL	NDA204017	Agile Therapeutics, Inc.	71671-100	levonorgestrel/ethinyl estradiol	LEVONORGESTREL; ETHINYL ESTRADIOL	HUMAN PRESCRIPTIOI DRUG
Twirla	71671-100-03	2.6 mg/1, 2.3 mg/1	PATCH	TRANSDERMAL	NDA204017	Agile Therapeutics, Inc.	71671-100	levonorgestrel/ethinyl estradiol	LEVONORGESTREL; ETHINYL ESTRADIOL	HUMAN PRESCRIPTIOI DRUG

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

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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**

For the year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

101 Poor Farm Road
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

(609) 683-1880
(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 exchange on which registered:**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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 shorter 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 emerging growth company. See 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. ☐

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2020 was approximately $196.8 million.

As of February 24, 2021, there were 87,628,904 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2020, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

Agile Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2020

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "designed," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, the development of our other potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our potential product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report on Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our ability to successfully commercialize Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, third-party payors and others in the healthcare community;
- our ability to obtain adequate coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- the size and growth of the markets for Twirla and our product candidates and our ability to serve those markets;
- the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as the effects of the COVID-19 pandemic on our potential customer base;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla and our potential product candidates or other materials required for a clinical trial or other tests and studies;
- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;
- the performance and financial condition of Corium or any of the suppliers;
- our ability to design and successfully complete a post-marketing long-term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and conduct a small post-marketing commitment, or PMC, study to assess the residual drug content of Twirla after use;
- our ability to maintain regulatory approval of Twirla and our ability to obtain regulatory approval of our potential product candidates, and the labeling under any approval we obtain;
- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;
- the success and timing of our clinical trials or other studies, including post-marketing studies for Twirla;
- our plans to develop our other potential product candidates;
- development of unexpected safety or efficacy concerns related to Twirla;
- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;
- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and
- our ability to successfully implement our strategy.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties, including those described in Item 1A *"Risk Factors."* These risks include, but are not limited to, the following:

- We are significantly dependent on the commercial success of Twirla, our only approved product. If we are unable to successfully commercialize Twirla, our business, financial condition, results of operations, and prospects and value of our common stock will be materially adversely affected;
- It will be difficult for us to profitably sell Twirla if third-party coverage and reimbursement for such product is limited, and reimbursement and healthcare containment initiatives and treatment guidelines may constrain our future revenues;
- If we are unable to develop effective marketing and sales capabilities for Twirla or maintain our agreements with third parties to market and sell Twirla, we may be unable to generate product revenues;
- Twirla could develop unexpected safety, efficacy or quality concerns, which would likely have a material adverse effect on us;

- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- Existing and future legislation may increase the difficulty and cost for us to commercialize Twirla and may affect the prices we may obtain;
- We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. Management has concluded that these factors raise substantial doubt about our ability to continue as a going concern.
- We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to commercialize Twirla or to complete the development and commercialization of our other potential product candidates;
- We remain subject to substantial ongoing regulatory requirements related to Twirla, and failure to comply with these requirements could lead to penalties, including withdrawal from the market, suspension, or withdrawal of product approval;
- We have no manufacturing capacity and anticipate continued reliance on Corium, our third party manufacturer, for the commercialization of Twirla and development of our potential product candidates. We may not have or be able to obtain sufficient quantities of Twirla or our potential product candidates to meet our required supply for commercialization or clinical trials, which would could materially harm our business;
- We rely on third parties to conduct aspects of our clinical trials and post marketing studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, we may not be able to maintain regulatory approval for Twirla or be delayed in obtaining or ultimately not be able to obtain marketing approval for our potential product candidates;
- We may not be able to protect our proprietary technology in the marketplace;
- We may infringe the intellectual property rights of others, which may prevent or delay our commercialization and product development efforts or increase the costs of commercializing Twirla or our potential product candidates, when and if approved;
- If we fail to develop and commercialize our current pipeline of additional potential product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited or never achieved;
- In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth;
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla or our potential product candidates, if approved; and
- We expect that our stock price may fluctuate significantly.

Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, any such inaccuracy may be material. In light of the significant uncertainties in these forward-looking

statements, you should not regard any of these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Twirla® is one of our trademarks used in this Form 10-K. This Form 10-K also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Item 1. Business

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We have remained steadfast in our commitment to innovate in women's healthcare where there continues to be unmet needs – not only in contraception – but also in other meaningful women's health therapeutic areas.

Our first product, Twirla, which was approved in February 2020 and launched in early December 2020, is a once-weekly prescription combination hormonal contraceptive patch. It delivers a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs, and lower than the estrogen dose found in other marketed contraceptive patches. We believe there is a market need for a contraceptive patch that is designed to deliver approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient dosage form that may support compliance in a noninvasive fashion. Twirla leverages our proprietary transdermal patch technology called Skinfusion®. Skinfusion is designed to allow drug delivery through the skin while optimizing patch adhesion and patient comfort and wearability, which may help support compliance.

With the approval of Twirla we are now focused on our advancement as a commercial company. During 2021, we plan to continue implementing our commercialization plan for Twirla, with the goal of becoming a contraceptive market leader, and ultimately, pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women's health.

Our Strategy

Our near-term goal is to establish an initial franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. To that end, we completed the validation of the commercial manufacturing process for Twirla in accordance with our approved marketing application in the fourth quarter of 2020 and commenced shipment of product to wholesalers in early December 2020. During 2020, we also continued efforts to build out our commercial organization with a number of key hires and new contractual relationships. We entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, which we refer to as Syneos Selling Solutions, to provide a contract sales force and related sales services for Twirla. In the third quarter of 2020, we hired and trained an initial sales team of 73 persons who are engaging with health care providers on Twirla through both in-person and virtual meetings. In April 2020, we entered into a commercial supply agreement with Corium for the manufacture and supply of Twirla, which replaced our former

development agreement. We hired a Chief Medical Officer in August 2020, who is leading an evaluation of our existing pipeline including potential development costs and timelines. We also expect to explore possible expansion through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collabortive arrangements.

Our current priorities are as follows:

- Continue to implement our commercialization plans for Twirla to ensure a successful launch in the United States, including maintaining a sales and marketing team and implementing a healthcare compliance program;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Expand access to Twirla through multiple business channels including third-party payor contracts, retail and specialty pharmacies, telemedicine and government contracting;
- Maintain and manage the supply chain for Twirla to support commercialization of Twirla across the United States;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Complete and submit the proposed protocols for the two FDA-required post-marketing commitment studies.

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and/or could adversely affect our commercialization plans and results. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on us. While to date we have been able to continue to execute our overall business plan, some of our business activities have been slowed and taken longer to complete and we continue to adjust to the challenges of operating in a largely remote setting with our employees. We have only recently launched our commercial activities for Twirla and begun engaging with healthcare providers to promote Twirla. We expect that as we broaden our sales detailing activities in some instances our sales force may encounter challenges engaging with healthcare providers during this on-going pandemic. Overall, we recognize the challenges of launching in a pandemic, will continue to closely monitor events as they develop and plan for alternative and mitigating measures that we can implement if needed.

Twirla

Twirla is our first and only approved product. Twirla received FDA approval on February 14, 2020 as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the reduced efficacy seen with increasing BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs. Twirla's label also includes the class-wide boxed warning, contraindications, and warnings and precautions applicable to all combined hormonal contraceptives, or CHCs.

Twirla is a prescription combined hormonal contraceptive patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, both of which have an established history of efficacy and safety in currently marketed combination oral contraceptives. Twirla delivers approximately 30 micrograms of EE per day, a dose of EE consistent with the dose delivered by many commonly prescribed oral contraceptives. Twirla is the only contraceptive patch that contains LNG, a widely prescribed progestin.

Our Skinfusion technology allows Twirla to be the first approved patch capable of delivering a contraceptive dose of LNG across the skin. The patch is applied once weekly for three weeks, followed by a week without a patch. Twirla is packaged with three individually wrapped patches per carton to provide for one 28-day cycle of therapy.

Twirla's approval is primarily based on safety and efficacy data from the Phase 3 SECURE trial. The SECURE trial was a new approach to clinical trials, and was intentionally designed to include broad enrollment criteria and a patient population of women likely to use hormonal contraceptives. In this purposefully inclusive trial, efficacy and safety were evaluated in a diverse study population, one that is more representative of the demographics of women across the US likely to use hormonal contraception.

The SECURE trial was a multi-center, single-arm, open-label, 13-cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2,031 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The trial was designed in consultation with the FDA, and incorporated a number of stringent trial design elements, including exclusion of treatment cycles not only for use of backup contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on body mass index, or BMI, or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups. These entry criteria resulted in the inclusion of a substantial number of women with high BMIs, who have frequently been underrepresented in prior contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent-to-treat population of subjects 35 years of age and under. The FDA also requested the inclusion of prespecified efficacy analyses related to BMI and body weight.

As part of Twirla's approval, and consistent with requirements for another recently approved CHC, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla in a minimum of 25 women. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance entitled *Transdermal and Topical Delivery Systems—Product Development and Quality Considerations.*

Contraceptive Landscape and Market Opportunity

U.S. Hormonal Contraceptive Market Background

Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Examples of non-hormonal products available in the United States include the diaphragm, male condom, female condom, and non-hormonal intrauterine device, or IUD. Hormonal contraceptives containing both estrogen and a progestin are referred to as CHCs, and contraceptives containing only progestin are referred to as P-only. There are several categories of hormonal contraception products available in the United States, including:

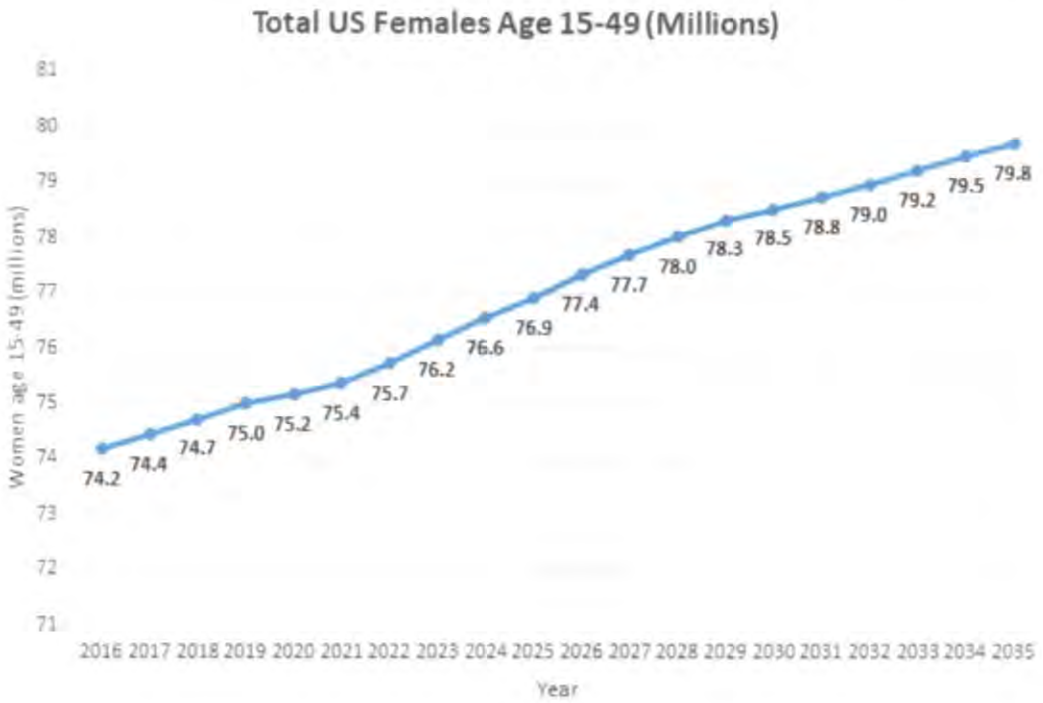
- oral contraceptive;
- vaginal ring;
- transdermal patch;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

The U.S. hormonal contraceptive market is a multi-billion-dollar market. Data from 2017 to 2019 from the Centers for Disease Control, or CDC, indicate that approximately 28% of women aged 15 to 49 use some form of hormonal contraception, which amounts to approximately 20 million U.S. women. The CHC portion of the market, which includes pills, two transdermal patches, including Twirla, and two vaginal rings, generates significantly greater prescription volume and sales compared to the P-only portion of the market, consisting of hormonal IUDs, injectables, implants, and P-only pills.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. For the past 5 years, sales revenue in the CHC market has been essentially flat, at approximately $4 billion per year; with a drop in 2020 sales to $3.7 billion, largely due to the introduction of generics to Nuvaring, which was the market leader in 2019. Total prescription volume, or TRx, declined from 2016 to 2020 by 27%, from 90 million to 65 million; however the number of cycles dispensed (1 cycle = 1 month supply) declined by only 6% over the same time period, as the average TRx size (cycles/TRx) grew from 1.4 to 1.8 over the same time period. Therefore, the value of a TRx has grown significantly over the past 5 years, particularly for branded products, where the average revenue per TRx nearly doubled from $144.48 in 2016 to $277.81 in 2020.

Despite the availability of generic contraceptives for over 30 years, branded products have maintained a significant, though declining, share of CHC sales, with 40% of total sales in 2020. In the five years ended December 2020, the average annual price increase among the top branded products was 8.8%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the top branded products was $131.40 in 2016 and rose to $160.71 by December 2020. The branded CHC transdermal patch (Ortho Evra) was discontinued in October 2014 and the branded generic CHC transdermal patch (Xulane) is currently priced at $122.15 per cycle. We have established a WAC price for Twirla at $159.75. The other non-oral form of CHC, the monthly vaginal ring, is currently priced at $162.63 per cycle for the branded version, Nuvaring, and $138.24 and$148.32 for generic versions. We cannot predict how the manufacturers of branded or generic products will manage prices going forward.

The U.S. contraceptive population (defined by the Centers for Disease Control and Prevention as women aged 15-49) is currently approximately 75 million women and is estimated to grow to nearly 80 million by 2035.



Source: U.S. Census Bureau, 2017 National Dataset (2016 is base population estimate for projections).

Contraceptive Pills

Based on 2017 to 2019 data from the CDC, of women who choose to use a hormonal contraceptive, approximately 55% use a contraceptive pill, vaginal ring or patch, the majority of whom use the contraceptive pill. The remaining 45% of women using hormonal contraception are split between using injectables, implants, or IUDs. Based on this information, we believe that contraceptive pills are the most popular choice because:

- patients and physicians are familiar with pills;
- pills were the first to market and have been aggressively promoted for a long period of time;
- historically, pills have been a covered benefit with good reimbursement in private and public healthcare plans; and
- pills are a non-invasive option.

However, compliance remains a significant draw-back with pills. Published studies have shown that the average woman who uses oral contraceptives misses approximately two to four pills per month, which increases the potential for unintended pregnancies. We believe that a patch can offer greater convenience than a pill, as it does not require daily administration and, for certain women, could lead to greater compliance and ease of use.

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the contraceptive market and achieved a 10% share of the CHC market by September 2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in an addition to the boxed warning that was unique to the Evra label. In 2020, the Xulane label was revised to reflect a contraindication in women with a BMI $\geq$ 30 kg/m^2 because of the reduced efficacy and increased potential risk for VTEs in this population. In making this revision, the information about increased estrogen exposure was removed from the boxed warning but remains in the warnings and precautions and pharmacokinetics sections of the label. The Evra market share declined rapidly following the 2005 labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013, where it stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent (Xulane®) in 2014. In more recent years, the Xulane share of the CHC market TRx has grown, from a 1.7% share in 2016 to a 2.8% share in 2020.

The FDA has maintained, in spite of the wording in the labeling for Evra, which has been discontinued, and its approved branded generic, that none of the epidemiologic studies provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, the generic equivalent of Evra (Xulane) generated sales of $331.5 million in 2020. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a generic version of Ortho Evra.

With its approval on February 14, 2020, Twirla is now the only transdermal contraceptive option currently available to women that delivers a low dose of estrogen. We believe that the rapid uptake and acceptance of Evra upon its introduction and its (and Xulane's) continued sales over the past several years demonstrate a market opportunity for multiple choices in transdermal contraceptive patches.

Twirla Potential Market Share

Three of our market research studies have included an allocation exercise to estimate the potential uptake of Twirla and peak market share. In all of these studies, ObGyns and nurse practitioners, or NPs, indicated their allocation of contraceptive prescriptions before and after reviewing a product profile like Twirla that reflects the safety and efficacy results from our SECURE clinical trial. In the 2010 study, which was conducted prior to the implementation of the ACA, ObGyns estimated use of a product like Twirla in 17% of their CHC patients. A proprietary calibration model developed by the research firm was applied to the peak share estimate, to adjust for physician overstatement, resulting in an estimated peak market share of 9% of the CHC market. In the study completed in December 2016, ObGyns, NPs, and physicians assistants, or PAs, estimated use of Twirla in 22% of their CHC patients, which was also calibrated to adjust for overstatement, resulting in an estimated peak market share of 14% of the CHC market. This estimate was confirmed in our most recent study completed in September of 2019, in which ObGyns and NPs/PAs estimated use of Twirla in 20% of their CHC patients, calibrated to 14% of the CHC market.

We continue to evaluate the commercial opportunity for Twirla. We believe that the potential new CHC users who are within Twirla's approved indication represent a significant population of women. Based on the Company's market research, analysis of the current and expected future U.S. contraceptive market, and review of other product launches in the category, the Company estimates that Twirla can potentially achieve a peak market share of 5-8%. As we pursue the commercialization of Twirla, we will continue to analyze the contraceptive market and update our market research for Twirla.

Twirla Commercialization Strategy

Our top priority is the successful commercialization of Twirla. Promptly after approval by the FDA in February 2020, we began implementation of our plan to market Twirla. During 2020, we validated our commercial manufacturing process, initiated work with managed care and patient payors to gain market access for Twirla, hired and trained an initial sales team through our contract sales partner, Syneos Selling Solutions, entered into distribution agreements with the three largest wholesalers in the United States and commenced commercial shipments of product to wholesalers in December 2020. In 2021, we intend to continue implementation of our commercial strategy for Twirla with a focus on promotional activities and expanding market access through multiple business channels, including third-party payor contracts, retail and specialty pharmacies, telemedicine, and government contracts.

Twirla Promotion Strategy

We have a limited number of sales and marketing employees and primarily rely on third-party agencies with experience in commercializing pharmaceutical products to advance the commercialization of Twirla. Our marketing efforts are initially focused on Obstetrician-gynecologists in the United States, and we plan to use a significant number of samples in the early stage of commercial launch to gain patient trial and acceptance. We believe that we can deploy a focused sales force effort targeting the ObGyn, NP and PA prescribers who are responsible for approximately 70% of branded CHC prescriptions. In areas of the country where it is not efficient to deploy a sales representative, and/or depending on the evolution of the COVID-19 pandemic, remote promotion can be used to reach prescribers. We plan to complement these efforts by expanding the channels we utilize to drive awareness of Twirla during the pandemic and will focus on promotion with key prescribers and customers groups, including consumers and commercial managed care plans.

We plan to use both branded and unbranded campaigns to create awareness of Twirla and available contraceptive options among consumers. We believe there are cost-effective means to reach our target demographic of females ages 18 to 34 years, who tend to engage in online activities to a high degree and are more likely to seek health information online and through social networks. Traditional mass-market direct-to-consumer advertising on television may not be required to reach these consumers. Marketing tactics aimed at today's female consumer need to be optimized for mobile technology because smartphones and text messaging are the preferred means of communication. We believe that a focused consumer promotion plan that uses digital media, potential social media advertising, and other mass-market advertising vehicles will generate consumer awareness and demand for Twirla. In the third quarter of 2020, we launched our unbranded educational awareness campaign, entitled *I'm So Done*. We rolled out our branded campaign in early 2021.

Twirla Coverage and Reimbursement Strategy

After approval of Twirla by the FDA, we began meeting with formulary decision makers as appropriate to secure positions for Twirla that minimize access barriers for prescribers and patients, and since then we estimate that we have been able to achieve formulary access for approximately forty to forty-five percent (40-45%) of the estimated covered lives by commercial third-party payors. Third-party payors are increasingly challenging the prices charged for pharmaceutical products. The United States government and other third-party payors are increasingly limiting both coverage and level of reimbursement for new drugs, in addition to questioning their safety and efficacy. In this challenging environment, we plan to continue our efforts to expand formulary access to Twirla during 2021 through contracting strategies and engaging with formulary boards on the clinical profile of Twirla. We believe that it is important in this category for women to have equal access to all methods, dosing regimens and hormonal options so that they and their provider can select the choice that is the most appropriate to meet their lifestyle and family planning goals.

Our Pipeline: Twirla Line Extensions and Potential Product Candidates

Twirla is our first and only approved product, and, to date, substantially all of our resources have been committed to obtaining approval of Twirla and initiating our commercialization of Twirla. While seeking approval of Twirla and preparing for commercial launch, we halted all work on our pipeline. We have initiated a full evaluation of our pipeline to establish a plan to advance the development of Twirla line extensions and other potential product candidates.

Our potential product pipeline consists of two types of product candidates: Twirla line extensions and other transdermal contraceptive product candidates. These potential product candidates are designed to address market needs and offer additional non-daily contraceptive options. Prior market research conducted in December 2016 indicated our potential line extension product candidates may be commercially viable and could garner a share of the contraceptive market. We have conducted an Advisory Board meeting with contraceptive experts and initiated a new market research program to update our previous insights and to advise on the pipeline programs.

The hormonal contraceptive market has a long history of manufacturers successfully using line extensions to extend the lifecycle of a brand, often by gaining additional exclusivity periods for the product extension under the provisions of the Hatch-Waxman Act and/or with additional patents. Our lifecycle strategy with Twirla is to introduce line extensions that will have exclusivity for some time period, either due to our intellectual property estate, or due to Hatch-Waxman exclusivity. The line extensions in our pipeline include using our Skinfusion technology to allow a 28-day regimen where women will experience shorter, lighter withdrawal bleeding, as well as extending the cycle beyond the typical 28-day regimen to allow women to experience fewer withdrawal bleeds each year. In addition, the potential line extension product candidates in our pipeline will utilize a unique aspect in the regimen, where a smaller patch, or SmP, that delivers a lower dose of both EE and LNG will be worn during the final seven days of each cycle, rather than having a patch-free week, to allow for withdrawal bleeding while minimizing hormonal fluctuations and potentially the side effects that accompany changes in hormone levels. These regimens are protected by patents issued to us in 2015.

Our potential Twirla line extensions include the following:

- AG200-15 Extended Regimen (ER) is an 84-day extended cycle regimen utilizing our approved Twirla TDS product designed to allow a woman to have four (4) episodes of withdrawal bleeding per year. There are several currently approved oral contraceptives that provide an 84- or 91-day extended cycle regimen, and in 2020, these products totaled 5% of CHC cycles dispensed. However, there is no approved contraceptive patch product offering an extended cycle regimen. AG200-15ER is designed to address the limitations of the currently approved oral contraceptive extended regimens by providing a more convenient, weekly TDS dosing schedule. We are currently evaluating the required development plan required for FDA approval of this regimen.

- AG200-15 SmP is a 28-day regimen designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy. AG200-15 SmP may also provide benefit in patients with sensitivity to abrupt changes in hormone levels. 28-day regimen CHCs that use a shortened hormone-free interval, or SHFI, by delivering hormones beyond the traditional 21 days comprised 16% of CHC-TRx volume and 43% of CHC sales in 2020, demonstrating high acceptability among patients and providers. AG200-15 SmP is designed to provide a simplified 28-day regimen through use of the same drug product as Twirla for the first three weeks of the cycle, and a smaller lower-dose patch, or SmP, in the fourth week, which will allow patients to continuously apply patches without interruption. AG200-15 SmP requires additional patch formulation development work on the SmP prior to potentially conducting a pharmacokinetic study.

- AG200-15 ER SmP is a 91-day extended cycle regimen utilizing our approved Twirla TDS and the SmP that is designed to allow a woman to have four (4) shorter, lighter withdrawal bleeding episodes per year. By extending the length of the contraceptive cycle, AG200-15 ER SmP is designed to potentially minimize breakthrough bleeding and spotting, which are commonly reported events with patients using an extended regimen contraceptive product. AG200-15 ER SmP utilizes the approved Twirla TDS during the 12-week (84-day) active phase of the cycle and the SmP during week 13 of the cycle. AG200-15 ER SmP requires additional patch formulation development work on the SmP prior to potentially conducting a pharmacokinetic study.

Our other potential product candidate is a progestin-only (P-only) contraceptive patch described below:

- AG890 is a P-only contraceptive patch, intended for use by women of reproductive potential to prevent pregnancy. The intended population would be women who are unable or unwilling to take estrogen, including those who are breastfeeding or who are at greater risk of VTE, such as women who smoke, are over 35 years of age, or who are obese. Currently, the P-only market consists of pills and several non-oral options, including IUS/IUDs, implants, and injections. AG890 is intended to fulfill an unmet medical need for a non-daily, easily reversible form of contraception in the P-only target population. Previously, we conducted a Phase 1 clinical trial with AG890 containing LNG. In addition, the National Institutes of Health, through a clinical trial agreement with us, conducted a Phase 1/2 trial with LNG-containing AG890. This Phase 1/2 study was a

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multicenter study to evaluate the pharmacokinetics, safety, and mechanisms of potential contraceptive efficacy of AG890. We are evaluating our analysis of the data from this trial as well as other potential progestins to be utilized for further development. Additional formulation development work for progestin and dose selection is required, along with additional studies to determine the optimal formulation and dose to advance to Phase 3.

We do not expect to be required to conduct preclinical toxicology studies for any of these potential product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we continue to review the clinical path and the budgetary requirements for each of these three potential product candidates.

Competition

The industry for contraceptive products is characterized by intense competition and strong promotion of proprietary products. We face potential competition from many different sources, including large pharmaceutical companies, specialty pharmaceutical and generic drug companies, and medical device companies. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We face competition from a variety of non-permanent birth control products. There are non-hormonal barrier methods, such as the contraceptive sponge, diaphragm, cervical cap or shield and condoms. Then, there are hormonal methods, which is the category for Twirla and our potential product candidates, such as oral contraceptives, injections, implants, hormonal IUDs and vaginal ring and transdermal contraceptive products.

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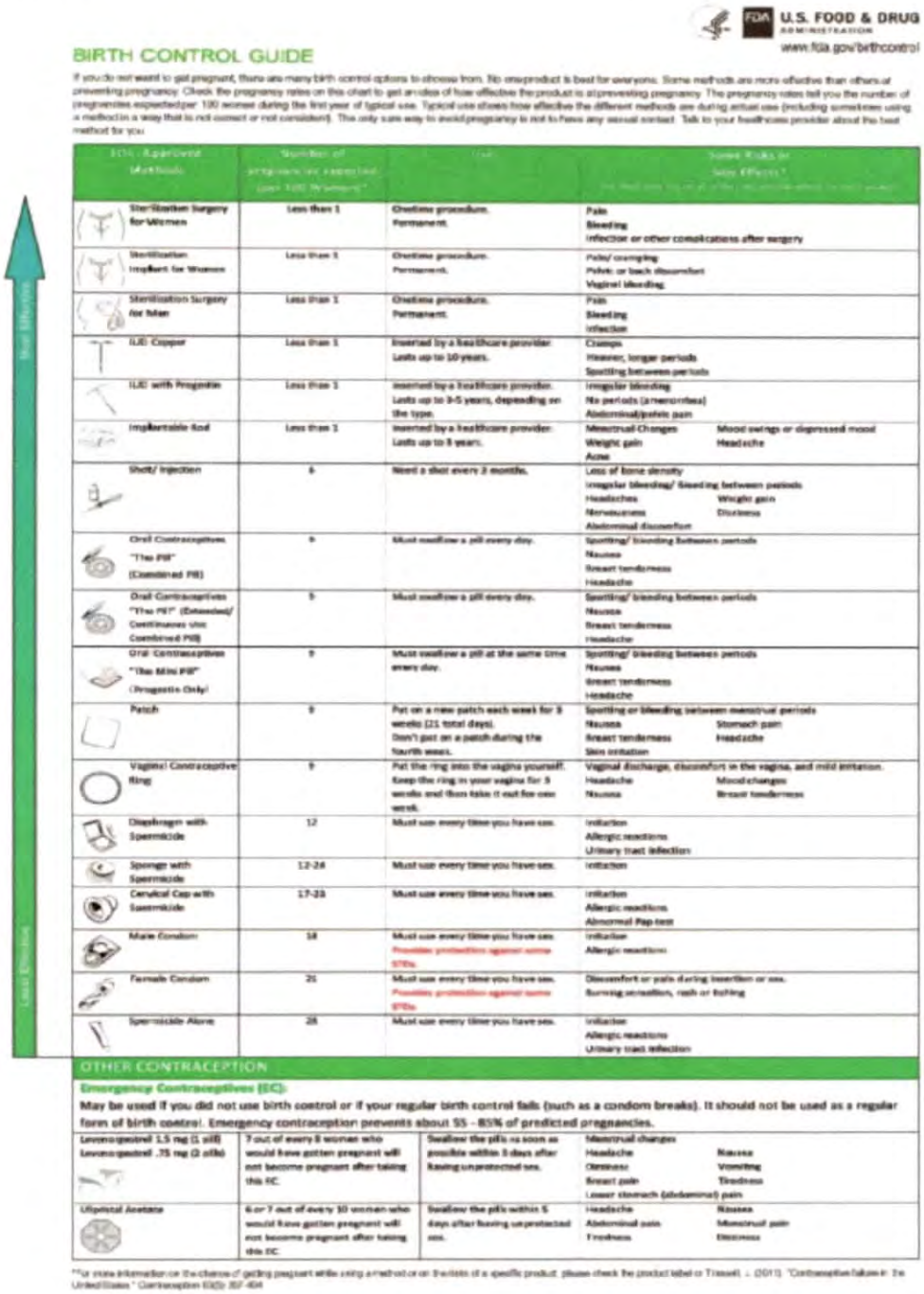
The following table is the FDA Birth Control Chart, which outlines the 18 unique forms of birth control and compares the effectiveness of each method.



U.S. FOOD & DRUG ADMINISTRATION
www.fda.gov/birthcontrol

BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

FDA - Approved Methods	Number of pregnancies expected (per 100 Women)*	How	Some Risks or Side Effects*
Sterilization Surgery for Women	Less than 1	One-time procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	One-time procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	One-time procedure. Permanent.	Pain Bleeding Infection
IUD: Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne Mood swings or depressed mood Headache
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ bleeding between periods Headaches Nervousness Abdominal discomfort Weight gain Dizziness
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Pill" (Extended/ Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea Breast tenderness Skin irritation Stomach pain Headache
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache Nausea Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection

Most Effective

Least Effective

OTHER CONTRACEPTION

Emergency Contraceptives (EC):

May be used if you did not use birth control or if your regular birth control fails (such as a condom breaks). It should not be used as a regular form of birth control. Emergency contraception prevents about 55 - 85% of predicted pregnancies.

Levonorgestrel 1.5 mg (1 pill) Levonorgestrel .75 mg (2 pills)	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills as soon as possible within 3 days after having unprotected sex.	Menstrual changes Headache Dizziness Breast pain Lower stomach (abdominal) pain	Nausea Vomiting Tiredness
Ulipristal Acetate	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills within 5 days after having unprotected sex.	Headache Abdominal pain Tiredness	Nausea Menstrual pain Dizziness

**For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5): 397-404.

Although there are more than 250 CHC products currently available, including brands and generics, just 14 branded products make up approximately 40% of total market revenue. Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The branded products with established market presence include Nuvaring®, marketed by Merck, and Annovera®, marketed by Therapeutics MD, the Loestrin® franchise, marketed by Allergan (formerly known as Actavis), consisting of three oral contraceptives, Minastrin® 24, LoLoestrin® and Taytulla®, and Beyaz®, Yaz®, Yasmin® and Natazia® marketed by Bayer. Xulane, a branded generic to Ortho Evra, generated $331.5 million in sales for Mylan in 2020. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a second generic version of Ortho Evra. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal, Mylan, Aurobindo, Xiromed, and Afaxys. Based on the market experience of other non-oral CHC dosage forms, including Evra and Nuvaring, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are other contraceptive products recently approved or in development that may compete with Twirla and our other potential product candidates. Phexxi®, a prescription non-hormonal vaginal gel approved for use as an on-demand contraceptive, was developed by Evofem and launched in August of 2020. Nextstellis™, a combined oral contraceptive containing drosperinone and a new form of estrogen, estetrol (E4), was developed by Mithra Pharmaceuticals and is licensed to Mayne Pharmaceuticals for marketing in the U.S. and Australia. Mayne has indicated they will recruit a new women's health team in the U.S. and expect to launch Nextstellis in the first half of 2021. The Population Council has a transdermal gel contraceptive and a vaginal ring contraceptive, both containing segesterone acetate (the same progestin contained in Annovera) and ethinyl estradiol in Phase 2 development. Bayer has an IUD containing both LNG and an NSAID (a non-steroidal anti-inflammatory), to reduce pain upon insertion in Phase 2. Bayer also signed a license agreement in January of 2020 with Dare Bioscience for U.S. commercial rights to Ovaprene, a hormone-free monthly contraceptive vaginal ring, which is in Phase 2 development. Allergan has a P-only patch for which they received a CRL from the FDA in 2013.

We are aware of only one other CHC transdermal patch, which is not approved in the U.S. Apleek was developed by Luye Pharma and Bayer, and it was approved in the United Kingdom in 2014. Luye acquired the global rights to Apleek from Bayer AG in August 2018. Apleek contains the active ingredients EE and gestodene, a third-generation progestin. There are no contraceptives containing gestodene approved in the U.S. We believe that if this product were to obtain FDA approval, the approved labeling is likely to contain the same language that products containing third generation progestins contain, which language states that these contraceptives have a two-fold increase in risk of VTE as compared with contraceptives containing second generation progestins.

Manufacturing

We do not own any manufacturing facilities and rely on Corium for all aspects of the manufacturing of Twirla. We, along with Corium, have made a significant investment in a proprietary process to manufacture Twirla. We believe we have developed a robust process to reliably manufacture Twirla on a commercial scale. We believe that the technical challenges and know-how involved in manufacturing, including proprietary chemistry, production to scale and use of custom equipment and reproducibility, present significant barriers to entry for other pharmaceutical companies who might potentially want to replicate our Skinfusion technology.

Strategic Agreements

Agreement with Corium

In April 2020, we entered into a manufacturing and commercialization agreement with Corium, which we refer to as the Corium Agreement, and which replaced our previous development agreement. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement includes a quarterly minimum purchase commitment and a fixed price per unit for two years depending on annual purchase volume.

The Corium Agreement terminates automatically after ten years, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still effect purchase orders after the notice of termination is given and until the time any such termination becomes effective.

Agreement with Syneos Selling Solutions

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee.

The Syneos Agreement terminates automatically on the second anniversary of the date of the first activity undertaken by Syneos Selling Solutions to detail Twirla, referred to as the Deployment Date, unless earlier extended upon the mutual written agreement of both parties. We may terminate the Syneos Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if we terminate the Syneos Agreement prior to the eighteen month anniversary of the Deployment Date, we will be obligated to pay Syneos Selling Solutions a termination fee, the amount of which varies depending on the date of termination.

Pricing and Reimbursement

In the United States, decisions regarding the extent of coverage and the amount of reimbursement to be provided for pharmaceutical products are made on a payor-by-payor basis. The principal decisions about reimbursement for new medicines by the U.S. Government are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services. As a result, coverage determinations are often a time-consuming and costly process that requires companies to provide scientific and clinical support for the use of approved products to multiple stakeholders which may include Group Purchasing Organizations (GPO's), Pharmacy Benefit Managers (PBM's), individual payer health plans, as well as government payors and federal purchasers including CMS, the Veterans Administration, Department of Defense and state Medicaid managed and Fee For Service plans, with no assurance on the level of coverage or that adequate reimbursement will be obtained. Third-party payors are increasingly challenging the prices charged for pharmaceutical products.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws, enforcement policies or administrative determinations with respect to the importation of drugs into the United States from other countries where they may be sold at lower prices.

In the United States, third-party payors include federal health care programs, such as Medicare, Medicaid, TRICARE, and Veterans Health Administration programs; managed care providers, private health insurers and other organizations. Several of the U.S. federal health care programs require that drug manufacturers extend discounts or pay rebates to certain programs in order for their products to be covered and reimbursed. For example, the Medicaid Drug Rebate Program requires pharmaceutical manufacturers of covered outpatient drugs to enter into and have in effect a national rebate agreement with the federal government as a condition for coverage of the manufacturer's covered

outpatient drug(s) by state Medicaid programs. The amount of the rebate for each product is based on a statutory formula and may be subject to an additional discount if certain pricing increases more than inflation. State Medicaid programs and Medicaid managed care plans can seek additional "supplemental" rebates from manufacturers in connection with states' establishment of preferred drug lists. A further requirement for Medicaid coverage is that the manufacturer enter into a Federal Supply Schedule, or FSS, agreement with the Secretary for Veterans Affairs to extend discounted pricing to the VA, DOD and other agencies.

Similarly, in order for a covered outpatient drug to receive federal reimbursement under the Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts on the covered outpatient drug to entities that are enrolled and participating in the 340B drug pricing program, which is a federal program that requires manufacturers to provide discounts to certain statutorily-defined safety-net providers. The 340B discount for each product is calculated based on certain Medicaid Drug Rebate Program metrics that manufacturers are required to report to CMS.

There has been recent negative publicity and increasing legislative and public scrutiny around pharmaceutical drug pricing in the U.S. Moreover, U.S. government authorities and third-party payors are increasingly attempting to limit or regulate drug prices and reimbursement. These dynamics may give rise to heightened attention and potential negative reactions to pricing decisions for Twirla and products for which we may receive regulatory approval in the future, possibly limiting our ability to generate revenue and attain profitability.

The United States government and other third-party payors are increasingly limiting both coverage and level of reimbursement for new drugs, in addition to questioning their safety,efficacy and clinical value. Consolidation among managed care entities has increased the negotiating power of these entities. Third-party payors increasingly use closed formularies, which might not include all of the approved products for a particular indication, to control costs by negotiating discounted prices in exchange for formulary inclusion. Third-party payors have traditionally used differential co-pays to attempt to drive patients to use either generic products or products for which they have a contract with the manufacturer. Typically, a third-party payor's formulary is organized into between three and six tiers. Each tier is then associated with a set range of co-pay amounts or a percent of the drug costs, with products in the lower tiers having a lower co-pay.

Reimbursement for female contraceptive products was changed by the enactment of the the Patient Protection and Affordable Care Act (PPACA), which was signed into law on March 23, 2010 and further updated on March 30,2010 to become the Affordable Care Act (ACA). On January 20, 2012, U.S. Department of Health and Human Services announced a final rule on health insurance coverage that provided for no cost sharing for FDA-approved contraceptives and contraceptive services for women of reproductive age if prescribed by health care providers, as part of women's preventive health services guidelines adopted by the Health Resources and Services Administration (HRSA) for the ACA. The final rule applied to all new health insurance plans in all states beginning August 1, 2012.

In May 2015, several government agencies, including the U.S. Department of Health and Human Services, or HHS, the Department of Labor, or DOL, and the U.S. Department of Treasury, or Treasury, jointly issued a clarification in the form of an FAQ which clarified the requirements for coverage of contraceptives under the ACA. This clarifying guidance went into effect in January 2016. The FAQ states that plans and issuers must cover without cost-sharing at least one form of contraception in each of the 18 current methods that the FDA has identified for women in its current Birth Control Guide. The patch is identified as a specific method in the FDA Birth Control Guide, and therefore insurers must cover at least one patch product with no cost-sharing to the patient. Under the FAQ, health plans are allowed to utilize reasonable medical management techniques within a method to control costs, such as covering a generic at no cost but charging a copay for the equivalent brand. However, if using medical management techniques within a method, plans must have a transparent waiver process where, if a provider determines that a particular FDA-approved item, including contraception, is medically necessary for an individual, then the plan must cover that item without cost sharing. While the FAQ is clear that a waiver process is required, plans have implemented the requirement inconsistently on a national basis.

On January 20, 2017, the Trump administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of

any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others. The Biden administration revoked the Trump administration Executive Order on January 28, 2021. Congress also could consider subsequent legislation to repeal and replace elements of the ACA. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim final rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. In July 2020, the Supreme Court reversed lower court injunctions applicable to these rules, effectively permitting implementation. However, the Biden administration potentially may elect to exercise its authorities under ACA differently from the previous administration, and it is, therefore, difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

Before the ACA was passed, many states had enacted contraceptive equity laws that required plans to treat contraceptives in the same way they covered other services. In addition, since the ACA was passed, a number of states have enacted laws that basically codify in state legislation the ACA benefit rules (requiring all plans regulated by the state to cover, without cost-sharing, each of the 18 FDA-approved contraceptive methods and in some cases have gone further and required coverage of all FDA approved contraceptives). Federal law applies to all plans while state law applies to only individual plans and fully-insured group plans. Currently, 30 states and the District of Columbia require insurance plans to cover contraceptives, with a wide range of coverage and cost-sharing requirements, and exemptions among these mandates. We continue to monitor healthcare reform efforts and agency implementation as well as state contraceptive legislation.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. FDA has also issued many guidance documents which outline its interpretation of its governing laws and regulations. Over the last year, the number of guidance documents has increased, as FDA issued a number of guidances, which are continually evolving, to assist companies navigating the COVID-19 pandemic. The process of obtaining regulatory approvals and subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold or termination, issuance of Warning, Untitled, or Cyber Letters, requests for product recalls, product seizures or detention, total or partial suspension or restriction of production, marketing or distribution, injunctions, fines, debarment, refusal to allow the import or export of product, adverse publicity, modification of promotional materials or labeling, refusals of government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, imprisonment, consent decrees and corporate integrity agreements, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

- Submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;
- Approval by an independent Institutional Review Board, or IRB, for each clinical site before each trial may be initiated;
- Performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with Current Good Clinical Practices, or cGCPs to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with FDA requirements for product manufacturing and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as the potential for completion of an FDA inspection of selected clinical sites to determine cGCP compliance; and
- FDA review and approval of the NDA.

Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB for each clinical trial site participating in the clinical trial must review and approve the plan for any clinical trial before it commences, and the IRB must continue to oversee the clinical trial while it is being conducted, including any changes.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered through controlled studies to a limited subject population with the target disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted diseases or conditions and to determine dosage

tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites, in two adequate and well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product candidate. In the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the applicability of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application. In addition to the above traditional kinds of data required for the approval of an NDA, the 21st Century Cures Act provides for FDA acceptance of additional kinds of data such as such as patient experience data, real world evidence for already approved products, and, for appropriate indications sought through supplemental marketing applications, data summaries.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. We have obtained a waiver from the conduct of a PREA study.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to FDA product manufacturing requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website. Failure to submit the required information to ClinicalTrials.gov can result in monetary penalties. Marketing application applicants must also report certain investigator financial interests to the FDA.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

U.S. Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A user fee for the Twirla contraceptive patch

was submitted with the original NDA. Application resubmissions by the same applicant do not require a new application fee. Under the PDUFA guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA's standard review goal is to act on 90% of all Non-New Molecular Entity applications within ten months of FDA receipt of the application. These time periods may be extended by the FDA should an applicant submit new information to the agency during the course of the FDA's review of the marketing application. The time period is also only a goal and may not be met by the FDA.

The FDA conducts a preliminary review of all original NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be submitted again with the additional information and is also subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held, as well as the manufacturing processes and controls, meet standards designed to ensure the product's continued safety, quality and purity.

The FDA may refer a marketing application to an external advisory committee for questions pertaining to issues such as clinical trial design, safety and efficacy, and public health questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it typically follows such recommendations and considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with the FDA's requirements for product manufacturing and adequate to assure consistent production of the product within required specifications by the manufacturer and all of its subcontractors and contract manufacturers. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with cGCP. Also, as part of its regulatory review, the FDA verifies the data contained in the NDA.

The testing and approval process for a drug product requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of a marketing application on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CRL. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the drug product and may require additional clinical or preclinical testing, or other information in order for the FDA to reconsider the application.

If an application receives a CRL, the applicant may resubmit the application, addressing all of the FDA-cited deficiencies, withdraw the application, or request the opportunity for a hearing. If the applicant resubmits the application, the application is subject to an initial FDA review. Within 30 days of receipt, the FDA will review a resubmission to determine whether it constitutes a complete response that addresses all deficiencies identified in a complete response letter. The agency then issues a letter to the applicant, stating whether the agency agrees that the resubmission is a complete response. If the FDA does not agree that the resubmission is a complete response, the review clock will not start until a complete response is received. If the agency agrees that the resubmission is a complete response, the FDA will classify the resubmission as either Class 1 or 2. The FDA aims to review Class 1 resubmissions within two months of receipt or Class 2 resubmissions within six months of receipt. Class 1 resubmissions are resubmissions of an NDA following a complete response letter that include minor updates or data reanalysis. Class 2 resubmissions include more

complex or extensive updates to the NDA. As with the PDUFA timelines for original submissions, these are also subject to extension if the sponsor submits new information. Resubmitted applications may also be subject to FDA inspection of clinical and manufacturing sites, as well as review by FDA advisory committees. Following its review of a resubmitted NDA, the FDA may issue an approval letter or another CRL.

Even if an applicant resubmits with the required additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product candidate, it may limit the approved indications for use of the product candidate and require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Moreover, the FDA may require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess certain aspects of a drug's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS could materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements, submission of a supplemental application, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of an approved drug product through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies FDA's existing practices into the FDCA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has

expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders within a specified timeframe. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the Paragraph IV certification, the FDA may not make an approval effective until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities, or NCEs, that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against the FDA making an ANDA and 505(b)(2) NDA approval effective for the condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Our NDA for Twirla was submitted under Section 505(b)(2), and we expect that some of our other drug candidates will utilize the Section 505(b)(2) regulatory pathway. Even though several of our drug products utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish the safety and efficacy of those active ingredients in the formulation and dosage forms that we are developing. All approved products, both innovator and generic, are listed in the FDA's Orange Book.

Recently, Congress, the Trump administration, and administrative agencies took certain measures to increase drug competition and thus, decrease drug prices. By example, in 2019, the FDA introduced a proposed rule and in 2020 the FDA finalized guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market based terms to entities developing generic and similar drug products. This bill also included provisions on shared and individual REMS for generic drug products.

Combination Drug/Device Regulation

Twirla and our potential product candidates are considered to be drug-device combination products by the FDA. While our potential product candidates, as a whole, are subject to the NDA approval process, drug-device combination products require compliance with additional FDA regulations. For instance, drug-device combination products must comply with the drug cGMPs, as well as some of the device Quality System Regulations, or QSRs. These dual requirements will require additional effort, FDA reporting, and monetary expenditure to ensure that Twirla and our potential product candidates comply with all applicable regulatory requirements.

U.S. Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to manufacturing recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, reporting of adverse experiences with the product and drug shortages, and compliance with any post-approval requirements imposed as a condition of approval, such as Phase 4 clinical trials, REMS and surveillance to assess safety and efficacy after commercialization. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also continuing, annual prescription drug program user fee requirements for any approved products. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and list drugs manufactured at their facilities with the FDA. Recently, the information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security, or CARES, Act to include the volume of drugs produced during the prior year.

Drug sponsors and manufacturers are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with FDA and state requirements for product manufacturing and other requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from FDA requirements for product manufacturing and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain FDA requirements for product manufacturing compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing, distribution or manufacturing of the product, complete withdrawal of the product from the market or requests for product recalls;
- Fines, or Untitled, Cyber or Warning Letters or holds on or termination of post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties including disgorgement, restitution, fines and imprisonment;

- Consent decrees, corporate integrity agreements or exclusion from federal healthcare programs;
- Debarment;
- Mandated modification of promotional materials and labeling and the issuance of corrective information; or
- The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies and third parties engaged on their behalf to promote their drug products are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment and refusal of government contracts.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and reporting regarding drug samples. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, are required to label drug product with a product identifier and are required to keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Other persons and entities within the drug supply chain are also subject to Drug Quality and Security Act requirements.

FDA's requirements with respect to drug manufacturing, marketing and distribution are continually evolving. FDA and Congress may pass new laws, regulations, and policies, as was done in March 2020 with the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. The CARES Act included various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

U.S. Fraud and Abuse, Data Privacy and Security and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include, among other things, anti-kickback, physician payment transparency and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been interpreted broadly to include anything of value. Additionally, the intent standard under the

Anti-Kickback Statute and criminal healthcare fraud statutes was also amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. On December 2, 2020, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rule, OIG removed safe harbor protections under the Anti-Kickback Statute for rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers and added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Implementation of the this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Claims may be pursued by whistleblowers through qui tam actions, even if the government declines to intervene. Intent to deceive is not necessary to establish civil liability, which may be predicated on reckless disregard for the truth. The federal government continues to use the False Claims Act, and the accompanying threat of significant liability, in investigations against pharmaceutical and health care companies. These investigations have involved, for example, allegations of providing free product to customers with the expectation that the customers would bill federal programs for the free product, as well as the promotion of products for unapproved uses and reporting false pricing information. Potential liability under the federal False Claims Act includes treble damages and significant per claim penalties. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses not expressly approved by the FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. The criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false fictitious or fraudulent. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

The Affordable Care Act authorized the imposition of civil monetary penalties on manufactures participating in the 340B program for failure to charge the statutory ceiling price, and required HHS to promulgate regulations establishing the standards for implementing this Civil Monetary Penalty, or CMP, authority. CMS' final CMP rule went into effect January 1, 2019.

The Affordable Care Act included a provision requiring certain providers and suppliers of items and services to Federal Health Care Programs to report and return overpayments within sixty days after they are "identified" (the "Overpayment Statute"). The law prohibits a recipient of a payment from the government from keeping an overpayment when the government mistakenly pays more than the amount to which the recipient is entitled even if the overpayment is not caused by any conduct of the recipient. In 2014 and 2016, the CMS released regulatory guidance (in the form of final rules) to Medicare providers, suppliers and managed care and prescription drug plans regarding how to comply with the

Overpayment Statute. Although these Medicare providers, suppliers and plans have faced federal False Claims Act liability since 2010 for failures to comply with the Overpayment Statute, these final rules interpreting the Overpayment Statute provide guidance regarding how to comply with applicable obligations, and guidance to government regulators and enforcement authorities regarding monitoring and prosecuting suspected violations. These final rules are not directly applicable to manufacturers, except if a manufacturer is a direct recipient of payment by an agency such as a research grant but may impact their customers and potential customers who are Medicare providers, suppliers, and plans.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information, known as protected health information. Among other things, HITECH makes security standards and certain privacy standards directly applicable to business associates, defined as persons or organizations of covered entities, other than members of the covered entity's workforce, that create, receive, maintain or transmit protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws, such as the California Consumer Privacy Act, may regulate the privacy and security of information that we maintain, many of which may differ from each other in significant ways and may not be preempted by HIPAA. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Other federal and state laws may govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For instance, the California Consumer Privacy Act may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. Other states, such as Virginia, also are enacting state specific privacy laws.

Additionally, federal physician payment transparency laws, including the federal Physician Payment Sunshine Act created under Section 6002 of the ACA and its implementing regulations, require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report annually to the government information related to payments or other "transfers of value" made or distributed to or at the request of covered recipients, such as, but not limited to, physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family.Manufacturers must submit reports by the 90th day of each calendar year. Disclosure of such information is made on a publicly available website.

There are also an increasing number of analogous state laws that regulate price increases, require manufacturers to file reports with states on pricing and marketing information, and to track and report gifts, compensation, other remuneration and items of value provided to healthcare professionals and healthcare entities. Many of these laws contain ambiguities as to what is required in order to comply with such laws. For example, several states have enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs,

file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. These laws may affect our future sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions once we commercialize could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to a variety of penalties, depending upon the law found to have been violated, potentially including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, refusal of government contracts, contract debarment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement Generally

The commercial success of Twirla and our other potential product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate coverage of and reimbursement levels for our potential product candidates. Government authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. In the United States, the E.U. and other potentially significant markets for our potential product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the E.U. will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our potential product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance organizations, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers and other third-party payors.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products, including pharmaceuticals. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Certain third-party payors routinely impose additional requirements before approving reimbursement of a prescription, including prior authorization and the requirement to try another therapy first. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our potential product candidates may not be considered medically necessary or cost-effective.

Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our potential product candidates, exclusion of our potential product candidates from coverage or the requirement for payment of increased manufacturer rebates on units dispensed. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our potential product candidates in whole or in part.

Healthcare Reform

Legislative proposals to reform healthcare or reduce costs under government healthcare programs may result in lower reimbursement for our potential product candidates or exclusion of our potential product candidates from coverage. There have been a number of legislative and regulatory changes to the healthcare system that could affect our ability to profitably sell our potential product candidates, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the former Trump Administration issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, in August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, as amended, will stay in effect through 2030. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our potential product candidates if they are approved.

On January 20, 2017, the then-new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices among others. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. In July 2020, the Supreme Court reversed lower court injunctions

preventing implementation of these rules. Congress also could consider subsequent legislation to repeal and replace elements of the ACA that are repealed. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. The FDA also released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

Foreign Regulation

We currently have no plans to seek approval for Twirla outside of the United States. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $13.5 million, $9.9 million, and $9.8 million for the years ended December 31, 2020, 2019, and 2018, respectively. In 2021, we expect to continue to incur research and development expenses as we evaluate the advancement of our existing pipeline and its possible expansion.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover our Skinfusion® technology, its methods of use, related technologies and other inventions that are important to our business. As more fully described below, our patents and patent applications are directed to our Skinfusion technology or aspects thereof including certain transdermal delivery systems having an active adhesive matrix and methods of using such transdermal delivery systems for controlling fertility. We also rely on manufacturing trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain new patents and maintain existing patents and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our potential product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our potential product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. If we were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We plan to continue to expand our intellectual property estate by filing patent applications directed to novel and nonobvious transdermal contraceptive products. The active pharmaceutical ingredients, or API, in our potential product candidates are generic and therefore our patents do not include claims directed solely to the API. We anticipate seeking additional patent protection in the United States and internationally for additional transdermal delivery systems and their methods of use.

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. Consequently, we do not know whether any of our potential product candidates will remain protected by enforceable and valid patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions generally are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of our entitlement to patent rights in the inventions covered in our issued patents and pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, USPTO, to determine priority of invention, or in post-grant challenge proceedings in the USPTO or foreign patent offices such as oppositions, reexamination, inter-partes review, post grant review, or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

More specifically, Twirla® is a transdermal contraceptive hormone delivery system. The system is a patch for application to the skin and contains two API, the hormones LNG, which is a synthetic progestin, and EE, a synthetic estrogen. The API are formulated with a combination of skin penetration enhancers, which promote penetration through the dermis and into the bloodstream, such that effective blood levels of the active agents are achieved to suppress ovulation and thereby prevent pregnancy. One of our other potential product candidates, AG890, is similar to Twirla, except that it contains only a single API, LNG.

In both our Twirla product candidate line and in AG890, the active adhesive system consists of the active ingredients in a polyacrylate adhesive polymer matrix comprising the permeation enhancers dimethylsulfoxide, ethyl

40

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change ☐ Name Change ☐ Location Change (in-state only)	* If making a change, provide current license number: WH 01807	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: BioCare, Inc. dba BioCareSD

Physical Address: 2826 South Potter Drive

City: Tempe State: Arizona Zip: 85282

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 800-304-3064 Website: https://www.biocaresd.com/

Name of Designated Representative (DR): Mark Steffes

Licensing Company Email: License@BiocareSD.com DR Email: mark.steffes@biocaresd.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.

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: Novo Nordisk, Inc. (NovoSeven RT)
Address: 800 Scudders Mill Road City: Plainsboro State: NJ Zip: 08536

Name: CSL Behring LLC (Kcentra, Humate-P)
Address: 900 Broken Sound Pkwy NW FL 4 City: Boca Raton State: FL Zip: 33487

Name: Baxalta US, Inc. (Advate)
Address: 1200 Lakeside Dr City: Bannockburn State: IL Zip: 60015

Name: Bayer Corporation (Kogenate)
Address: 100 Bayer Rd Building 4 City: Pittsburgh State: PA Zip: 15205

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: Arizona
Parent Company (if any): Bobcat Buyer, Inc.
Corporation Name: BioCare, Inc.
Mailing Address: 2826 South Potter Drive
City: Tempe State: Arizona Zip: 85282
Telephone: 800-304-3064 Email: License@BiocareSD.com
Contact Person Name: Margaret (Peggy) Yena

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 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 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/ Not applicable		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** Not applicable	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K**	✓			
• **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.

Scott Steinman

Print Name of Authorized Person Submitting Application

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

11/29/2021

Date

Board Use Only	Date Received: _____	Amount: $500 check 1119

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: 09/28/2020
Receipt Number: 202091681
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO	EXPIRES
W002886	10/31/2022

Issued to :

BioCare, Inc. dba BioCareSD
Vitalant
2826 S. POTTER DRIVE
TEMPE, AZ 85282

BioCare, Inc. dba BioCareSD
2826 S. POTTER DRIVE
TEMPE, AZ 85282

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 : Vitalant
LICENSE NUMBER : W002886
EXPIRES : 10/31/2022

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.

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

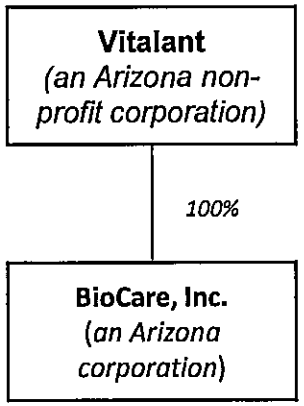
Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

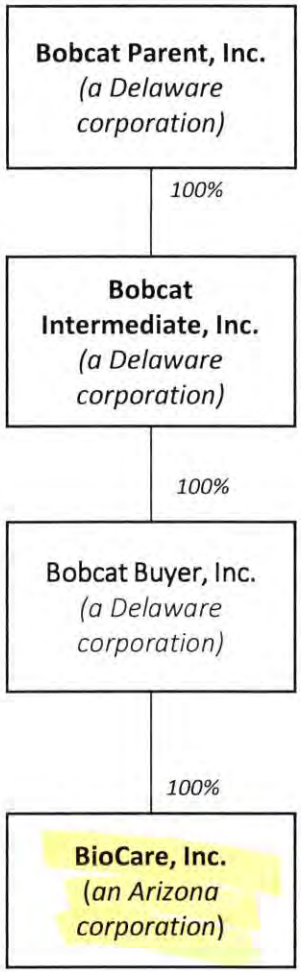
Name	Address	Accreditation Date
BioCare, Inc dba BioCareSD	2826 S Potter Dr Tempe, AZ 85282	Reaccreditation in process

Verified MS
1/18/22

BioCare, Inc. – Pre-Closing Structure



BioCare, Inc. – Post-Closing Structure



	Officers	*Directors*
Bobcat Parent, Inc. *(a Delaware corporation)*	President: Jonathan Maschmeyer	Jonathan Maschmeyer
Bobcat Intermediate, Inc. *(a Delaware corporation)*	President: Jonathan Maschmeyer	Jonathan Maschmeyer
Bobcat Buyer, Inc. *(a Delaware corporation)*	Chief Executive Officer: Linda Matthews Chief Operating Officer: Andrew Kirk Vice President, Finance: Scott Steinman	Linda Matthews Andrew Kirk Scott Steinman
BioCare, Inc. *(an Arizona corporation)*	Chief Executive Officer: Linda Matthews Chief Operating Officer: Andrew Kirk Vice President, Finance: Scott Steinman	Linda Matthews Andrew Kirk Scott Steinman

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

BIOCARE, INC.

ACC file number: 21232558

was incorporated under the laws of the State of Arizona on 09/15/2016;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **09/28/2021**

Matthew Neubert, Executive Director

BioCare®

Employees

Agado, Omar
Albin, Victoria
Alexander, Robert
Bass, Michael
Beck, Jeffrey
Blanchard, Debbie
Bohm, Karen
Breslin, Ann
Chandel, Varinder
Chun, Luke
Craddock, Bobbie
Cuevas, Cristal
David, Joni
Duffy, Holly
Dulman, Daniel
Flessor, Andrew
Furlanetto, Stephen
Gilman, Scott
Hopping, Kathleen
Imtiaz, Madiha
Jeffries, Sean
Kirk, Andrew
Kolo, Steven
Long, Michael
Luick, Kimberly
Martin, Michelle
Matthews, Linda
Moore, Roger
Morgan, Randall
Murray, Deeahn
Ojeda, Schon
Osman, Christine
Pantazopoulos, Barbara
Patterson, Cheryl
Perry, Tanner
Pharr, Matthew
Preston, Linda
Robinson, Jason
Ross, Scott
Schoonover, Jodi
Snodgrass, Michael
Steffes, Mark
Steinman, Scott
Tew, Robert
Thorne, Amy
Traphagan, Brian
Twitchell, Randall
Vanderaa, Andrew
Walker, Deanna
Warner, Shirley
Washington, Terrance
Westbay, Cody
Wiltz, Pamela
Yena, Margaret

Independent Contractors

Brink, Alta

As of 11/29/2021

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 BioCare, Inc. dba BioCareSD

Physical Address 2826 South Potter Drive

City Tempe State Arizona Zip 85282

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 800-304-3064 Website https://www.biocaresd.com/

Licensing Company Email License@BiocareSD.com

Section 2: Personal Information

First Mark Middle _____ Last Steffes

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] South Marron Circle

City Mesa State AZ Zip 85212

Telephone [redacted] Email mark.steffes@biocaresd.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 Section is N/A; no military active duty

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 MS

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)	
Kennesaw State University		1983 - 1988	
Address	City	State	Zip
1000 Chastain Rd NW	Kennesaw	GA	30144
Diploma/Degree obtained, if any			
Bachelor's Degree in 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			

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
09/2015 - present	[redacted] South Marron Circle	Mesa	AZ	85212
08/2006 - 06/2015	3908 Rockledge Road	Bloomington	IL	61704
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)
BioCare, Inc, dba BioCareSD			06/28/2018 - present
Business Address	**City**	**State**	**Zip**
2826 South Potter Drive	Tempe	AZ	85282
Phone	**Title**		**Number of Employed Hours**
800-304-3064	Director of Operations		6830

Description of Duties

Directs support services and warehouse teams and is accountable for: product storage, inventory management, product distributions, enterprise resource planning (ERP) system processes (inventory, sales order entry, distributions)

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

Description of Duties

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

Description of Duties

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

Description 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				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12.1.2021
Date

Applicant's initials US

I, Mark Steffes, **certify that as the designated representative for**

BioCare, Inc. dba BioCareSD,

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

Mark Steffes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/2021

Date

Applicant's initials MS

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 Steffes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/2021

Date

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

State of Arizona, ss. County of Maricopa

I, Urissa Francille Boline, 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

12/01/2021

Date

Subscribed and Sworn to before me this 1st day of December.

Notary Public Signature

URISSA FRANCILLE BOLINE
NOTARY PUBLIC - ARIZONA
MESA COUNTY
COMMISSION #551347
MY COMMISSION EXPIRES
SEPTEMBER 30, 2022

(Seal)

Applicant's initials MS

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. 800039406

Application/License No. _____

BioCare, Inc. dba BioCareSD (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2826 South Potter Drive, Tempe, AZ 85282 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of Minnesota (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 169 North, 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 12/01/21 (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 December, 2021.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Bryan J. Dickson, 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

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: **Larkin S. Flanagan, Bryan James Dickson, Kevin Bucher**, 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 1 day of December, 2021.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

4P

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Y

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change ☐ Name Change ☐ Location Change (in-state only)	* If making a change, provide current license number: WH WH01950	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Health Coalition, Inc.

Physical Address: 8324 NW 30th Terrace

City: Doral State: FL Zip: 33122

Mailing Address (if different from physical address): 8320 NW 30th Terrace

City: Doral State: FL Zip: 33122

Telephone: 305-662-2988 Website: www.healthcoalition.com

Name of Designated Representative (DR): Walter R. Shikany III

Licensing Company Email: licensing@healthcoalition.com DR Email: licensing@healthcoalition.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)?		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 see attachment 1	
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

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 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: Octapharma USA Inc
Address: 121 River Street, # 1201 City: Hoboken State: NJ Zip: 07030

Name: Sagent Pharmaceuticals Inc
Address: 1901 N Roselle Road, Suite 450 City: Schaumburg State: IL Zip: 60195

Name: Pfizer Inc
Address: 235 East 42nd Street City: New York City State: NY Zip: 10017

Name: Amneal Biosciences LLC
Address: 400 Crossing Boulevard, 3rd Floor City: Bridgewater State: NJ Zip: 08807

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any): N/A
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: Florida see attachment 2
Parent Company (if any): N/A
Corporation Name: Health Coalition, Inc.
Mailing Address: 8320 NW 30th Terrace
City: Doral State: FL Zip: 33122
Telephone: 305-662-2988 Email: licensing@healthcoalition.com
Contact Person Name: Walter R Shikany III

Section 6: Partnership

Partnership Name:
Mailing Address: N/A
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address: N/A
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 see attachment 3 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 4		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		N
1. Copy of FDA registration 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.** see attachment 5	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** see attachment 6		✓		
• **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 **6 months.** see attachment 2	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/ see attachment 7		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/ see attachment 8 & 9		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** N/A	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** see attachment 10	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered. N/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.

Walter R Shikany III, President & CEO

Print Name of Authorized Person Submitting Application

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

10/06/21

Date

Board Use Only	Date Received: _____	Amount: 500 check# 9883

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 1 – Disciplinary Action List

HCI | HEALTH COALITION, INC.

knowledge
reliability
service

HEALTH COALITION, INC.

DISCIPLINARY ACTIONS

Issuing Entity: Board of Pharmacy, Department of Consumer Affairs, State of California
Date of Occurrence: **October 4, 2016**
Offense Details: Failure to notify the Board of the change of Designated Representative in Charge within 30 days of the change. New (current) DR had to take the California Designated Representative test prior to submitting the change.
Outcome: Administrative fine was paid, and our license remained active and clear.

Issuing Entity: Board of Pharmacy, Department of Consumer Affairs, State of California
Date of Occurrence: **June 21, 2011**
Offense Details: Failure to notify the Board of the change of Designated Representative in Charge within 30 days of the change. New DR had to take the California Designated Representative test prior to submitting the change.
Outcome: Administrative fine was paid, and our license remained active and clear.

Issuing Entity: Florida Department of Health
Date of Occurrence: **February 8, 1999**
Offense Details: Purchase of prescription drugs from a vendor not permitted to engage in distribution in the State of Florida at the time.
Outcome: Administrative fine was paid, and our license remained active and clear.

Issuing Entity: Florida Department of Health
Date of Occurrence: **March 26, 1997**
Offense Details: Storage of prescription drugs at a third-party cold storage location not permitted to store it on behalf of Health Coalition, Inc. by the State of Florida. Purchase of prescription drugs from a vendor not permitted to engage in distribution in the State of Florida at the time.
Outcome: Administrative fine was paid, and our license remained active and clear.

Disclosures

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.

RECEIVED OCT 1 0 2016

October 04, 2016

HEALTH COALITION INC
ATTN: WALTER R. SHIKANY III, EIC
8324 NW 30TH TERRACE
MIAMI, FL 33122

RE: CI 2016 72440
HEALTH COALITION INC
OSD 4205

The attached Citation CI 2016 72440, has been issued to HEALTH COALITION INC, OSD 4205. A copy has been sent to the main offices, and a copy is being sent to the designated-representative-in-charge for informational purposes only. As designated-representative-in-charge it is your responsibility to ensure the out of state distributor's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the out of state distributor'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 Ericka Busby, Enforcement Analyst at (916) 574-7731.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2016 72440	HEALTH COALITION INC, OSD 4205

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$400.00

CONDUCT:

Business and Professions Code section 4161(j) requires a representative-in-charge to be responsible for compliance with state and federal laws governing wholesalers. Additionally, the section requires every nonresident wholesaler to notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. Specifically, Giovana Flores (EXC 21314) dissociated as designated representative-in-charge on March 25, 2016 and Walter Shikany III (EXC 23936) took over as the new designated representative-in-charge on September 9, 2016. Health Coalition Inc. operated without the supervision of a designated representative-in-charge for 168 days and failed to notify the board in writing until September 12, 2016, 171 days later.

CITATION ISSUED ON: October 04, 2016 | **TOTAL AMOUNT OF FINE(S): $400.00**

PAYMENT OF FINE(S) DUE BY: November 03, 2016

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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

June 21, 2011

DATED MATERIAL ENCLOSED

HEALTH COALITION INC
ATTN: WALTER SHIKANY, PRESIDENT
8324 NW 30TH TERRACE
MIAMI, FL 33122

RE: CI 2010 46515
HEALTH COALITION INC
OSD 4205

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of 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 web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 21, 2011: Unless the Citation is contested payment of fine(s) must be received by the Board.
- July 05, 2011: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 21, 2011: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Linda Kapovich at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2010 46515	HEALTH COALITION INC, OSD 4205

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	Nonresident wholesaler; shall identify and notify the board within 30 days for the date that a Designated representative-in-charge ceases to be the Designated representative-in-charge	$500.00

CONDUCT:

Failure to Notify & Identify of a Change in Designated Representative-in-charge – Health Coalition Inc (OSD 4205) was not in compliance with Business and Professions Code section 4161 (j), which requires a nonresident wholesaler to identify and notify the Board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. On 12/23/2010, Health Coalition Inc (located at 8324 NW 30th Terrace, Miami, FL 33122) failed to identify and notify the Board of a new designated representative-in-charge within 30 days of prior designated representative-in-charge Maria Rodriguez's disassociation on 8/4/2010. This is a violation of pharmacy law.

CITATION ISSUED ON: June 21, 2011	TOTAL AMOUNT OF FINE(S): $500.00
PAYMENT OF FINE(S) DUE BY: July 21, 2011	

Jeb Bush
Governor

FLORIDA DEPARTMENT OF HEALTH

Robert G. Brooks, M.D.
Secretary

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

NOTICE OF VIOLATION
Case No: 98-03657
Current Permit No: 22:00344

February 8, 1999

Terri Shikani, President
Health Coalition
4906 S.W. 72 Avenue
Miami, FL 33155

Dear Ms. Shikani:

Agents of the Department of Health detected the following violation of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (F.S.) and Florida Administrative Code Rule 64F-12, Regulation for Drugs Devices and Cosmetics during an inspection of your facility located at the above address on September 10, 1998:

> Health Coalition purchased prescription drugs from persons not permitted by the department to engage in the wholesale distribution of prescription drugs in or into the state of Florida. The following entities were not permitted at the time of the transactions: Genetics Institute; Millenium Health, Inc.; Medical Distribution, Inc.; Biologic, Inc.; J-Mark Enterprises; Ultracare; Blood Community Center; and MedImmune, Inc.; Medcare Infusion Services; and Option Care. This is a violation of s. 499.005(14), F.S. (Fine $2,500) Health Coalition was previously cited for this violation in case #96-03321. (See Exhibit A for policies and procedures previously submitted)

The above referenced violation should not be regarded as an all-inclusive list of deficiencies that may be or may have been in existence at your facility, and violations may not be limited to the products cited above. It is your responsibility to ensure that your facility is in compliance with all requirements of the Florida Drug and Cosmetic Act and the rules adopted thereunder.

In order to resolve this matter, the department proposes the following alternatives, either of which must be accomplished by your firm within thirty (30) days of its receipt of this letter:

A. If your firm agrees with the findings in this letter and further agrees to waive its right to an administrative hearing pursuant to Florida law (ss. 120.569 and 120.57, Florida Statutes), the department and Health Coalition can resolve this matter by your execution of the enclosed Agreement, which includes payment of an administrative fine. You are also required to send the department supporting documentation describing the actions taken and the policies and procedures put into place to prevent the recurrence of these violations. This corrective action should address monitoring or other activities to assure the policies and procedures are implemented and functioning as intended.

LAW OFFICES
PETER G. GRUBER, P.A.
ATTORNEY AND COUNSELOR

TELEPHONE: 670-1010
AREA CODE: 305
TELECOPIER NO: 670-0223

ONE DADELAN CENTER, SUITE 910
9100 SOUTH DADELAND BOULEVARD
MIAMI, FLORIDA 33156

March 18, 1999

Sandra R. Stovall
Compliance Officer
Florida Department of Health
Bureau of Pharmacy Services
2818-A Mahan Drive
Tallahassee, Florida 32308

Re: Our client: Health Coalition, Inc.
Notice of Violation
Case No. 98-03657
Current Permit No. 22:00344
Payment of fine and submission of Agreement

Dear Ms. Stovall:

Pursuant to our several telephone conversations enclosed please find the following:

1. An *Agreement* duly executed by Walter R. Shikany, Jr., President of Health Coalition, Inc. and attested by the corporate secretary.

2. Our client's check in the amount of One Thousand Five Hundred and 00/100 ($1,500.00) Dollars payable to Florida Drug, Device and Cosmetic Trust Fund as per your correspondence of March 4, 1999 reducing the previous fine.

This shall confirm that Health Coalition, Inc., agrees to adhere to the procedures and policies previously set forth in correspondence to the Department of Health and that it will more closely monitor its activities therewith. Our client now appreciates that any entity with which it does business must be registered with the State of Florida.

Please allow me to take this opportunity to personally convey my appreciation to you for the courtesies you have extended and your cooperation in expeditiously and effectively resolving this matter with our client. It was a pleasure to have worked with you. Thank you again for your prompt attention.

Very truly yours,

PETER G. GRUBER, P.A.

By: _____
Peter G. Gruber, Esquire

AGREEMENT

Case No. 98-03657
Current Permit No. 22:00344

Health Coalition, Inc., by and through its President, Walter R. Shikany, Jr., hereby acknowledges the payment of a fine in the amount of One Thousand Five Hundred and 00/100 ($1,500.00) Dollars and further waives its right to a hearing pursuant to Chapter 120, Florida Statutes, related to a *Notice of Violation*, Case No. 98-03657.

The payment of the aforementioned fine and waiver of the right to a hearing is not intended nor does it constitute an admission of liability or violation of Florida Statutes which is hereby expressly denied. Health Coalition, Inc., agrees to comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes and the rules promulgated and adopted thereunder.

I am fully authorized to bind Health Coalition, Inc., to the terms of this *Agreement*.

Dated this 18 day of March, 1999.

HEALTH COALITION, INC.

By: _____
Walter R. Shikany, Jr., President

Attest:

By: _____
Corporate Secretary (corporate seal)

10537

HEALTH COALITION INC.
4900 SW 72 AVENUE
MIAMI, FL 33155

FIRST UNION NATIONAL BANK
OF FLORIDA
MIAMI SPRING, FL 33166
63-1012/632

10537

***One Thousand Five Hundred & no/100 Dollars

DATE 03/18/99

AMOUNT ***1,500.00

PAY
TO THE
ORDER
OF

FLORIDA DRUGS, DEVICES & COSMETICS
TRUST FUND
HSFP - 2818-A MAHAN DRIVE
TALLAHASSEE, FL 32308

AUTHORIZED SIGNATURE

⑈010537⑈ ⑆063201625⑆ 2079900446475⑈

8 SECURITY FEATURES INCLUDED. DETAILS ON BACK.

Fedex Standard 4/23
-AP

HEALTH COALITION
4906 S.W. 72nd Avenue
Miami, Florida 33155
(305) 662-2988

April 23, 1997

Ms. Sandra R. Stovall
Bureau of Pharmacy Services
Department of Health
2633 Mahan Drive
Tallahassee, FL 32308

Dear Ms. Stovall,

Enclosed please find the administrative fine in the amount of $1,000 ($750 from Health Coalition and $250 from NABI) and documentation describing the actions Health Coalition has taken to prevent the violations cited in your notice.

Health Coalition was unaware at the time of the violation that a permit was needed for each storage facility, but has now instituted this as part of our Standard Operating Procedures (see attached excerpt).

Also attached is a copy of NABI's Prescription Drug Wholesaler license (expired 3/31/97) and their completed application for renewal. As requested, we have also enclosed the original signed "Notice of Violation." If you have any additional questions, please call me at (800)456-7283.

Sincerely,

Walter R. Shikany
Vice President of Sales

FLORIDA DEPARTMENT OF HEALTH

Lawton Chiles
Governor

James T. Howell, M.D., M.P.H.
Secretary

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

NOTICE OF VIOLATION
Case No: 96-03321
Current Permit No: 22:00344

March 26, 1997

Ms. Terri Shikany, President
Health Coalition, Inc.
4906 S.W. 72nd Avenue
Miami, Florida 33155

Dear Ms. Shikany:

Investigators of the Department of Health detected the following violations of Chapter 499, Florida Statutes (F.S.) and Florida Administrative Code Rule 10D-45, Regulation for Drugs Devices and Cosmetics during an inspection of your facility located at the above address and Jacob Fleishman & Sons, Inc., at 1177 N.W. 81 Street, Miami, on December 30, 1996.

Health Coalition, Inc., was wholesaling prescription drugs in an unpermitted establishment. Health Coalition, Inc., was storing its prescription drugs at Jacob Fleishman & Sons. Each establishment in which prescription drugs are held must be permitted. (See s. 499.01(1)(d), F.S.) **This is a violation of s. 499.005(22), F.S.** (Fine $750)

Health Coalition, Inc., purchased prescription drugs from a person not permitted by the department to engage in the wholesale distribution of prescription drugs. In 1995, Health Coalition, Inc., purchased prescription drugs from Univax Biologics, Inc., (a company that is no longer in business). However, at the time, Univax Biologics, Inc., was not permitted by the department as an out-of-state prescription drug wholesaler. **This is a violation of ss. 499.012(2)(c) and (3)(a), F.S., and s. 499.005(14), F.S.** (Fine $250)

The above referenced violations should not be regarded as an all-inclusive list of deficiencies which may be or may have been in existence at your facility, and violations may not be limited to the above cited products. It is your responsibility to ensure that your facility is in compliance with all requirements of the Florida Drug and Cosmetic Act and the rules adopted thereunder.

In order to resolve this matter, the department proposes the following alternatives, either of which must be accomplished by your firm within thirty (30) days of its receipt of this letter:

A. If your firm agrees with the findings in this letter and further agrees to waive its right to an administrative hearing pursuant to Florida law (s. 120.57, Florida Statutes and Rule 10-2.036, Florida Administrative Code), the department and Health Coalition, Inc., can resolve this matter by your execution of the attached Agreement, which includes

payment of an administrative fine. You are also required to send the department supporting documentation describing the actions taken and the policies and procedures put into place to prevent the recurrence of these violations.

If you agree to this resolution, please sign and date the Agreement. Return the original signed Agreement and the original NOTICE OF VIOLATION, an attached cashier's check, certified check, or money order for **One Thousand Dollars ($1,000)** made payable to the **Florida Drug, Device and Cosmetic Trust Fund**, and your plan of corrective action to:

Bureau of Pharmacy Services
Department of Health
2633 Mahan Drive
Tallahassee, FL 32308

B. However, if you believe circumstances exist that the department should consider before concluding this investigation, you may provide the department, within fifteen (15) days of receipt of this letter, your rationale and evidence to support your position. If the department does not agree with the rationale and evidence submitted by your firm, or we cannot reach a satisfactory resolution of this matter, the department may, thirty (30) days after your firm's receipt of this letter, initiate appropriate legal action, including:

1. Filing and serving of an administrative complaint for a hearing pursuant to Chapter 120, F.S., which can result in the imposition of an administrative fine not to exceed Five Thousand Dollars ($5,000.00) per violation per day. Each day the violation continues constitutes a separate violation. Each such separate violation is subject to a separate fine.
2. Revocation or suspension of the firm's permit.
3. Seizure for destruction of adulterated or misbranded products.
4. Seeking an injunction in Circuit Court to obtain compliance.
5. Initiating any other remedy authorized by law.

If you have any questions, or need further assistance in this matter, please contact me at the address identified above or by telephone at (904) 487-1257.

Sincerely,

Sandra R. Stovall

Sandra R. Stovall
Compliance Officer

Attachment: Agreement Form

AGREEMENT
Case No: 96-03321
Current Permit No: 22:00344

Health Coalition, Inc., by and through its president / owner, Terri Shikany, hereby agrees to pay a fine of One Thousand Dollars ($1,000) and submit corrective action documentation. By signing this Agreement, Health Coalition, Inc., agrees to waive its right to a hearing under Chapter 120, Florida Statutes related to this Notice of Violation Letter.

I am fully authorized to bind Health Coalition, Inc., to the terms of this Agreement. I hereby affirm the violations cited in this letter have been corrected and that Health Coalition, Inc., will comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and the rules adopted thereunder.

Corporate Seal:

by: _____ 4/22/97
President/Owner Date

attested by: Terri R Shikany 4/22/97
Corporate Secretary Date

HEALTH COALITION INC. 63

Vendor No / Name: FDOFH / FLORIDA DEPARTMENT OF HEALTH 6

Invoice	Reference	Inv Date	Inv Amt	Amt Paid	Discount	Adj Amt	Net Am
032697		03/26/97	750.00	750.00	0.00	0.00	750.0

(Acct 00106-) Check Date = 04/22/97 Check Total = 750.0

6

HEALTH COALITION INC.
4508 SW 72 AVENUE
MIAMI, FL 33155

FIRST UNION NATIONAL BANK
OF FLORIDA
MIAMI SPRING, FL 33166
63-1012/632

6393

***Seven Hundred Fifty & no/100 Dollars

DATE 04/22/97

AMOUNT ****750.0

PAY TO THE ORDER OF
FLORIDA DEPARTMENT OF HEALTH
BUREAU OF PHARMACY SERVICES
2633 MAHAN DRIVE
TALLAHASSEE, FL 32308

AUTHORIZED SIGNATURE

⑈006393⑈ ⑆063201625⑆ 2079900146475⑈

FLORIDA DEPT OF HEALTH

NORTH AMERICAN BIOLOGICALS, INC. CHECK NO. 2605!

VENDOR: 012516

VOUCHER NO	INVOICE NO	INVOICE DATE	INVOICE AMOUNT	AMOUNT PAID	DISCOUNT TAKEN	NET AMOUNT
042301	040997 7350-993-8000	04/09/97	250.00	250.00	.00	250.
				Check Total		250.

PLEASE DETACH AND RETAIN THIS STATEMENT BEFORE DEPOSITING THE CHECK

THE FACE OF THIS DOCUMENT HAS A MULTICOLORED BACKGROUND ON WHITE PAPER

NABI
The Quality Source

P.O. BOX 310701
BOCA RATON, FL 33431-0701
PHONE: (561) 989-5800
TELEFAX (561) 989-5882

NATIONSBANK OF GEORGIA
DEKALB, GEORGIA

63-63
631

CHECK NO. 2605

MATCH THE AMOUNT IN WORDS WITH THE AMOUNT IN NUMBERS

PAY ONLY TWO HUNDRED FIFTY DOLLARS AND 00 CTS

********$250.00

DATE: 04/14/97 VENDOR NO: 012516

PAY TWO HUNDRED FIFTY DOLLARS AND 00 CENTS **********

TO THE ORDER OF FLORIDA DEPT OF HEALTH

VOID OVER $250.00

FORM NO 3760L

Health Coalition Standard Operating Procedures: Compliance

Health Coalition maintains and adheres to the laws and guidelines set forth for wholesale drug distributors by the State of Florida. The following descriptions highlight specific policies and procedures that Health Coalition implements with respect to licenses and permits, inventory management, recall/withdrawal procedures, crisis management, and the disposition of outdated and/or expired product.

Drug Licenses & Permits

State Licensing

Evidence and documentation of a permit to engage in the wholesale distribution of prescription drugs must be presented to Health Coalition before any product may be purchased. In addition, Health Coalition holds a license to distribute prescription drugs in the State of Florida and in each state where it is required. All licenses are reviewed annually in order that they meet the requirements of the state laws and that they may be kept current. Upon receipt of a notice of expiration of a license, actions are taken immediately to renew the drug license.

Permits for Storage Facilities

Health Coalition, Inc. will hold a permit for each location or site where prescription drugs are stored. In the event that Health Coalition obtains a new site for the storage of its products, a separate license must be obtained for each new establishment before storage will commence.

Crisis Management

Health Coaliton follows a Disaster Preparedness and Recovery Plan in the event of a crisis situation such as a strike, fire, flood, hurricane, or other natural disasters and/or emergencies (See Attached).

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 2 – Florida Corporate Filing Certificate and IRS W-9

State of Florida
Department of State

I certify from the records of this office that HEALTH COALITION, INC. is a corporation organized under the laws of the State of Florida, filed on August 4, 1988.

The document number of this corporation is K30186.

I further certify that said corporation has paid all fees due this office through December 31, 2021, that its most recent annual report/uniform business report was filed on January 7, 2021, 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 Thirteenth day of August, 2021

Secretary of State

Tracking Number: 9752354413CU

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

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

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.

Health Coalition, Inc.

2 Business name/disregarded entity name, if different from above

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) ▶ _____

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.

8320 NW 30th Terrace

Requester's name and address (optional)

6 City, state, and ZIP code

Doral, FL 33122

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

6	5	-	0	0	6	8	2	0	8

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** ▶ [signature] **Date** ▶ 01/14/21

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.*

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 3 – VAWD Certificate & Home State License (Florida)

The National Association of Boards of Pharmacy®
hereby awards

Verified-Accredited Wholesale Distributors®
Accreditation

to

Health Coalition, Inc

located at

8324 NW 30th Ter, Doral, FL 33122

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

February 8, 2019 - February 7, 2022
Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

Verified 1/19/22
MS

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS (850) 487-1395
2601 BLAIR STONE ROAD
TALLAHASSEE FL 32399-1047

HEALTH COALITION, INC.
8320 NW 30TH TERRACE
MIAMI FL 33122

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

22344 ISSUED: 02/05/2020

RX DRUG WHOLESALE DISTRIBUTOR
HEALTH COALITION, INC.

HAS REGISTERED under the provisions of Ch.499 FS.
Expiration date: FEB 28, 2022 L2002050000630

DETACH HERE

RON DESANTIS, GOVERNOR HALSEY BESHEARS, SECRETARY

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

LICENSE NUMBER	
22344	

The PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: FEB 28, 2022

HEALTH COALITION, INC.
8324 N.W. 30TH TERRACE
MIAMI FL 33122

ISSUED: 02/05/2020 DISPLAY AS REQUIRED BY LAW SEQ # L2002050000630

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

HEALTH COALITION, INC.
8324 NW 30TH TERRACE
MIAMI FL 33122

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

TEMP20287 ISSUED: 01/03/2022

TEMPORARY PERMIT
HEALTH COALITION, INC.

under the provisions of Ch FS.
Expiration date MAR 29 2022 L2201030000443

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	
TEMP20287	

The TEMP PERMIT
Named below
Under the provisions of Chapter FS.
Expiration date: MAR 29, 2022

HEALTH COALITION, INC
8324 NW 30TH TERRACE
MIAMI FL 33122

ISSUED: 01/03/2022 DISPLAY AS REQUIRED BY LAW SEQ # L2201030000443

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 4 – $25,000 Surety Bond

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. 0807912

Application/License No. WH01950

HEALTH COALITION, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8320 NW 30TH TERRACE, DORAL, FL 33122 (Address of Applicant/Principal), as PRINCIPAL, and HARCO NATIONAL INSURANCE COMPANY (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 PO BOX 10800, RALEIGH, NC 27605 (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 AUGUST 18, 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 18TH day of AUGUST, 2021.

APPLICANT/PRINCIPAL
HEALTH COALITION, INC.

Authorized Representative

SURETY COMPANY
HARCO NATIONAL INSURANCE COMPANY

Surety Company's Representative

DAVID C. JOSEPH, 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

POWER OF ATTORNEY

Bond # 0807912

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

LINDA C. SHEFFIELD, CONWAY C. MARSHALL, STEPHEN BEAHM, DAVID C. JOSEPH, JESSICA PALMERI, ROXANNE CRAVEN, ANDREA BECKER, CLARK P. FITZ-HUGH, DARLENE A. BORNT, CATHERINE C. KEHOE, KRISTINE DONOVAN, ELIZABETH W. KEARNEY

New Orleans, LA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation'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 seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2018

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1964 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2018, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC No. 50079910 NEW JERSEY My Comm. Exp. 04-04-2023

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, August 18, 2021

A00586

Irene Martins, Assistant Secretary

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 5 – List of Corporate Officers and Directors with General Company Information

HCI | HEALTH COALITION, INC.

Telephone Numbers:

(305) 662-2988
(800) 456-7283

Fax Number:

(305) 667-5389

Designated Representative:

Walter R. Shikany III, Esquire

Officers/Directors:

President & CEO and Director — Walter R. Shikany III, Esquire
Executive Vice-President and Director — Terri R. Shikany

Ownership (until December 30, 2021):

Walter R. Shikany, Jr. (51%)
10 Edgewater Dr., Apt 15K
Coral Gables, FL 33133

WRS III Trust (49%)
10 Edgewater Dr., Apt 15K
Coral Gables, FL 33133

Ownership (effective December 31, 2021):

Shikany Marital Trust (51%)
86-6744249
10 Edgewater Dr., Apt 15K
Coral Gables, FL 33133
305-662-2988

WRS III Trust (49%)
46-6473168
10 Edgewater Dr., Apt 15K
Coral Gables, FL 33133
305-662-2988

E-mail Address:

licensing@healthcoalition.com

Website:

www.healthcoalition.com

Affiliation:

VAWD certified (Verified Accredited Wholesale Distributor)
HDA (Healthcare Distribution Alliance)

HCI | HEALTH COALITION, INC.

Corporate Profile

Description of Business:

Health Coalition, Inc. is a nationally licensed wholesale drug distributor, VAWD accredited, DQSA compliant, and fully insured. We have offered unsurpassed reliability for over 30 years. As an innovator in the specialty pharmaceutical distribution marketplace since 1988, we were the first wholesale distributor to introduce 24-hour service. Our customer base consists of many facets in the industry, such as acute care and non-acute care facilities with prescription pharmaceuticals and supplies.

Date of Incorporation:	August 4, 1988
State of Incorporation:	Florida
Federal I.D. Number:	65-0068208
Sales Tax Resale Certificate Number:	23-8012097979-5
Florida Drug Wholesale Permit:	22344
HIN:	6B4MF9V00
SIC:	51220308
NAICS:	424210

Facility Information:

- Total facility square footage is 5,153 for wholesale drug distribution only
- Security/Alarm Systems - full perimeter, motion detectors, and video cameras in a gated and locked building
- Temperature/Humidity Control – monitored temperature & humidity devices with alarm set-up to activate outside of ranges
- Hours are Monday thru Friday from 8:30am to 7:30pm and closed Saturday & Sunday with 24 hour on-call service
- No controlled substances / No DEA registration
- Annual submission to FDA CDER Direct

Receiving Address :

8324 NW 30th Terrace
Doral, FL 33122

Remit to Address:

8320 NW 30th Terrace
Doral, FL 33122-1915

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

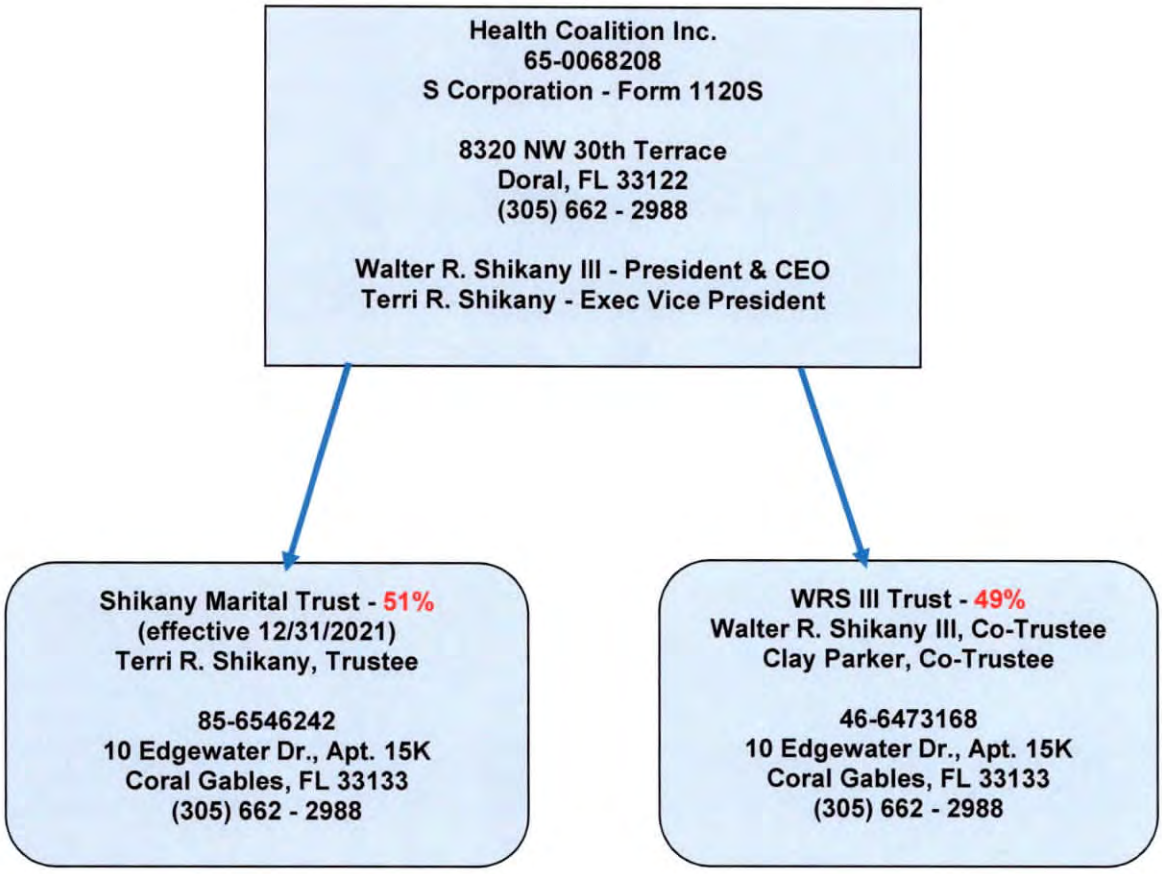
Attachment # 6 – Shareholder List

HCI | HEALTH COALITION, INC.

knowledge
reliability
service

Health Coalition, Inc. Ownership Structure

Effective December 31, 2021



ACTION BY UNANIMOUS WRITTEN CONSENT
BY BOARD OF DIRECTORS AND SHAREHOLDERS OF
HEALTH COALITION, INC.
IN LIEU OF SPECIAL MEETING

The undersigned, being the Directors and Shareholders of **HEALTH COALITION, INC.** (the "Corporation"), do hereby undertake the following action and adopt the following resolutions by unanimous written consent, in accordance with the Bylaws of the Corporation and the appropriate provisions of the laws of the State of Florida:

BE IT RESOLVED:

1. That the Stock Power assigning 51% of the outstanding shares in the Corporation from **TERRI R. SHIKANY, AS TRUSTEE OF THE WALTER R. SHIKANY, JR. LIVING TRUST DATED DECEMBER 21, 2012, AS AMENDED** to **TERRI R. SHIKANY, AS TRUSTEE OF THE SHIKANY MARITAL TRUST**, is hereby approved.

The action contained herein shall be effective as of December 31, 2021 (the "Effective Date").

DIRECTORS:

TERRI R. SHIKANY

WALTER R. SHIKANY, III

SHAREHOLDERS:

THE WALTER R. SHIKANY, JR. LIVING TRUST DATED DECEMBER 21, 2012, AS AMENDED

TERRI R. SHIKANY, TRUSTEE

THE WRS III TRUST DATED DECEMBER 21, 2012

WALTER R. SHIKANY, III, CO-TRUSTEE

CLAY PARKER, CO-TRUSTEE

STOCK POWER

EFFECTIVE AS OF December 31, 2021, I, **TERRI R. SHIKANY, AS TRUSTEE OF THE WALTER R. SHIKANY, JR. LIVING TRUST DATED DECEMBER 21, 2012, AS AMENDED** ("Trust"), Shareholder of **HEALTH COALITION, INC.**, a Florida Corporation, hereby assign and transfer unto **TERRI R. SHIKANY, AS TRUSTEE OF THE SHIKANY MARITAL TRUST**, Fifty-One Percent (51%) of the outstanding shares in **HEALTH COALITION, INC.**, a Florida Corporation, standing in the name of the Trust on the books of said Corporation and do hereby irrevocably constitute and appoint the Secretary of the Corporation to transfer the said stock on the books of said Corporation with full power of substitution in the premises.

Dated: June 9, 2021.

In presence of:

THE WALTER R. SHIKANY, JR. LIVING TRUST DATED DECEMBER 21, 2012, AS AMENDED

Witness #1 – Signature

TERRI R. SHIKANY, TRUSTEE

Stephanie Kalajainen
Witness #1 – Printed Name

Witness #2 – Signature

Karen Loucel
Witness #2 – Printed Name

ACCEPTANCE BY ASSIGNEE

The undersigned assignee hereby accepts the foregoing Stock Power and agrees to be bound by the terms and conditions of the By-Laws of **HEALTH COALITION, INC.**, a Florida Corporation.

In presence of:

THE SHIKANY MARITAL TRUST

Witness #1 – Signature

TERRI R. SHIKANY, TRUSTEE

Stephanie Kalajainen
Witness #1 – Printed Name

Witness #2 – Signature

Karen Loucel
Witness #2 – Printed Name

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.
Shikany Marital Trust

2 Business name/disregarded entity name, if different from above

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) ▶ _____

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.
10 Edgewater Drive Apt. 15K

Requester's name and address (optional)

6 City, state, and ZIP code
Coral Gables, FL 33133

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 6 - 6 7 4 4 2 4 9

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 ▶ Jeri Shikany, Trustee Date ▶ 6/30/2021

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.*

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 7 – Designated Representative Application for Walter R. Shikany III

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 Health Coalition, Inc.

Physical Address 8324 NW 30th Terrace

City Doral State FL Zip 33122

Mailing Address (if different from physical address) 8320 NW 30th Terrace

City Doral State FL Zip 33122

Telephone 305-662-2988 Website www.healthcoalition.com

Licensing Company Email licensing@healthcoalition.com

Section 2: Personal Information

First Walter Middle Robbins Last Shikany III

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

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

Mailing Address [redacted] Catalonia Avenue

City Coral Gables State FL Zip 33134

Telephone [redacted] Email licensing@healthcoalition.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 WRS

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 Miami School of Law		08/02 - 05/05	
Address	City	State	Zip
1320 S Dixie Highway	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Juris Doctorate			

School Name		From - To (MM/YY – MM/YY)	
University of Miami		08/96 - 05/00	
Address	City	State	Zip
1320 S Dixie Highway	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelor of Business Administration - Finance			

School Name		From - To (MM/YY – MM/YY)	
Guilliver Prep		08/92 - 06/96	
Address	City	State	Zip
6575 N Kendall Drive	Pinecrest	FL	33156
Diploma/Degree obtained, if any			
High School			

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
09/19 - Present	[redacted] Catalonia Avenue	Coral Gables	FL	33134
10/13 - 09/19	3350 SW 27th Avenue #1004	Miami	FL	33133
07/10 - 10/13	3350 SW 27th Avenue #1607	Miami	FL	33133
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)
Health Coalition, Inc.			2000 - Present
Business Address	**City**	**State**	**Zip**
8324 NW 30th Terrace	Doral	FL	33122
Phone	**Title**		**Number of Employed Hours**
305-662-2988	President & CEO since 09/2020		over 40,000
Description of Duties			
see attachment 1			

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

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

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

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)

10/06/21
Date

Applicant's initials

I, Walter R. Shikany III, **certify that as the designated representative for**

Health Coalition, 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

Walter Shikany III

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 10/06/21

Applicant's initials WRS

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.

Walter Shikany III
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/06/21
Date

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

State of Florida, ss. County of Dade

I, Walter R. Shikany III, 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

10/06/21
Date

Subscribed and Sworn to before me this 6 day of October 2021

Yashira Morales
Notary Public Signature

YASHIRA MORALES
MY COMMISSION # GG 915708
EXPIRES: January 23, 2024
Bonded Thru Notary Public Underwriters

(Seal)

Applicant's initials WRS

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 1 – Designated Representative Application: Walter R Shikany III Resume

Walter R. Shikany III
[redacted] Catalonia Avenue, Coral Gables, FL 33134
Tel: [redacted] Email: wshikanyiii@healthcoalition.com

WORK EXPERIENCE

Health Coalition, Inc., Miami, FL
Wholesale Distributor of Pharmaceuticals – Domestic

President & CEO ***2020 - Present***

- Responsible for strategic vision and leadership, long and short-range financial plans, and supervision of all departments.

Acting Director of Sales ***2005 - Present***

- Responsible for the administration and guidance of the Sales Team including Territory Business Managers and Call Center Team.
- Maintain and develop sales and business for the company to meet sales budget and gross profit for the company.

Corporate Counsel ***2005 – Present***

- Responsible for review of legal documents and engaging outside counsel.

Certified Designated Representative ***2009 – Present***

- Responsible for overseeing the acquisition, storage, and regulation requirements including receiving and shipping for all warehousing aspects including but not limited to compliance and perfect inspection reports by all government agencies.
- Maintain all state requirements for Certified Designated Representative for the state of Florida and/or any other governmental agency requiring such designation.

Sales Executive ***2000 - 2002***

- Twice awarded Sales Executive of the Month for overachieving sales target 134% of quota.
- Developed strategic relationships with hospitals, homecare centers, and physicians' offices.
- Created and managed a $2.5 million dollar territory.
- Introduced comprehensive pharmaceutical consignment programs to major university hospital systems.
- Proficient in Pivitol customer relationship management software.

Florida Agency for Healthcare Administration, Miami, FL **Spring 2005**
Litigation Skills Clinical

Trescott, Drucker, and Vasallo, PL., Coral Gables, FL **Summer 2004**
Law Clerk

- Successfully worked on multiple cases bringing them through discovery, pleadings, trial, and post trial stages.
- Researched various tax law issues.
- Assisted in the development and maintenance of estate plans.

Thomas Morgan, PA., Coconut Grove, FL **Spring 2004**
Law Clerk

- Prepared pleadings, memorandums of law, and summarized depositions.
- Succeeded on motions in opposition to summary judgment.

EDUCATION

University of Miami School of Law, Coral Gables, FL
Juris Doctorate May 2005
Admitted to Florida Bar November 10, 2005

Honors:

- Selected as mentor to incoming law students.
- Received Litigation Certification in the State of Florida.

University of Miami, Coral Gables, FL
Bachelor of Business Administration / Finance May 2000

Honors:

- Graduated with Honors and member of honors program.
- Member of Golden Key Honor Society.
- Dean's List 4 semesters.
- Provost's Honor Roll 1 semester.

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 8 – Personal History Application for Walter R. Shikany III

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Walter R Shikany III

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Health Coalition, Inc.

Physical Address 8324 NW 30th Terrace

City Doral State FL Zip 33122

Mailing Address (if different from physical address) 8320 NW 30th Terrace

City Doral State FL Zip 33122

Telephone 305-662-2988 Website www.healthcoalition.com

Licensing Company Email licensing@healthcoalition.com

Section 2: Personal Information

First Walter Middle Robbins Last Shikany III

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

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

Mailing Address [redacted] Catalonia Avenue

City Coral Gables State FL Zip 33134

Telephone [redacted] Email licensing@healthcoalition.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 WRS

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 Miami School of Law		08/02 - 05/05	
Address	City	State	Zip
1320 S Dixie Highway	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Juris Doctorate			

School Name		From - To (MM/YY – MM/YY)	
University of Miami		08/96 - 05/00	
Address	City	State	Zip
1320 S Dixie Highway	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelor of Business Administration - Finance			

School Name		From - To (MM/YY – MM/YY)	
Guilliver Prep		08/92 - 06/96	
Address	City	State	Zip
6575 N Kendall Drive	Pinecrest	FL	33156
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
09/19 - Present	[redacted] Catalonia Avenue	Coral Gables	FL	33134
10/13 - 09/19	3350 SW 27th Avenue # 1004	Miami	FL	33133
07/10 - 10/13	3350 SW 27th Avenue # 1607	Miami	FL	33133

Applicant's initials WBS

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)	
Health Coalition, Inc.			2000 - Present	
Business Address		**City**	**State**	**Zip**
8324 NW 30th Terrace		Doral	FL	33122
Phone	**Title**			
305-662-2988	President/CEO since 09/2020			
Description of Duties				
see attachment 1				

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.)		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)

Date

Applicant's initials LRS

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.

Walter Shikany III
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 10/06/21

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

State of Florida, ss. County of Dade

I, Walter R. Shikany III, 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** 10/06/21

Subscribed and Sworn to before me this 6 day of October 2021.

Notary Public Signature

YASHIRA MORALES
MY COMMISSION # GG 915708
EXPIRES: January 23, 2024
Bonded Thru Notary Public Underwriters

(Seal)

Applicant's initials WRS

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 1 – Personal History

Application: Walter R Shikany III Resume

Walter R. Shikany III
[redacted] Catalonia Avenue, Coral Gables, FL 33134
Tel: [redacted] Email: wshikanyiii@healthcoalition.com

WORK EXPERIENCE

Health Coalition, Inc., Miami, FL
Wholesale Distributor of Pharmaceuticals – Domestic

President & CEO ***2020 - Present***

- Responsible for strategic vision and leadership, long and short-range financial plans, and supervision of all departments.

Acting Director of Sales ***2005 - Present***

- Responsible for the administration and guidance of the Sales Team including Territory Business Managers and Call Center Team.
- Maintain and develop sales and business for the company to meet sales budget and gross profit for the company.

Corporate Counsel ***2005 – Present***

- Responsible for review of legal documents and engaging outside counsel.

Certified Designated Representative ***2009 – Present***

- Responsible for overseeing the acquisition, storage, and regulation requirements including receiving and shipping for all warehousing aspects including but not limited to compliance and perfect inspection reports by all government agencies.
- Maintain all state requirements for Certified Designated Representative for the state of Florida and/or any other governmental agency requiring such designation.

Sales Executive ***2000 - 2002***

- Twice awarded Sales Executive of the Month for overachieving sales target 134% of quota.
- Developed strategic relationships with hospitals, homecare centers, and physicians' offices.
- Created and managed a $2.5 million dollar territory.
- Introduced comprehensive pharmaceutical consignment programs to major university hospital systems.
- Proficient in Pivitol customer relationship management software.

Florida Agency for Healthcare Administration, Miami, FL **Spring 2005**
Litigation Skills Clinical

Trescott, Drucker, and Vasallo, PL., Coral Gables, FL **Summer 2004**
Law Clerk

- Successfully worked on multiple cases bringing them through discovery, pleadings, trial, and post trial stages.
- Researched various tax law issues.
- Assisted in the development and maintenance of estate plans.

Thomas Morgan, PA., Coconut Grove, FL **Spring 2004**
Law Clerk

- Prepared pleadings, memorandums of law, and summarized depositions.
- Succeeded on motions in opposition to summary judgment.

EDUCATION

University of Miami School of Law, Coral Gables, FL
Juris Doctorate May 2005
Admitted to Florida Bar November 10, 2005

Honors:

- Selected as mentor to incoming law students.
- Received Litigation Certification in the State of Florida.

University of Miami, Coral Gables, FL
Bachelor of Business Administration / Finance May 2000

Honors:

- Graduated with Honors and member of honors program.
- Member of Golden Key Honor Society.
- Dean's List 4 semesters.
- Provost's Honor Roll 1 semester.

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 9 – Personal History Application for Terri R. Shikany

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Terri R Shikany

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Health Coalition, Inc.

Physical Address 8324 NW 30th Terrace

City Doral State FL Zip 33122

Mailing Address (if different from physical address) 8320 NW 30th Terrace

City Doral State FL Zip 33122

Telephone 305-662-2988 Website www.healthcoalition.com

Licensing Company Email licensing@healthcoalition.com

Section 2: Personal Information

First Terri Middle Richie Last Shikany

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

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

Mailing Address [redacted] Edgewater Drive Apt 15K

City Coral Gables State FL Zip 33133

Telephone [redacted] Email www.healthcoalition.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 TRS

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)	
Miami Dade Junior College		08/71 - 05/72	
Address	**City**	**State**	**Zip**
11380 NW 27th Avenue	Miami	FL	33167
Diploma/Degree obtained, if any			
No			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		08/70 - 05/71	
Address	**City**	**State**	**Zip**
4202 East Fowler Avenue	Tampa	FL	33620
Diploma/Degree obtained, if any			
No			

School Name		From - To (MM/YY – MM/YY)	
Palmetto Senior High School		08/67 - 06/70	
Address	**City**	**State**	**Zip**
7431 SW 120th Street	Pinecrest	FL	33156
Diploma/Degree obtained, if any			
High School			

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
05/06 - Present	10 Edgewater Drive, Apt 15K	Coral Gables	FL	33133
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 TRS

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)	
Health Coalition, Inc.			1992 - Present	
Business Address		**City**	**State**	**Zip**
8320 NW 30th Terrace		Doral	FL	33122
Phone	**Title**			
305-662-2988	Executive Vice President			
Description of Duties				
see attachment 1				

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.)		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

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) Date

Applicant's initials TRS

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.

Terri Shikany
Print Name (First, Last)

Terri Shikany
Original Signature (electronic, copies or stamps not accepted)

10/08/2021
Date

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

State of Florida, ss. County of Dade

I, Terri R. Shikany, 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.

Terri Shikany
Original Signature

10/08/2021
Date

Subscribed and Sworn to before me this 6 day of October 2021.

Yashira Morales
Notary Public Signature

YASHIRA MORALES
MY COMMISSION # GG 915708
EXPIRES: January 23, 2024
Bonded Thru Notary Public Underwriters
(Seal)

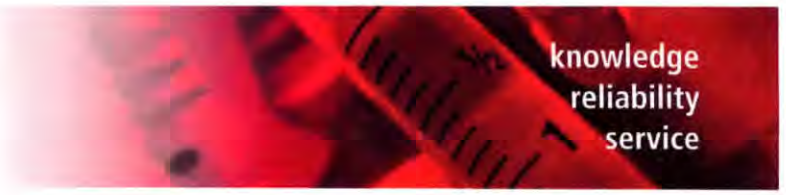
Applicant's initials TRS

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 1 – Personal History Application: Terri R Shikany Executive Vice President Duties

HCI | HEALTH COALITION, INC.



Health Coalition, Inc.

Duties of the Executive Vice President

- Assist in the overall operations of the company office
- Oversee the Human Resources Department
- Assure company is compliant in all areas of Labor and EEOC guidelines
- Assist in the development and on-going training for Sales, Sales Support, and other Departments
- Act as a liaison to outside charities to assure the company gives bac to both the community and the world
- Work with outside vendors for maintenance and other relevant contracts
- Assist the President/CEO to position the company for growth

8320 NW 30th Terrace, Doral, Florida 33122 T 800 456 7283 T 305 662 2988 F 305 667 5389 www.healthcoalition.com

2021 OWNERSHIP CHANGE APPLICATION

51% SHIKANY MARITAL TRUST

Attachment # 10 – Employee List

HCI | HEALTH COALITION, INC.

*** CONFIDENTIAL *** Licenses and Permits held by Health Coalition, Inc. *** CONFIDENTIAL ***

EMPLOYEE NAME	DEPARTMENT
Almanza, Jeniffer	Sales Support
Artola, Frenchy	Sales Support
Fallis, Peyton	Sales
Ferra, Rachelle	Purchasing
Francois, Ydreillina Jean	Sales Support
Garcia, Ashley	Sales Support
Gilbow, Sharon	Purchasing
Grant, Paula	Sales
Kalata, Debra	Accounting
Lacy, Darren	Sales
Larenas, Alex	Warehouse
Loucel, Karen	Human Resources
Morales, Yashira	Sales Support
Mosley, Armon	Accounting
Parra, Daniel	Sales & Marketing
Rivera, Jonathan	Sales
Rodriguez, Jeffrey	Warehouse
Rogova, Olga	Accounting
Schultz, Kimberly	Purchasing
Shikany III, Walter	Executive
Shikany, Terri	Executive
Sicilio, Jeff	IT
Storr, Tammy	Sales
Suarez, Manny	Warehouse
Varney, Patricia	Accounting

HCI | HEALTH COALITION, INC.

October 6, 2021

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

RE: Non-Resident Wholesale Drug Distributor License # WH01950

Dear BOP Representative,

I am writing to you on behalf of Health Coalition, Inc., a Florida based Prescription Drug Wholesale Distributor, permit No. 22344. Health Coalition, Inc. conducts wholesale business in 49 states and the District of Columbia and has been in operation, without issue, since 1988. It does not possess, nor has it ever possessed, a DEA controlled substances registration. Health Coalition, Inc. is VAWD accredited.

Enclosed please find Health Coalition, Inc.'s Change of Ownership Application along with check # 9883 for $500.00.

BACKGROUND

- On 09/08/2020, Walter R. Shikany, Jr. passed away due to complications associated with Covid-19.
- With an effective date of 12/31/2021, Walter R. Shikany, Jr's 51% ownership will be transferred to the Shikany Marital Trust, EIN 86-6744249, with Walter R. Shikany, Jr.'s widow Terri R. Shikany as Trustee.
- Walter R. Shikany, Jr. owned his 51% interest in Health Coalition, Inc. in his Revocable Trust, under his social security number, during his lifetime, which continues to still own the 51% in Health Coalition, Inc. until the transfer to the Shikany Marital Trust to be effective 12/31/2021.
- Walter R. Shikany, Jr. did not have a probate estate, as all assets were titled in his Revocable Trust, and, therefore, he did not own his 51% interest in Health Coalition, Inc. in his estate or tenancy by the entireties.

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knowledge
reliability
service

Should you have any questions or require additional information/documentation, please do not hesitate to contact me at 305-662-2988 or licensing@healthcoalition.com.

On behalf of Health Coalition, Inc., I thank you for your time and attention to this very important matter.

Sincerely,

Debra A Kalata
Assistant Controller
Health Coalition, Inc.

attachments

HCI | HEALTH COALITION, INC.

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September 3, 2021

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

RE: Non-Resident Wholesale Drug Distributor License # WH01950

Dear BOP Representative,

Enclosed please find Health Coalition, Inc.'s Ownership Transfer Application along with check # 9862 for $500.00.

Per Walter R Shikany III's June June 9th letter (see attachment 6), his 49% ownership interest in Health Coalition, Inc. will be transferred from his individual ownership under his social security number to his trust titled the "WRSIII Trust", EIN 46-6473168 for which he is co-trustee for his benefit and control, in trust.

Should you have any questions, please do not hesitate to contact me at 305-662-2988 or licensing@healthcoalition.com.

On behalf of Health Coalition, Inc., I thank you for yo

Sincerely,

Debra A Kalata
Assistant Controller

attachments

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OF PHARMACY

4Q

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located? ☐ Nevada ■ Out-of-State

Is your facility a reverse distributor? ☐ Yes ■ No

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*	WH 01862	■ 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)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Padagis South Carolina LLC

Physical Address: 110 Hidden Lake Circle, STE A

City: Duncan State: SC Zip: 29334

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-775-2054 Website: www.padagis.com

Name of Designated Representative (DR): David Stahl

Licensing Company Email: Stephanie.FitzSimmons@padagis DR Email: David.Stahl@padagis.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.

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

Name: Henry Schein Inc
Address: 255 Vista Blvd City: Sparks State: NV Zip: 89434
Name: Kaiser - Reno DC
Address: 12055 Sage Point Ct City: Reno State: NV Zip: 89506
Name: Only two customers in the state of NV
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Ultimate Parent 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: Michigan
Parent Company (if any):
Corporation/Organization Name: Padagis South Carolina LLC
Mailing Address: 110 Hidden Lake Circle, STE A
City: Duncan State: SC Zip: 29334
Telephone: 800-775-2054 Email: Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@
Contact Person Name: Stephanie FitzSimmons; Trisha Nguyen

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 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 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.** Facility is an LLC. LLC do not have shareholders or ownership percentages		✔		
• **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. 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**	✔			
• **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)**	✔	✔	✔	✔
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.

Colter VanStedum

Print Name of Authorized Person Submitting Application

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

11/4/21

Date

Board Use Only	Date Received: _____	Amount: 500	Check# 644143	✓ Processed 1/12/22

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
Padagis South Carolina LLC	110 Hidden Lake Circle, Suite A Duncan, SC 29334	08/06/19

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Contact

South Carolina Secretary of State

Business Entities Online

File, Search, and Retrieve Documents Electronically

Padagis South Carolina LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Foreign

Incorporated State: Michigan

Important Dates

Effective Date: 09/02/2021

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: Corporation Service Company

Address: 508 Meeting Street
West Columbia, South Carolina 29169

Official Documents On File

Filing Type	Filing Date
Application for a Certificate of Authority to Transact Business	09/02/2021
Application to Reserve a Limited Liability Company Name	06/09/2021

For filing questions please contact us at **803-734-2158**

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The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®
Accreditation

to

Perrigo Pharmaceuticals Company

located at

110 Hidden Lake Cir, Ste A, Duncan, SC 29334

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

August 6, 2019 - August 5, 2022
Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | *www.nabp.pharmacy*

PRC 1053808

PERMIT NO. 20150
DATE ISSUED: 07/23/2021

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Non-Dispensing Drug Outlet Permit

2021-2022

Expires 06/30/2022

Robert Hubbard, Board Chair

Lauren Thomas, Vice Chair

PADAGIS SOUTH CAROLINA LLC
Permit Holder: DAVID STAHL
110 HIDDEN LAKE CIRCLE SUITE A
DUNCAN SC 29334

SEE REVERSE SIDE FOR OPENING INSTRUCTIONS

South Carolina Department of Labor, Licensing and Regulation
BOARD OF PHARMACY
Post Office Box 11927
Columbia, SC 29211-1927

PERMIT ENCLOSED

60
PADAGIS SOUTH CAROLINA LLC
110 HIDDEN LAKE CIRCLE SUITE A
DUNCAN SC 29334

Registrant Verification For

PADAGIS SOUTH CAROLINA LLC

DEA Number:	RP0606701
Expiration Date:	03/31/2022
Additional Company Info:	
Registered Address:	110 HIDDEN LAKE CIR
	STE A
City:	DUNCAN
State:	SC
Zip Code:	29334
Business Activity:	DISTRIBUTOR
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	10/20/2021

Department of Justice · Drug Enforcement Administration · Diversion Control Division

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0606701	03-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	DISTRIBUTOR	09-13-2021

PADAGIS SOUTH CAROLINA LLC
110 HIDDEN LAKE CIR
STE A
DUNCAN, SC 29334-8300

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.

Padagis

Padagis Entities – Officer Listing

Entity	Officers	Officer Contact:
Padagis US LLC (Delaware)	Executive Vice President – Chief Commercial Officer - John Wesolowski Executive Vice President – Chief Growth Officer - Colter Van Stedum Tax Officer – William DeGood	1251 Lincoln Rd. Allegan, MI 49010 (800)-775-2054
Padagis South Carolina LLC (Michigan)	Executive Vice President – Chief Commercial Officer - John Wesolowski Executive Vice President – Chief Growth Officer - Colter Van Stedum Tax Officer – William DeGood	

South Carolina Secretary of State

Business Entities Online

File, Search, and Retrieve Documents Electronically

Padagis South Carolina LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Foreign

Incorporated State: Michigan

Important Dates

Effective Date: 09/02/2021

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: Corporation Service Company

Address: 508 Meeting Street
West Columbia, South Carolina 29169

Official Documents On File

Filing Type	Filing Date
Application for a Certificate of Authority to Transact Business	09/02/2021
Application to Reserve a Limited Liability Company Name	06/09/2021

For filing questions please contact us at **803-734-2158**

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SC DHEC Bureau of Drug Control Controlled Substances Registration Verification

Registration Number	*Name / Address*	*County*	*Issuance Date*	*Expiration Date*	*Schedule*
4520150	PADAGIS SOUTH CAROLINA LLC 110 HIDDEN LAKE CIR STE A DUNCAN, SC 29334	SPARTANBURG	8/9/2021	4/1/2022	3N4
4020150	PADAGIS SOUTH CAROLINA LLC 110 HIDDEN LAKE CIR STE A DUNCAN, SC 29334	SPARTANBURG	8/9/2021	4/1/2022	22N33N45
4420150	PADAGIS SOUTH CAROLINA LLC 110 HIDDEN LAKE CIR STE A DUNCAN, SC 29334	SPARTANBURG	8/9/2021	4/1/2022	3N

Verification Disclaimer: This is to attest to the accuracy of the information contained on the website and to verify that the information is updated at least daily. The information on this site is primary source verification, and is non-modifiable by outside entities.

Padagis™

Site Leads (Indebtedness to the applicant)
Padagis South Carolina LLC
110 Hidden Lake Circle, STE A
Duncan, SC 29334

1. **Ofir Seva, EVP Chief Operating Officer**
2. **David Stahl, Regional Manager and Designated Representative**

Padagis South Carolina LLC

Employee Name
Leverette, Shelia D.
Deoro, Lucille C.
King, Charlene P.
Mcneil, Anthony R.
Stahl, David S.
Davis Jr., Terry L.
Terrell, John A.
Partridge, Michael S.
Bowlby, James A.
Hill, Jeffery S.
Pruitt, Ernest C.
Gurski, Randall E.
Rodriguez, Manny
Whiteside, Robert E.
Smith, Tommy L.
Hooker, Donna M.
Smith, Kim H.
Whitaker, William
Owens, Christopher
Wilmore Jr., Robert
Jones, Barry
Moffat, Joseph
Hutchesion, Alex
Watts, Timothy
Corry, Angela M.
Hankins, Kelvin T.
Bomar, Marcus
Edge, Andrea
Neal, Bobby L.
Reece, Michael
Lewis, Tommy
Hogue, Timothy R.
Smith, Perez L.
Stroud, Joshua W.
Hamilton, Melissa R.
Millwood, Scottie D.
Jordan, David P.
Stell, Juniper L.
Pringle, Anthony B.
Hampton, Damonte D.

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: Padagis South Carolina LLC

Physical Address: 110 Hidden Lake Circle, STE A

City: Duncan State: SC Zip: 29334

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-775-2054 Website: www.padagis.com

Licensing Company Email: Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First: David Middle: Stuart Last: Stahl

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

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

Mailing Address: 110 Hidden Lake Circle, STE A

City: Duncan State: SC Zip: 29334

Telephone: 800-775-2054 Email: David.Stahl@padagis.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: 1995 to: 1998

Military Occupation/Specialty: Adminstrative

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: DS

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)	
Michigan State University		1999-2022	
Address	City	State	Zip
	Lansing	MI	48823
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Waverly High School		1990-1994	
Address	City	State	Zip
	Lansing	MI	48917
Diploma/Degree obtained, if any			
General 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
August 2012 - Prese	[redacted] Notting Hill Lane	Greer	SC	29651
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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: Padagis South Carolina LLC				From - To (MM/YY – MM/YY): July/2021 - Present
Business Address: 110 Hidden Lake Circle, STE A		City: Duncan	State: SC	Zip: 29334
Phone: 800-775-2054	Title: Regional Manager		Number of Employed Hours: ~ See below	
Description of Duties: Responsible for pharmaceutical finished product distributions and general warehouse operations. The Padagis South Carolina warehouse is ~300,000 sq ft with 40 employees.				
Business Name: Perrigo Pharmaceuticals Company				From - To (MM/YY – MM/YY): Jan/2004 - July/2021
Business Address: 110 Hidden Lake Circle, STE A		City: Duncan	State: SC	Zip: 29334
Phone:	Title: Regional Manager		Number of Employed Hours: ~32,000	
Description of Duties: Responsible for pharmaceutical finished product distributions and general warehouse operations. The Padagis South Carolina warehouse is ~300,000 sq ft with 40 employees.				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description 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)

11-4-21
Date

Applicant's initials

I, David Stahl, **certify that as the designated representative for** Padagis South Carolina 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

David Stahl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-4-24

Date

Applicant's initials DS

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 Stahl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-4-21

Date

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

State of South Carolina, ss. County of Spartanburg

I, Juniper L. Stell, 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

11-04-2021

Date

Subscribed and Sworn to before me this 4th day of November, 2021.

Notary Public Signature

JUNIPER L. STELL
NOTARY PUBLIC
My Comm. Exp. Jun 15, 2031
STATE OF SOUTH CAROLINA

(Seal)

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 Padagis South Carolina LLC

Physical Address 110 Hidden Lake Circle, STE A

City Duncan State SC Zip 29334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First Colter Middle _____ Last VanStedum

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

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

Mailing Address [redacted] Lincoln Road

City Allegan State MI Zip 49010

Telephone 800-775-2054 Email Colter.VanStedum@padagis.com

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

Section 3: Military Service (NRS 622.120)

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)

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 CVS

Section 5: List your high school and college experience beginning with the most current. (Use a separate [illegible] additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Grand Valley State University		08/08 - 05/10	
Address	**City**	**State**	**Zip**
1 Campus Dr	Allendale	MI	49401
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Central Michigan University		08/01 - 05/05	
Address	**City**	**State**	**Zip**
1200 S. Franklin Street	Mt. Pleasant	MI	48859
Diploma/Degree obtained, if any			
BSBA			

School Name		From - To (MM/YY – MM/YY)	
Hudsonville High School		08/97 - 06/01	
Address	**City**	**State**	**Zip**
5037 32nd Ave	Hudsonville	MI	49426
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 [illegible] if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2014 - Present	[redacted] W Bay Ct.	Hudsonville	MI	49426
06/14 - 10/14	4886 Faringdom Grove Dr	Hudsonville	MI	49426
06/13 - 06/14	6084 16th Ave	Hudsonville	MI	49426
09/06 - 06/13	6202 Sheldon Dr	Hudsonville	MI	49426

Applicant's initials CVS

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships, business associations with which you have been employed or an officer, director or partner for the past 10 years.

Business Name		From - To (MM/YY – MM/YY)
Padagis		07/2021 - Present
Business Address	**City**	**State / Zip**
1251 Lincoln Road	Allegan	MI 49010
Phone	**Title**	
800-775-2054	Executive Vice President	

Description of Duties

Reporting to the CEO, I am responsible for growth of the business and have functional reporting responsibility for R&D, Regulatory, Project Management, Pipeline and Business Development.

Business Name		From - To (MM/YY – MM/YY)
Perrigo Pharmaceuticals Company		07/06 - 07/21
Business Address	**City**	**State / Zip**
515 E Avenue	Allegan	MI 49010
Phone	**Title**	
	Vice President	

Description of Duties

Reporting to the President of Perrigo Pharmaceuticals, I was responsible for Project Management, Pipeline and Business Development.

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.

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)

11/5/2021
Date

Applicant's initials CVL

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.

Colter VanStedum

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/5/2021

Date

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

State of Michigan, ss. County of Kent

I, Colter Van Stedum, 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

11/5/2021

Date

Subscribed and Sworn to before me this 5th day of Nov, 2021.

Notary Public Signature

Eden Pikaart, Notary Public
State of Michigan, County of Kent
My Commission Expires 3/22/2027
Acting in the County of Ottawa

(Seal)

Applicant's initials CVS

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 Padagis South Carolina LLC

Physical Address 110 Hidden Lake Circle, STE A

City Duncan State SC Zip 29334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First William Middle James Last DeGood

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

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

Mailing Address [redacted] Lincoln Road

City Allegan State MI Zip 49010

Telephone 800-775-2054 Email William.DeGood@padagis.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 _____

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)	
Michigan State University		08/92 - 12/96	
Address	City	State	Zip
426 Auditorium Road	East Lansing	MI	48824
Diploma/Degree obtained, if any			
BA Accounting			

School Name		From - To (MM/YY – MM/YY)	
South Christian High School		08/89 - 06/92	
Address	City	State	Zip
7979 Kalamazoo Avenue SE	Byron Center	MI	49315
Diploma/Degree obtained, if any			
High School Diploma			

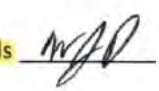
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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
09/09 - current	[redacted] Sandy Ridge Dr.	Dorr	MI	49323
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 

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)	
Padagis			07/21 - Present	
Business Address		**City**	**State**	**Zip**
1251 Lincoln Road		Allegan	MI	49010
Phone	**Title**			
800-775-2054	Tax Officer			
Description of Duties				
Responsible for all U.S. tax matters of the company and coordination with the Israel local team, also responsible for establishing and monitoring the company's worldwide transfer pricing ensuring we have the appropriate documentation.				

Business Name			From - To (MM/YY – MM/YY)	
Perrigo Company plc			07/05 - 07/21	
Business Address		**City**	**State**	**Zip**
515 Eastern Ave		Allegan	MI	49010
Phone	**Title**			
	Director, International Tax			
Description of Duties				
Responsible for dealing with Perrigo's international locations and their tax matters, both local country and U.S. tax impacts. Also responsible for transfer pricing and certain aspects of financial reporting related to tax.				

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

William A. DeMark
Original Signature (electronic, copies or stamps not accepted)

11-09-21
Date

Applicant's initials WAD

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.

William DeGood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-09-21

Date

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

State of Michigan, ss. County of Allegan

I, William J. DeGood, 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

11-09-21

Date

Subscribed and Sworn to before me this 9 day of NOVEMBER, 2021

Notary Public Signature

(Seal)

Applicant's initials

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 Padagis South Carolina LLC

Physical Address 110 Hidden Lake Circle, STE A

City Duncan State SC Zip 29334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-775-2054 Website www.padagis.com

Licensing Company Email Stephanie.FitzSimmons@padagis.com; Trisha.Nguyen@padagis.com

Section 2: Personal Information

First John Middle Edgard Last Wesolowski

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

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

Mailing Address [redacted] Lincoln Road

City Allegan State MI Zip 49010

Telephone 800-775-2054 Email John.Wesolowski@padagis.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 _____

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)	
Hackett Central Prep			9/81 - 6/85	
Address		City	State	Zip
1000 W. Kilgore		KALAMAZOO	MI	49008
Diploma/Degree obtained, if any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
KVCC			9/85 - 6/87	
Address		City	State	Zip
6767 W Q Ave		KALAMAZOO	MI	49009
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Western Michigan University			9/87 - 4/91	
Address		City	State	Zip
1903 W. Michigan Ave		KALAMAZOO	MI	49008
Diploma/Degree obtained, if any				
BS - Aviation				

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
10/04 - present	[redacted] Harrington Road	Delton	MI	49046
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
Padagis			July/2021 - Present
Business Address	**City**	**State**	**Zip**
1251 Lincoln Road	Allegan	MI	49010
Phone	**Title**		
800-775-2054	Executive Vice President		
Description of Duties			
EVP - Sales, Marketing, Contracting, Distribution			

Business Name			From - To (MM/YY – MM/YY)
Perrigo Company plc			Feb 2012 - July 2021
Business Address	**City**	**State**	**Zip**
515 Eastern Ave	Allegan	MI	49010
Phone	**Title**		
1-800-719-9260	Sr. Vice President, Commercial Operations		
Description of Duties			
SVP - Sales, marketing, Contracting			

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.

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?		✔

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)

11/11/2021
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.

John Wesolowski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/2021

Date

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

State of Michigan, ss. County of Barry

I, John Wesolowski, 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

11/11/2021

Date

Subscribed and Sworn to before me this 11th day of November 2021

Notary Public Signature

Jody J May

Notary Public, Barry County, MI
My Commission Expires July 20, 2025
Acting in the County of Barry

(Seal)

Applicant's initials

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. 107308012

Application/License No. _____

Padagis South Carolina LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 110 Hidden Lake Circle, Ste. A., Duncan, SC 29334 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (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 Tower Square , Hartford, CT 06183 (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 August 25, 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 25th day of August, 2021.

APPLICANT/PRINCIPAL

Pacaris South Carolina LLC

By: _____
Authorized Representative

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SURETY COMPANY

Travelers Casualty and Surety Company of America

By: _____
Surety Company's Representative

Donna M Planeta, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness Bethany Stevenson

_____
Witness Eric Strba

Countersigned by:

_____
Nevada ~~Resident~~ Non-Resident Agent Aimee Perondine
License No. 3134182

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty 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 Donna M Planeta of Chicago , IL , their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge the following bond:

Surety Bond No.: 107308012
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Padagis South Carolina LLC
Obligee: Nevada State Board of Pharmacy

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 25th day of August , 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.

4R

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Y

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☐ No

Section 1: General Information

Facility Name: UPS SUPPLY CHAIN SOLUTIONS, INC.

Physical Address: 6200 NEW CUT ROAD

City: FAIRDALE State: KY Zip: 40118

Mailing Address (if different from physical address): 211 LAKE DRIVE, SUITE F

City: NEWARK State: DE Zip: 19702

Telephone: 502-939-5226 Website: WWW.UPS.COM

Name of Designated Representative (DR): JOSHUA MASSINGILL

Licensing Company Email: RALICENSING@UPS.COM DR Email: JMASSINGILL@UPS.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?	✓	See attachment #1
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.

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: UPS SUPPLY CHAIN SOLUTIONS, INC
Address: 6204 NEW CUT ROAD City: FAIRDALE State: KY Zip: 40118
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

N/A AL 14SEP2021

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A AL 14SEP2021

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

Section 5: Non-Publicly Traded Corporation

State of Incorporation: DELAWARE
Parent Company (if any): UNITED PARCEL SERVICE OF AMERICA, INC.
Corporation Name: UPS SUPPLY CHAIN SOLUTIONS, INC.
Mailing Address: 12380 MORRIS ROAD
City: ALPHARETTA State: GA Zip: 30005
Telephone: 678-746-4100 Email: TPAGE@UPS.COM
Contact Person Name: Thomas Page

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A AL 14SEP2021

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 See attachment #2		
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		
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 11/04/2021		

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	Partnership	Sole Owner
• **List of all Officers and Directors.** See attachment #1	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See attachment #4		✓		
• **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 **6 months.** See attachment #5	✓	✓	✓	✓
• **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/ See attachment #6		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** N/A	✓			
• **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. 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 11/04/2021		✓	✓	✓

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.

JOSHUA MASSINGILL

Print Name of Authorized Person Submitting Application

Joshua Massingill

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

04-Nov-2021

Date

Board Use Only	Date Received: _____	Amount: 500	CHECK # 1046983

Processed 1/20/22

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Third Party Logistic

NUMBER: TPL00379

EFFECTIVE DATE: 05/05/2021

EXPIRATION DATE: 06/30/2022

Issued to:
UPS SUPPLY CHAIN SOLUTIONS INC

6200 NEW CUT ROAD
FAIRDALE, KY 40118

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.

211 LAKE DRIVE
STE F
NEWARK, DE 19702

ralicensing@ups.com

State Of Delaware

Entity Details

1/21/2022 4:55:24PM

File Number: 2170882
Incorporation Date / Formation Date: 8/29/1988
Entity Name: UPS SUPPLY CHAIN SOLUTIONS, INC.
Entity Kind: Corporation
Entity Type: General
Residency: Domestic
State: DELAWARE
Status: Good Standing
Status Date: 8/29/1988

Registered Agent Information

Name: CORPORATION SERVICE COMPANY
Address: 251 LITTLE FALLS DRIVE
City: WILMINGTON
Country:
State: DE
Postal Code: 19808
Phone: 302-636-5401

Tax Information

Last AnnualReport Filed: 2020
Tax Due: $ 0
Annual Tax Assessment: $175
Total Authorized Shares: 1000

Filing History (Last 5 Filings)

Seq	Description	No of Pages	Filing Date mm/dd/yyyy	Filing Time	Effective Date mm/dd/yyyy
1	Merger [Survivor]	3	3/27/2007	12:37 PM	4/1/2007
2	Change of Agent 9000010	1	1/18/2007	3:03 PM	1/18/2007
3	Merger [Survivor]	3	4/29/2005	1:23 PM	5/1/2005
4	Restated; Domestic	2	7/1/2004	11:22 AM	7/1/2004
5	Merger [Survivor]	4	12/9/2002	10:35 AM	12/31/2002

attachment # 5

State Of Delaware

Entity Details

4/23/2021 4:13:37PM

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 #2

NABP ACCREDITED
DRUG DISTRIBUTOR

UPS Supply Chain Solutions, Inc

located at
6200 New Cut Road, Fairdale, KY 40118

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

12/14/2021 - 12/13/2024
Period of Accreditation

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	Email	% ownership
Wesley P. Wheeler **President**	12380 Morris Road Alpharetta, GA 30005	(919) 606-5575	wwheeler@ups.com	0
Thomas Page **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-3836	tpage@ups.com	0
Stephen Hydrick **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-4404	shydrick@ups.com	0
Seth Bruckner **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-7413	sbruckner@ups.com	0
William M. Jacques **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-8718	wjacques@ups.com	0

Parent Company Information:
United Parcel Service of America, Inc.
5S Glenlake Parkway NE
Atlanta, GA 30328
P ~ (404) 828 6022
FEIN ~ 95-1732075
State/Date of Incorporation ~ DE 5/9/30

Attachment #4

Attachment #6

UPS SUPPLY CHAIN SOLUTIONS, INC.

6200 NEW CUT ROAD

FAIRDALE, KY 40118

Q: Section #9

- Personal History Record Application must be completed by each shareholder/stockholder/partner/owner"

A:

"UPS Supply Chain Solutions, Inc., is a wholly owned subsidiary of United Parcel Services, Inc. (UPS). There are no owners of UPS Supply Chain Solutions"

NAME	ROLE
Joshua Massingill	Senior Facility Manager
David Hummel	Distribution Supervisor II
Michael Hamilton	Distrib Customer Care Spec
Brennan Neville	Distribution Specialist

Jefferson Cannon	Senior Warehouse Worker
Parveen Kumar	Warehouse Worker III
Andrew Stivers	Warehouse Worker III
Chad Grider	Warehouse Worker III
Gena Fleming	Warehouse Worker III
Terrance Johnson	Warehouse Worker III
Angela Dawson	Warehouse Worker II
Jacquelyn (Grace) Lee	Warehouse Worker II
Seth Toro	Warehouse Worker II

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 UPS SUPPLY CHAIN SOLUTIONS, INC.

Physical Address 6200 NEW CUT ROAD

City FAIRDALE State KY Zip 40118

Mailing Address (if different from physical address) 211 LAKE DRIVE, SUITE F

City NEWARK State DE Zip 19702

Telephone 502-939-5226 Website WWW.UPS.COM

Licensing Company Email RALICENSING@UPS.COM

Section 2: Personal Information

First JOSHUA Middle JENNINGS Last MASSINGILL

Alias(es, nicknames, name changes, etc.) JOSH MASSINGILL

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

Mailing Address [redacted] ELI DRIVE AL 14SEP2021

City LOUISVILLE State KY Zip 40291

Telephone [redacted] Email JMASSINGILL@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.)		✓

Date of Service: From: NA to: NA

Military Occupation/Specialty NA

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?	NA	NA

Applicant's initials JM

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	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Mount Caramel High School	1108 North G St	Lompoc	CA	93436	08/01 - 02/03	NA - Continued below
Mount Caramel High School	336 Spalding Lane	Cox's Creek	KY	40013	02/03 - 05/05	High School Diploma
University of Louisville	2301 S 3rd St.	Louisville	KY	40292	08/06 - 05/12	Working towards a bachelor of science in business management

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 - 11/21 Current	[redacted] Eli Drive	Louisville	KY	40291
11/15 - 03/18	[redacted] Saxony Park Circle	Louisville	KY	40299
11/14 - 11/15	[redacted] Port Captain Way	Louisville	KY	40245
08/13 - 11/14	[redacted] Mulberry Row Way	Louisville	KY	40299
11/11 - 08/13	[redacted] Eastern Parkway	Louisville	KY	40217

Applicant's initials JM

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 Healthcare		04/21 - Current 11/21	
Business Address	**City**	**State**	**Zip**
6300 New Cut Rd	Fairdale	KY	40118
Phone	**Title**	**Number of Employed Hours**	
502-939-5226	Facility Manager	1,176	
Description of Duties			
Leading and overseeing the day to day distribution operation.			

Business Name		From - To (MM/YY – MM/YY)	
UPS Healthcare		12/17 - 04/21	
Business Address	**City**	**State**	**Zip**
1920 Outerloop	Louisville	KY	40219
Phone	**Title**	**Number of Employed Hours**	
502-939-5226	Account Manager	6,720	
Description of Duties			
Overseeing and managing 3PL Rx device and drug distribution. Including controlled substances.			

Business Name		From - To (MM/YY – MM/YY)	
UPS Healthcare		02/15 - 12/17	
Business Address	**City**	**State**	**Zip**
1920 Outerloop	Louisville	KY	40219
Phone	**Title**	**Number of Employed Hours**	
502-939-5226	Distribution Supervisor	5,544	
Description of Duties			
Overseeing and managing 3 PL Rx device and drug distribution. Including controlled substances.			

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

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

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

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

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description 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.)		✓ JM
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	NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓ JM
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.)		✓ JM
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?		✓ JM
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)?		✓ JM
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓ JM
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.		✓ JM
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).		✓ JM
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?		✓ JM

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 JM

I, JOSHUA MASSINGILL, **certify that as the designated representative for**

UPS SUPPLY CHAIN SOLUTIONS, INC., 6200 NEW CUT ROAD, FAIRDALE, KY 40118,

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

JOSHUA MASSINGILL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04-Nov-2021

Date

Applicant's initials JM

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.

JOSHUA MASSINGILL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04-Nov-2021

Date

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

State of DELAWARE, ss. County of NEW CASTLE

I, AMY BETH LUCATAMO, 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)

Applicant's initials

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 <u>not</u> 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

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 Ringuist
Agent of the Board

BEFORE THE IOWA BOARD OF PHARMACY

Re: Wholesale Drug License of **UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,** License No. 5820 Respondent	))))))	Case No. 2010-162 **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

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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 21st 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 21st 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: 10/4/13

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

9/12/12
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 H. 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

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. E656814

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
6200 New Cut Road Fairdale, KY 40118, 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
6200 New Cut Road Fairdale, KY 40118 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 05/14/2021.
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 13th day of May, 2021

APPLICANT/PRINCIPAL

Authorized Representative

Jennifer Powers
Asst. Treasurer

SURETY COMPANY

Surety Company's Representative

Lisa Gelsomino, 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

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. E656814

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. 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 13th day of May , 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 13th day of May , 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 13th day of May , 2021 .

Assistant Secretary

4S

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: AmerisourceBergen Drug Corporation

Physical Address: 4860 Indianapolis Rd.

City: Whitestown State: IN Zip: 46075

Mailing Address (if different from physical address): Legal Dept. – Licensing, 1 West First Avenue

City: Conshohocken State: PA Zip: 19428

Telephone: (317) 769-1465 Website: www.amerisourcebergen.com

Name of Designated Representative (DR): Christopher Lysdahl

Licensing Company Email: ABDCDrugLicensing@amerisourcebe DR Email: Clysdahl@amerisourcebergen.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: Specialty Pharmacies/Distributors, Military, Long	☒ Others: OTC Medications

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

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 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/in 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

State of Incorporation: DE

Parent Company (if any): AmerisourceBergen Services Corporation

Corporation 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: John G. Chou

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 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 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**	✓			
• **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.

John Chou

Print Name of Authorized Person Submitting Application

J. D. Chou

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

9.14.21

Date

Board Use Only	Date Received: _____	Amount: 500 Check # 14323	Processed 10/15/21

AmerisourceBergen

AmerisourceBergen Drug Corporation ("ABDC"), is part of the AmerisourceBergen Corporations. AmerisourceBergen Drug Corporation is a National Wholesale Distributor located in Whitestown, IN. ABDC is a distributor of specialty health care products such as prescription drugs, OTC medications, Controlled Substances (Class II-Class V), and medical devices, across the United States. ABDC's hours of operation are 24 Hours Monday – Thursday and Sunday as well as 8:00 a.m. – 5:00 p.m. EST on Friday and 9:00 a.m. – 5:00 p.m. EST. ABDC distributes products to specialty pharmacies, wholesalers, specialty distributors, hospital pharmacies, retail pharmacies, physician offices, long term care/assisted living facilities, military, and repackagers.

AmerisourceBergen Drug Corporation
4860 Indianapolis Rd., Whitestown, IN 46075
Christopher Lysdahl: (317) 769-1465

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

License Number	Expire Date
48002236A	09/30/2022

AmerisourceBergen Drug Corporation

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
48002236A	**09/30/2022**

AmerisourceBergen Drug Corporation

Signature

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

CSR

Registration Number	Expire Date
61101405B	12/31/2021

DRUG SCHEDULES

1	2	2N	3	3N	4	5
	Yes	Yes	Yes	Yes	Yes	Yes

AmerisourceBergen Drug Corporation

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
61101405B	**12/31/2021**

AmerisourceBergen Drug Corporation

Signature

State of Indiana

DEMOGRAPHIC INFORMATION

Name: AmerisourceBergen Drug Corporation

ADDRESS INFORMATION

Line 1:
Line 2: 4860 Indianapolis Road
City/State/Zip: Whitestown IN 46075
County: Boone

LICENSE INFORMATION

Lic #:	48002236A	Profession:	Pharmacy Board	Type:	Wholesale Drug Distributor	Secondary:	
Status:	Active	Issued:	8/10/2016	Expiration:	9/30/2022		
Method:	Application						

DISCIPLINE INFORMATION

-

RELATED LICENSES

No Related Licenses

DOCUMENTS

No Public Documents Available

State of Indiana

DEMOGRAPHIC INFORMATION

Name: AmerisourceBergen Drug Corporation

ADDRESS INFORMATION

Line 1:
Line 2: 4860 Indianapolis Road
City/State/Zip: Whitestown IN 46075
County: Boone

LICENSE INFORMATION

Lic #:	61101405B	Profession:	Pharmacy Board	Type:	CSR	Secondary:	Wholesale Distributor
Status:	Active	Issued:	11/10/2016	Expiration:	12/31/2021		
Method:	Application						

DISCIPLINE INFORMATION

-

RELATED LICENSES

No Related Licenses

LICENSE CSR INFORMATION

Drug Schedule 1:	No	Drug Schedule 2:	Yes	Drug Schedule 2n:	Yes
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:	11/10/2016	Inspection Grade:	Pass
Inspection Type:	Controlled Substances Inspection Report	Inspection Date:	1/20/2021	Inspection Grade:	Pass
Inspection Type:	Controlled Substances Inspection Report	Inspection Date:	9/27/2017	Inspection Grade:	Pass

DOCUMENTS

No Public Documents Available

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 TWENTIETH DAY OF DECEMBER, A.D. 2021.

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# 20214163435

Authentication: 205036444

Date: 12-20-21

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

AMERISOURCEBERGEN DRUG CORPORATION
4860 INDIANAPOLIS RD
WHITESTOWN, IN 46075-9533

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0509490	07-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	DISTRIBUTOR	06-17-2021

AMERISOURCEBERGEN DRUG CORPORATION
4860 INDIANAPOLIS RD
WHITESTOWN, IN 46075-9533

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
RA0509490	07-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	DISTRIBUTOR	06-17-2021

AMERISOURCEBERGEN DRUG CORPORATION
4860 INDIANAPOLIS RD
WHITESTOWN, IN 46075-9533

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)

787

NABP ACCREDITED

DRUG DISTRIBUTOR

AmerisourceBergen Drug Corporation

located at

4860 Indianapolis Rd, Whitestown, IN 46075

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

07/22/2019 - 07/21/2022
Period of Accreditation

Verified 1/20/22
MS

Wholesale Distributor and Third-Party Logistics Providers Reporting

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/WDD3PLREPORTING/WDD.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDERS REPORTING&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/WDD3PLREPORTING/WDD.CFM)

+

EMAIL (MAILTO:?SUBJECT=WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDERS REPORTING&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/WDD3PLREPORTING/WDD.CFM)

About this Database (https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm) | Back to Search Page (index.cfm)

Search Results for: "amerisourcebergen drug corporation"

Show 10 rowsCSV

Filter:

Facility Name	Facility Type	License Number	License State	License Expire	Reporting Year	Address	Facility Contact Name	Facility Contact Email
AmerisourceBergen Drug Corporation	WDD	7118	US-CA	05/01/2022	2021	7775 W Buckeye Road STE 150 Phoenix AZ	Francis Zagarrigo	fzagarrigo@amerisourcbergen.com
Amerisourcebergen Drug Corporation	WDD	OSD4609	US-CA	06/01/2021	2021	501 W 44th Ave Unit 1 Denver CO	Kate Gordon	kgordon@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	OSD4598	US-CA	06/01/2021	2021	238 Sand Island Access Rd. M-1 Honolulu HI	James Sutherland	jsutherland@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	OSD7169	US-CA	10/01/2021	2021	4860 Indianapolis Road Whitestown IN	Krystal Echavarria	KEchavarria@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	OSD6962	US-CA	11/01/2021	2021	10910 Lee Vista Boulevard Suite 401 Orlando FL	Marisol Olmo	molmo@amerisourcebergen.com

Verified 1/20/22 MS

Facility Name	Facility Type	License Number	License State	License Expire	Reporting Year	Address	Facility Contact Name	Facility Contact Email
Amerisourcebergen Drug Corporation	WDD	WHI.0006014	US-CO	10/31/2022	2021	501 W 44th Ave Unit 1 Denver CO	Kate Gordon	kgordon@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	WHO.0008237	US-CO	10/31/2022	2021	7775 W Buckeye Road STE 150 Phoenix AZ	Francis Zagarrigo	fzagarrigo@amerisourcbergen.com
AmerisourceBergen Drug Corporation	WDD	CSW.0004943	US-CT	06/30/2022	2021	4860 Indianapolis Road Whitestown IN	Krystal Echavarria	KEchavarria@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	dm9400192	US-DC	03/31/2021	2021	9900 J.E.B. Stuart Parkway Glen Allen VA	Diane Coffey	dcoffey@amerisourcebergen.com
AmerisourceBergen Drug Corporation	WDD	A4-0001124	US-DE	09/30/2022	2021	9900 J.E.B. Stuart Parkway Glen Allen VA	Diane Coffey	dcoffey@amerisourcebergen.com

Showing 11 to 20 of 179 entries
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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 1300 Morris Drive, Chesterbrook, PA 19087.

OFFICERS

NAME	TITLE
Steven H. Collis	Chief Executive Officer
John G. Chou	EVP and Special Advisor to the Chairman & CEO
James F. Cleary, Jr.	Executive Vice President, Chief Financial Officer
John F. Quinn, Jr.	Senior Vice President & Treasurer

PERSONAL AND CONFIDENTIAL *– Do not reproduce without the express written consent of AmerisourceBergen Drug Corporation*

ASD Healthcare
AmerisourceBergen

Employee List

Steven Collis, CEO

James Cleary, Jr., Executive VP and CFO

John G. Chou, Executive VP, General Counsel, Secretary

John F. Quinn, Jr., Senior Vice President, Corporate Treasurer

Christopher Lysdahl, Warehouse Manager, Designated Rep

Krystal Echavarria, Manager, Regulatory Compliance

Jennifer M. Aldred, Licensing Specialist

Christopher Lysdahl

[redacted]N. East St. | Westfield, IN. 46074 | Cell Phone [redacted]
E-mail clysdahl@amerisourcebergen.com

Objective

To obtain a Director of Operations position within AmerisourceBergen that will challenge me, as well as, broaden my understanding of the business and allow me to use my 20+ years of team leadership and 5+ years continuous improvement background to lead a high performing team.

Qualifications

- Recognized for commitment to customers, dedication, attention to detail, professionalism and follow-up
- Use clear, concise communication skills in conjunction with organizational skills to perform daily duties
- Successfully completed several leadership development courses such as: Behavioral Interviewing, Confrontation Management, and Leading High Performing Teams
- Familiar with the use and implementation of continuous improvement tools and also have obtained Lean Six Sigma green belt program through ASU

Skills

- Leadership/Supervision
- Problem Solving and root cause analysis
- Quality and Productivity Improvement – Lean Six Sigma Green Belt with 6 years of continuous improvement experience
- Organizational Development and experience building strong/diverse teams
- Motivating, and engaging teams to reach maximum output potential

Work Experience

AmerisourceBergen

Day Operations Manager – Indianapolis DC, October 2019 – Present

- Manage all day-shift operations to include leading the receiving, stocking, and slotting teams
- Order and manage supplies for the warehouse operation
- Ensure all compliance and safety trainings are completed in a timely manner

Continuous Improvement Manager, January 2016 – October 2019

- Manage the kickoff of continuous improvement projects at AmerisourceBergen's distribution centers while teaching DC teams about the tools and show where and when it's appropriate to use them

- Work with the Sr. Director of Continuous Improvement and the rest of the CI Managers, to keep training material used at the DCs standardized and relevant
- Work closely with the DCs Director of Operations to build and implement a custom continuous improvement program specific to the Distribution Center
- Work with the distribution center after the initial 10 week kickoff phase to ensure gains are sustained and to help identify or offer support to any new CI projects

AmerisourceBergen, Phoenix, AZ.

Inventory Manager, October 2013 – January 2016

- Responsible for managing returns, slot moves, exceptions, and outdate programs at the Phoenix DC
- Make sure the Inventory aspects of the DC stay within the compliance guidelines set forth by the CSRA department, as well as complete any SOX audit controls
- Lead the yearly physical inventory at the Phoenix DC
- Work with operations to ensure the highest standards for quality control through the resolution and reporting of receiving, stocking and pick errors

AmerisourceBergen, Phoenix, AZ.

Warehouse/Shipping Supervisor, April 2011 – October 2013

- Responsible for nightly warehouse and shipping operations.
- Balance labor force to ensure on-time deliveries within tight dispatch timeframes
- Train employees on all safety, security, and Standard Operating Procedures
- Track and enforce all productivity standards

Express Scripts, Tempe, AZ.
Warehouse/Receiving Supervisor, September 2006 – November 2010

- Responsible for ensuring all pharmaceuticals are unloaded and received in a timely manner to ensure that no patients prescription gets delayed
- Manage labor hours in order to stay within the confines of specified budget
- Establish, track and enforce productivity and quality standards for team
- Manage warehouse inventory by rotating stock, cycle counting product, and random audits to ensure compliance with all company policies and procedures
- Develop work instructions, and routinely update corporate policies and procedure documents to ensure consistent and predictable processes
- Involvement in Lean Kaizen events to improve productivity and minimize process waste
- Worked closely with inventory, expedite, and purchasing departments to ensure inventory levels were optimal (helped reduce the amount of inventory held in the warehouse by 40% by identifying slow-moving drug, and overstock)

Forward Air Inc., Groveport, OH
Dock Worker, November 2003 – September 2006

- Unload freight off inbound trucks and bring to the staging area
- Load outbound trucks to ensure no damaged freight in transit to destination
- Create manifests and print bills for shipments

Michelina's Inc., Jackson, OH
Dock/Freezer Supervisor, April 2003-November 2003

- Responsible for enforcement of all safety, attendance and productivity standards
- Trained all new employees on proper use of equipment and safety policies
- Monitored inventory reports for discrepancies, investigated the causes of any issues and took corrective action as needed
- Inspected products for priority shipments

Fleming Co., Superior, WI
Shipping Supervisor, October 2001-April 2003

- Supervised up to 90 employees
- Enforced all safety, productivity and quality standards
- Ensured all pick orders were completed and loaded in a timely manner for the load to depart by the dispatch time
- Monitored man hours spent in order to stay within the confines of the budget set forth
- Given the responsibility of training all new supervisors after one year in a supervisory role

Warehouse Trainer, February 2001-October 2001

- Trained all new employees on proper company policies and procedures
- Ensured proper use of equipment, as well as safe handling of product

Order Clerk, August 1999-February 2001

- Entered and issued all pick orders to dock employees
- Monitored productivity reports and reported violations to supervisors
- Tracked inventory in computer to find lost or misplaced product

Northman Security, Superior, WI
Security Guard, August 1998-August 1999

- Provided Fleming Co. with physical security, controlling entry and exit to the facility
- Inspected and tested sprinkler systems, and ensured compliance with safety standards

Military Training
Security Specialist, March 1994-March 1998
United States Air Force, Barksdale Air Force Base, LA

- Guarded the highest priority of Air Force resources
- Selected to join the Elite Gate guard section for Airmen with impeccable appearance and military bearing

- Response force leader responsible for deploying force team members to deny unauthorized access to restricted areas
- In four years of service, was awarded the Achievement Medal, National Defense Service Medal, NATO Medal, and the Armed Forces Service Medal
- Contributed to two Outstanding Unit Awards

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 AmerisourceBergen Drug Corporation

Physical Address 4860 Indianapolis Rd.

City Whitestown State IN Zip 46075

Mailing Address (if different from physical address) Legal Dept. – Licensing, 1 West First Avenue

City Conshohocken State PA Zip 19428

Telephone (317) 769-1465 Website www.amerisourcebergen.com

Licensing Company Email ABDCDrugLicensing@amerisourcebergen.com

Section 2: Personal Information

First Christopher Middle David Last Lysdahl

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

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

Mailing Address 4860 Indianapolis Rd.

City Whitestown State IN Zip 46075

Telephone (317) 769-1472 Email Clysdahl@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.)		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: 1994 to: 1998

Military Occupation/Specialty 3P051 Security Police

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?	x	

Applicant's initials

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)	
Superior Senior High School		1990-1993	
Address	**City**	**State**	**Zip**
2600 Catlin Ave	Superior	WI	54880
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
3/1/2020	353 N. East St.	Westfield	IN	46074
10/2020-3/2020	1370 Quail Run Court	Zionsville	IN	46077
3/2020-4/2019	4877 W Carla Visa Court	Chandler	AZ	85224
4/2014-4/2019	8301 E. Indianola Avenue	Scottsdale	AZ	85054
10/2018-4/2014	3232 W. Maldonado Road	Phoenix	AZ	85041
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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		April 2011-Present
Business Address	**City**	**State / Zip**
See attached resume		
Phone	**Title**	**Number of Employed Hours**
317-769-1472	Warehouse Manager, Inventory Manager, Warehouse Supervisor	Est. 20K Hours
Description of Duties		

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

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

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

08/23/21
Date

Applicant's initials

I, Christopher Lysdahl, **certify that as the designated representative for**

AmerisourceBergen Drug Corporation,

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

Christopher Lysdahl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/23/21

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.

Christopher Lysdahl
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/23/21
Date

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

State of Indiana, ss. County of Boone

I, Christopher Lysdahl, 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

08/23/21
Date

Subscribed and Sworn to before me this 23rd day of Aug. 2021.

Notary Public Signature

ANNETTE E SPRINGER
Seal
Notary Public – State of Indiana
Hamilton County
My Commission Expires Feb 14, 2025

(Seal)

Applicant's initials

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. 08861011

Application/License No. _____

AMERISOURCEBERGEN CORPORATION (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1300 Morris Drive Chesterbrook, PA 19087 (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 MD (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 9/20/2006 (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 20th day of September, 2006.

APPLICANT/PRINCIPAL
AMERISOURCEBERGEN CORPORATION

_____
Authorized Representative

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

_____
Surety Company's Representative

Wayne G. McVaugh, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness Sandra Bronson

_____
Witness

Countersigned by:

_____
Nevada Resident Agent

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 G. 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. #MI, 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, NC 27560
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 345 International Blvd. Suite 400A, Brooks, KY 40109 2811 Horace Shepard Drive., Dothan, AL 36303 5566 Arrow Hwy, Montclair, CA 91763
Integrated Commercialization Solutions, LLC:	1195 Trademark Drive, #102-B Reno, NV 8951 6450 LaSalle Drive, Suite B/D Lockbourne, OH 43137 167 International Blvd., STE A, Brooks, KY 40109 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.

SEAL

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 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

4T

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

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

Is your facility a reverse distributor? ☐ Yes ☑ No

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*	WH 02089	☑ 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)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: DEN-MAT HOLDINGS, LLC

Physical Address: 1017 W. CENTRAL AVE

City: LOMPOC State: CA Zip: 93436

Mailing Address (if different from physical address): PO BOX 1729

City: LOMPOC State: CA Zip: 93438

Telephone: (805) 346-3700 Website: www.denmat.com

Name of Designated Representative (DR): Nicholas Gonzales

Licensing Company Email: denmatlicense@denmat.com DR Email: ngonzales@denmat.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.

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: DENTAL TECHNOLOGIES INC
Address: 6901 N. HAMLIN AVE City: LINCOLNWOOD State: IL Zip: 60712

Name: BSOLVE DENTAL
Address: 2 BELL DRIVE City: BLANTYRE, GLASGOW State: U.K. Zip: G72 0FB

Name: MEDICAL PRODUCTS LAB
Address: 9990 GLOBAL ROAD City: PHILADELPHIA State: PA Zip: 19115

Name: XTTRIUM LABORATORIES INC.
Address: 1200 E. BUSINESS CENTER DR City: MT PROSPECT State: IL Zip: 60056

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): DMHP LLC
Corporation/Organization Name: DEN-MAT HOLDINGS, LLC
Mailing Address: PO BOX 1729
City: LOMPOC State: CA Zip: 93438
Telephone: (805) 346-3700 Email: denmatlicense@denmat.com
Contact Person Name: Carol Newberry

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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/.		✓	✓	✓

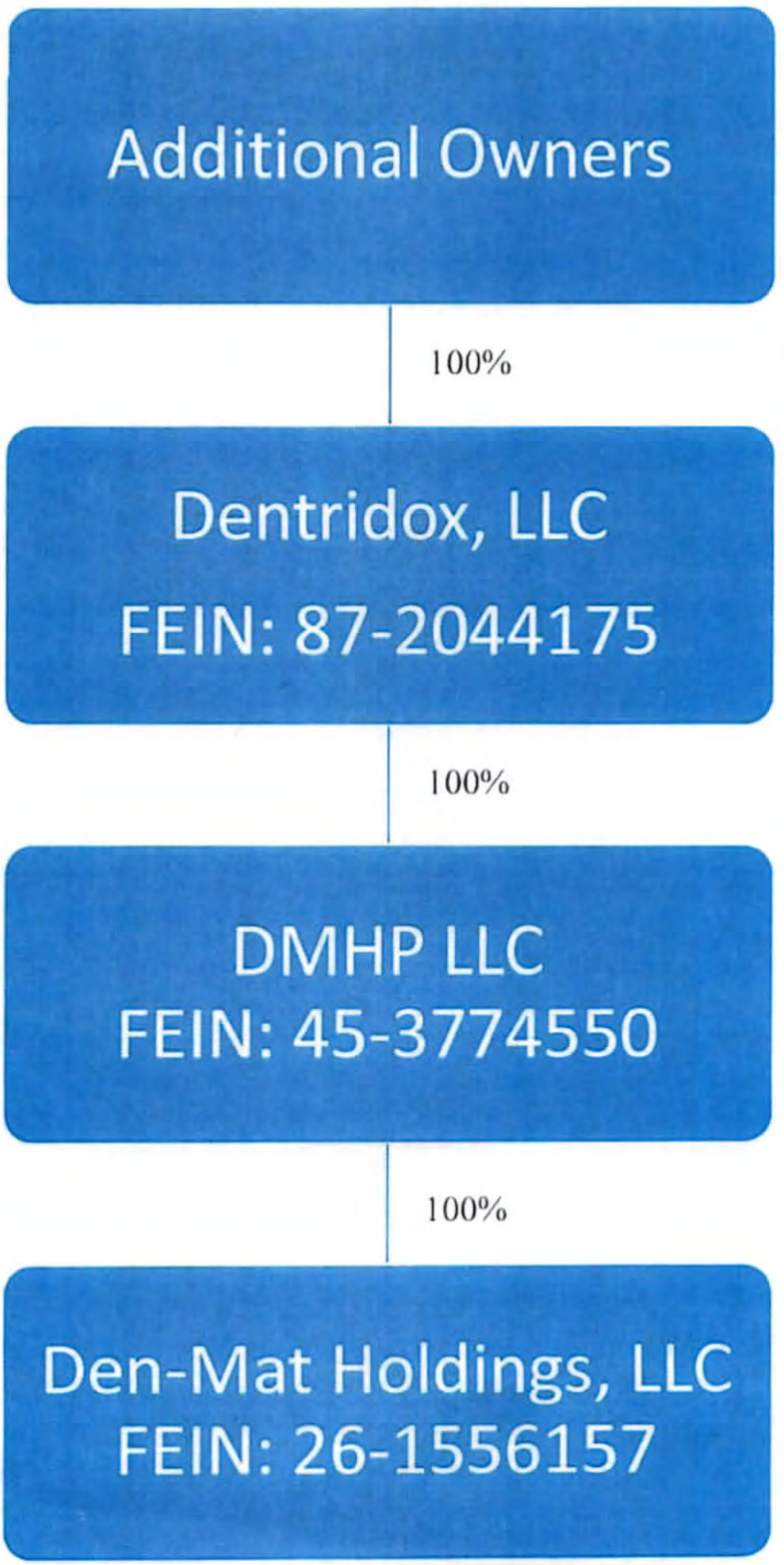
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application 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.

Robert Cartagena
Print Name of Authorized Person Submitting Application

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

8 DEC 2021
Date

Board Use Only	Date Received: _____	Amount: 500 CC	Processed 1/25/22


Additional Owners
100%
Dentridox, LLC
FEIN: 87-2044175
100%
DMHP LLC
FEIN: 45-3774550
100%
Den-Mat Holdings, LLC
FEIN: 26-1556157

The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®

Accreditation

to

Den-Mat Holdings, LLC

located at

1017 W Central Ave, Lompoc, VA 93436

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 28, 2019 - April 27, 2022

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | *www.nabp.pharmacy*

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
DEN-MAT HOLDINGS, LLC
1017 W Central Ave
Lompoc , CA 93436
Registration Number: 2018957
FEI Number*: 2018957
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
DEN-MAT HOLDINGS, LLC
1017 W. CENTRAL AVENUE
Lompoc, CA US 93436
Owner/Operator Number: 2018957

Official Correspondent:
Tom Juarez
Den-Mat Holdings, LLC
1017 W. CENTRAL AVENUE
Lompoc, CA 93436
Phone: 805-3463700-3780

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 02/08/2021

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	DEN-MAT HOLDINGS, LLC
California Name:	DEN-MAT HOLDINGS, LLC
File Number:	200719410193
Registration Date:	07/10/2007
Entity Type:	FOREIGN LIMITED LIABILITY COMPANY
Jurisdiction:	DELAWARE
Status:	ACTIVE (GOOD STANDING)

As of November 14, 2021 (Certification Date), the entity is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect 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 November 15, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: RXB1WLY

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at bebizfile.sos.ca.gov/certification/index.

Wholesale Drug Permit

Renewal License

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. WLS 6457
RECEIPT NO. 00175190

VALID UNTIL OCTOBER 01, 2022

DEN-MAT HOLDINGS LLC
1017 WEST CENTRAL AVE
LOMPOC CA 93436

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

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) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

09/01/21

09/01/21 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

DenMat

OFFICERS OF DEN-MAT HOLDINGS, LLC

David Casper
Chief Executive Officer
O: (805) 346-3710
C: [redacted]

Robert Cartagena
Chief Operating Officer
O: (805) 346-3720
C: [redacted]

Timothy Heher
Chief Financial Officer
O: (805) 346-3740
C: [redacted]

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DEN-MAT HOLDINGS, LLC

Physical Address 1017 W. CENTRAL AVE

City LOMPOC State CA Zip 93436

Mailing Address (if different from physical address) PO BOX 1729

City LOMPOC State CA Zip 93438

Telephone (805) 346-3700 Website www.denmat.com

Licensing Company Email denmatlicense@denmat.com

Section 2: Personal Information

First Nicholas Middle Anthony Last Gonzales

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] Wilson Drive

City Santa Maria State CA Zip 93455

Telephone [redacted] Email ngonzales@denmat.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 _____

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 PHOENIX		06/02 - 11/10	
Address	**City**	**State**	**Zip**
3110 E. Guasti Rd.	Ontario	CA	91761
Diploma/Degree obtained, if any			
BSB/M			

School Name		From - To (MM/YY – MM/YY)	
Sierra Vista High School		09/84 - 06/88	
Address	**City**	**State**	**Zip**
3600 Frazier St.	Baldwin Park	CA	91706
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)	
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
09/20 - Present	[redacted] Wilson Drive	Santa Maria	CA	93455
10/14 - 09/20	412 E. Alvin	Santa Maria	CA	93454
10/13 - 10/14	13127 Francisquito Ave	Baldwin Park	CA	91706
6/01 - 10/13	7560 Malven Ave	Rancho Cucamonga	CA	91730
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
DEN-MAT HOLDINGS, LLC			11/14 - Present
Business Address	**City**	**State**	**Zip**
1017 W. CENTRAL AVE	LOMPOC	CA	93436
Phone	**Title**		**Number of Employed Hours**
(805) 346-3700	V.P., MANUFACTURING		14,560
Description of Duties			
Responsible for daily activities of all manufacturing, receiving, warehouse, and shipping.			

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			

Continue on next page if additional space is needed.

Applicant's initials _____

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

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

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

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

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 # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/05/2006		CA	Baldwin Park	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
6PK02221		CHP - Baldwin Park Station		
Reason/Charge				
23152(A) VC MISD				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Defendant - Nicholas Anthony Gonzales				
Name of Business/Industry/Entity				

Provide explanation below:

In March of 2006, I was arrested for driving under the influence. I went out to dinner with friends and consumed a couple of drinks, then switched to drinking coffee. I thought I was okay to drive home. I was pulled over on the freeway and the officer asked me if I had been drinking. I replied that I had two drinks with dinner earlier in the evening and was asked to submit to a sobriety test. I failed the sobriety test and was arrested. I went to court in April of 2006 and was convicted of 23152(a) Driving Under the Influence. I was sentenced to probation and required to take some classes, which I completed successfully. I was also required to pay a fine, which has been paid in full.

Original Signature (electronic, copies or stamps not accepted)

14-DEC-21
Date

Applicant's initials

I, Nicholas Anthony Gonzales, **certify that as the designated representative for** DEN-MAT HOLDINGS, 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

Nicholas Gonzales

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13-DEC-21

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.

Nicholas Gonzales

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13-DEC-21

Date

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

State of California, ss. County of Santa Barbara

I, Nicholas Anthony Gonzales, 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-DEC-21

Date

Subscribed and Sworn to before me this _____ day of _____.

Notarization Attached

Notary Public Signature

(Seal)

Applicant's initials

CALIFORNIA JURAT WITH AFFIANT STATEMENT

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 Barbara

Subscribed and sworn to (or affirmed) before me this 14th day of December 2021, by Nicholas Gonzales, proved to me on the basis of satisfactory evidence to be the person who appeared before me.

CAROL G. NEWBERRY
Notary Public - California
Santa Barbara County
Commission # 2303250
My Comm. Expires Sep 23, 2023

Notary Public

Last	First	Job Title Description	Business Unit Description
Fonseca	Sadie	Accounts Payable Clerk	Accounting
Terrones	Yvette	Accounting Associate-AR	Accounting
Eccles	Aleca	Accounting Associate-AR	Accounting
Rodriguez	Alex	Collections Specialist	Accounting
Lewis	Kellie	Accounting Associate-AP	Accounting
Hastin	Kayla	Lead, Accounting Associate A/R	Accounting
Delgado	Linda	Payroll Administrator	Accounting
Fonseca	Marcy	Supervisor, A/R & Collections	Accounting
Lengele	Sharon	Accounting Manager	Accounting
Chavez	Richard	Controller	Accounting
Heher	Tim	Chief Financial Officer	Accounting
Newberry	Carol	VP Executive Administration	Administration
Cartagena	Bobby	Chief Operating Officer	Administration
Casper	Dave	Chief Executive Officer	Administration
Paniagua	Steven	Compounder	Compounding
Garcia	Fernando	Sr. Lead, Compounder	Compounding
Leake	Amanda	Customer Care Advisor	Customer Care
McDonough	Maddie	Customer Care Advisor	Customer Care
Sparks	Andria	Customer Care Advisor	Customer Care
Velotta	Brittany	Customer Care Advisor	Customer Care
Grim	Jimmy	Customer Care Advisor	Customer Care
Powell	Tally	Customer Care Advisor	Customer Care
Sciurba	Sonia	Customer Care Advisor	Customer Care
Tuck	Rebekah	Customer Care Advisor	Customer Care
Williams	Amanda	Sr. Customer Care Advisor	Customer Care
Barajas	Carey	Sr. Customer Care Advisor	Customer Care
Villagomez	Rey	Customer Care Advisor	Customer Care
Stevenson	Jake	Sr. Customer Care Advisor	Customer Care
Tuck	Aaron	Sr. Customer Care Advisor - SDP	Customer Care
Guzman	Vanessa	Lead, Customer Care Advisor	Customer Care
Alvarado	Caritina	Manager, Customer Care	Customer Care
Burch	Mayra	Lightroom Assembler	Equipment Lasers/Curing Light
Orozco	Robert	Lightroom Technician	Equipment Lasers/Curing Light
Segura	Elizabeth	Lightroom Assembler	Equipment Lasers/Curing Light
Nielson	Lane	Lightroom Assembler	Equipment Lasers/Curing Light
Minano Pacheco	Pedro	Lightroom Assembler	Equipment Lasers/Curing Light
Cisneros Negrete	Rosa	Lightroom Technician	Equipment Lasers/Curing Light
Diaz Hernandez	Maria	Lead, Lightroom & PeriOptix	Equipment Lasers/Curing Light
Lopez	Suzie	Supervisor, Light Room	Equipment Lasers/Curing Light
Calderon	Javier	Equipment Operator	Filling
Concepcion	Lalaine	Packager - Filling	Filling
Corona Almaraz	Maria	Packager - Filling	Filling
Cruz Hernandez	Lilia	Packager - Filling	Filling
Garza	Erika	Document Associate	Filling
Hernandez	Claudia	Packager - Filling	Filling
Salguero	Veronica	Material Handler	Filling
Morales	Marta	Sr. Document Associate	Filling
Cabacungan	Cristina	Packager - Filling	Filling
Minano	Mariela	Lead, Packager	Filling
Morss	Gigi	Supervisor, Packaging	Filling
Rayas	Zuleima	Manufacturing Technician	Final Assembly
Rayas Arellano	Adilenne	Manufacturing Technician	Final Assembly
Gutierrez	Silvia	Packager - Final Assembly	Final Assembly
Love	Jason	Manufacturing Technician	Final Assembly

Morales	Diana	Packager - Final Assembly	Final Assembly
Montes	Juan	Manufacturing Technician	Final Assembly
Escamilla	Angie	Packager - Final Assembly	Final Assembly
Garcia	Fatima	Packager - Final Assembly	Final Assembly
Martinez Jr	Michael	Personalization Associate	Final Assembly
Rayas	Vanessa	Material Handler	Final Assembly
Sanchez	Mayra	Team Lead, Final Assembly	Final Assembly
Valdez	Cecilia	Packager, Special	Final Assembly
Almazan	Priscila	Team Lead, Impressions	Final Assembly
Rocha	Silvia	Team Lead, Final Assembly	Final Assembly
Barragan	Maria	Team Lead, Manufacturing Technician	Final Assembly
Noriega Madrid	Sandra	Document Associate	Final Assembly
Tirado	Salve	Material Handler	Final Assembly
Vargas	Sandra	Lead, Production Final Assembly	Final Assembly
Meza Ramirez	Jesus	Supervisor, Production Final Assembly	Final Assembly
Lauderdale	Stacy	Human Resources Manager	Human Resources
Pengilly	Lisa	IT Specialist	Information Technology
Borg	Cindy	Sr. Manager, IT Applications	Information Technology
Wade	Kyle	Sr. Manager, Network & Telecom	Information Technology
Parks	Greg	Sr. Director, I.T.	Information Technology
Sirangua Ramirez	Maria	Prep Guide Technician	Lab ART
Cole	Mylin	Sr. Prep Guide Technician	Lab ART
Cox	Chelsea	Administrative Assistant - Lab	Lab Core
Ensor	Mellissa	Model Evaluation Technician	Lab Core
Anaya	Angelica	Sr. Model Evaluation Technician	Lab Core
Cortes	Fabiola	Sr. Model Evaluation Technician	Lab Core
Cooper	Michael	Sr. Model Eval Technician/Consultant	Lab Core
Atiles	Kathy	Sr. Manager, Laboratory Operations	Lab Core
Limon	Rebeca	Customer Care Representative - Lab	Lab Customer Service
McHugh	Carla	Sr. Customer Care Representative - Lab Ortho	Lab Customer Service
Savey	Becca	Sr. Customer Care Rep - Lab	Lab Customer Service
Oliveira	Christina	Sr. Customer Care Rep - Lab	Lab Customer Service
Morales	Annamarie	Sr. Customer Care Rep - Implant Consultant	Lab Customer Service
Campbell	April	Supervisor, Lab Customer Care	Lab Customer Service
Sanchez Zaragoza	Janette	CAD/CAM Scanner - Core	Lab Design Core
Buenrrostro	Marcos	Supervisor, Digital Design	Lab Design Core
Montes	Leo	CAD/CAM Associate	Lab Design SOS
Hernandez-Lerena	Efreen	CAD/CAM Technician	Lab Design SOS
Riewaldt	Crystal	Order Entry Associate	Lab Entry/Ship/Rcvg
Lopez	Marylinn	Sr. Order Entry Associate	Lab Entry/Ship/Rcvg
Ceja	Erika	Lead, Expediter	Lab Expediting
Samayoa	Ivis	Stain & Glaze Technician	Lab Finishing Core
Diaz	Stephanie	Ceramist	Lab Finishing Core
Gregory	Christine	Ceramist	Lab Finishing Core
Fernandez	Michael	Ceramist	Lab Finishing Core
Koroni	Michael	Ceramist II	Lab Finishing Core
Bae	Mi Ja	Ceramist II	Lab Finishing Core
Shalit	Yelena	Ceramist	Lab Finishing Core
Ramirez	Juanita	Ceramist II	Lab Finishing Core
Ostapiuk	Steve	Sr. Ceramist	Lab Finishing Core
Oh	Paul	Sr. Ceramist	Lab Finishing Core
Gray	Trisha	Sr. Supervisor, Production & Order Entry	Lab Finishing Core
Ceja	Omar	Sr. Dental Appliance Technician	Lab Finishing SOS
Ramos	Joe	Sr. Lead, Dental Appliance Technician	Lab Finishing SOS
Garcia	Alex	Invest/Press Technician	Lab Invest/Press Core

Hernandez-Aguilar	Emiliano	Sr. Invest Press Technician	Lab Invest/Press Core
Diaz Torres	Daniel	Milling & 3D Printing Technician	Lab Milling SOS
Napoles Quevedo	Jose	Milling & 3D Printing Technician	Lab Milling/Printing
Martinez - Gomez	Javier	Lead, Milling & 3D Printing Technician	Lab Milling/Printing
McDaniel	Aaron	Supervisor, Lab Production	Lab Milling/Printing
Buenrostro Corral	Oscar	Supervisor, Production & SOS FInishing	Lab Milling/Printing
Robinson	Robert	Model Worker	Lab Model Prep
Ayala	Salvador	Sr. Lead, Model Worker	Lab Model Prep
Barajas Rodriguez	Manny	Ortho Aligner Technician	Lab Ortho
Bobo	Yessica	Ortho Aligner Technician	Lab Ortho
Halls	Jason	CAD/CAM Technician	Lab Ortho
Navarro	Alex	Ortho Aligner Technician	Lab Ortho
Lopez	Griselda	Ortho Aligner Technician	Lab Ortho
Cheney	Kayla	Ortho Aligner Technician	Lab Ortho
Jarquin	Chris	Ortho Aligner Technician	Lab Ortho
Vang	Tou	Ortho Aligner Technician	Lab Ortho
Cheney	Albert	Ortho Aligner Technician	Lab Ortho
Welch	Matthew	Lead, CAD/CAM Technician - Ortho	Lab Ortho
Stevenson	Joe	Assistant Supervisor, Lab Ortho	Lab Ortho
Moore	Kathy	Dental Appliance Technician	Lab PerioTray
Ayuso Santos	Misael	CAD/CAM Associate	Lab PerioTray
Diaz-Magdaleno	Lily	CAD/CAM Associate	Lab PerioTray
Diaz-Magdaleno	Michelle	CAD/CAM Associate	Lab PerioTray
Soto Jr	Vicente	CAD/CAM Associate	Lab PerioTray
Bumatay	Jason	Dental Appliance Technician	Lab PerioTray
de Diaz	Leticia	Dental Appliance Technician	Lab PerioTray
Orozco	Selena	Quality Control Technician	Lab QC Core
Noum	Rose	Quality Control Technician	Lab QC Core
Lacsina	Elissa	Sr. Lead, Quality Evaluation Technician	Lab QC Core
Hernandez	Robert	Manufacturing Technician II	Loupes/Lights Px
Padilla	Lupita	Manufacturing Technician II	Loupes/Lights Px
Espinoza Hernandez	Ricardo	Manufacturing Technician II	Loupes/Lights Px
Morales	Alvin	Maintenance Mech B	Maintenance
Natividad	Alex	Maintenance Mech A	Maintenance
Barker	Zack	Supervisor, Facilities & Maintenance	Maintenance
Schillinger	Doreen	Global Product Manager	Marketing Administration
Kilicoglu	Bora	Marketing Manager	Marketing Administration
Mathias	Jen	Marketing Manager	Marketing Administration
Mann	Paula	Director of Marketing	Marketing Administration
Trexler	Barry	Executive Vice President, Sales & Marketing	Marketing Administration
Meza Ramirez	Christian	Production Artist	Marketing Digital
Vinn	Luisa	LumiSmile Program Support Rep	Marketing Digital
Burkart	Daniel	Social Media Manager	Marketing Digital
Pearson	Jillian	Digital Marketing Specialist	Marketing Digital
Khalil	Ali	Sr. Graphic Designer	Marketing Digital
Norwood	Shari	Principal Designer	Marketing Digital
Roberts	Ken	Director, Digital Marketing	Marketing Digital
Yang	Emily	Electrical Engineer	Operations
Silva	Francisco	Manager, Production	Operations
Gonzales	Nick	VP, Manufacturing	Operations
Velasquez	Martha	Sr. Print Shop - Mailroom Associate	Printing/Mailroom
Huffman	Maria	Supply Chain Associate	Purchasing & Planning
Xiong	Melinda	Supply Chain Associate	Purchasing & Planning
Vornbrock	Eunjie	Sr. Supply Chain Associate	Purchasing & Planning
Valdez	Stephanie	Sr. Manager, Supply Chain	Purchasing & Planning

Torres Vega	Alejandro	QC Technician	Quality Control
Gardner	John	QC Technician	Quality Control
Lacsina	Santiago	QC Technician	Quality Control
Cruz-Ernandes	Martin	QC Technician	Quality Control
Valderrama	Francisco	QC Technician	Quality Control
Sotto	Lycel	QC Technician II	Quality Control
San Juan	Armi	QC Technician II	Quality Control
Tan	Rowena	Sr. Document Control Coordinator	Quality Control
Gonzalez	Adelaida	Supervisor, Quality Control	Quality Control
Massey	Nichole	Quality Assurance Specialist	Quality Control
Alvarado	Rosie	Supervisor, Document Control	Quality Control
Rojas	Ginny	Quality Assurance Specialist	Quality Control
Brown	Jim	Quality Engineer	Quality Control
Grigor	Carol	Manager, QA/QC	Quality Control
Maynes	Kim	Regulatory Specialist	Regulatory
Alvarez	Brianna	Regulatory Specialist	Regulatory
Buenavista	Fatima	Regulatory Specialist	Regulatory
Juarez	Tom	Director, Regulatory Affairs/Quality Assuranc	Regulatory
Tan	Rolando	Sr. R&D Technician	Research & Development
Park	Esther	R&D Chemist	Research & Development
Shin	Daehwan	Director, Product Development Materials	Research & Development
LaLone	Breanna	Special Markets Support Representative	Sales GP/Dist/Schools
Swiggett	Kelsey	Sr. Manager, Business Development	Sales GP/Dist/Schools
Alexander	Williams	Business Development Specialist - Orthodontic	Sales GP/Dist/Schools
Tuck	Bruce	Sr. Manager, Business Development	Sales GP/Dist/Schools
Chavez	Alejandra	International Sales Support Representative	Sales International
Caro	Anna	Manager, Int'l Sales Support & Service	Sales International
Danak	Sam	Area Sales Manager	Sales International
Hopkins	Roberta	National Field Advisor	Sales Outside
Iglesias	Dan	Material Handler	Shipping
Johnson	Christopher	Shipping Associate	Shipping
Chaney	Megan	Shipping Associate	Shipping
Castaneda Cuevas	Sara	Shipping Associate	Shipping
Olivo Espinoza	Edna	Lead, Shipping & Receiving Prep Associate	Shipping
Ortiz	Antonio	Sr. Shipping Associate	Shipping
Lewis	Veronica	Sr. Shipping Associate	Shipping
Ortiz	Jenebeth	Event Manager	Trade Show Marketing
Markus	Kelly	Digital Marketing Specialist - Education	Trade Show Marketing
Archer	Jennifer	VP, Clinical Education	Trade Show Marketing
Strand	Tony	Driver/Pit Operator	Warehouse/Inventory Control
Vejiga	Ed	Driver/Pit Operator	Warehouse/Inventory Control
Copado	Ana	Inventory Associate	Warehouse/Inventory Control
Nanalis	Eduardo	Driver/Pit Operator	Warehouse/Inventory Control
Zacarias	Fabiola	Shipping Coordinator	Warehouse/Inventory Control
Buchan	Albert	Lead, Warehouse	Warehouse/Inventory Control
Munoz	Lola	Sr. Asst Supervisor, Shipping & Receiving	Warehouse/Inventory Control
Rodriguez	Elizabeth	Manager, Shipping & Receiving	Warehouse/Inventory Control

This bond supersedes and replaces Seneca Insurance Company, Inc. Bond Number POA1001573

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. 800048034

Application/License No.

Den-Mat Holdings, LLC
Applicant /Principal
, doing or intending to do business as a

pharmaceutical wholesaler, whose address for purposes of service is

1017 West Central Avenue, Lompoc, CA 93436 , as
Address of Applicant /Principal

PRINCIPAL, and Atlantic Specialty Insurance Company , a
Surety Company

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 169 North, Suite 800, Plymouth, MN 55441 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 Five THOUSAND DOLLARS ($ 5,000.00), 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 November 7, 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 $ 5,000.00 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 20th day of October, 2020

APPLICANT/PRINCIPAL
Den-Mat Holdings, LLC

Authorized Representative

SURETY COMPANY
Atlantic Specialty Insurance Company

Surety Company's Representative

Donna M Planeta, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

DEN-MAT HOLDINGS, LLC · LOMPOC, CALIFORNIA, U.S.A. · dm DenMat®

SIGNED and SEALED in the presence of:

Witness Kathryn Pryor

Witness Jacqueline Susco

Countersigned by: Eric Strba

Nevada Resident Agent
Nevada Non-Resident License No. 3325461

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

OneBeacon
INSURANCE GROUP

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: **Michelle Anne McMahon, Donna M Planeta, Joshua Sanford, Aimee R Perondine, Aiza Anderson, Danielle D Johnson, Bethany Stevenson, Tanya Nguyen, Saykham Chanthasone, Rebecca Stevenson, Bryan M. Caneschi**, 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: **sixty million dollars ($60,000,000)** 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-ninth day of April, 2019.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-ninth day of April, 2019, 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.

MANDALY ANN LAMERE
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2023

_____
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 20th day of October, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2023

_____
Christopher V. Jerry, Secretary

4U

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☐ Nevada ☒ Out-of-State
Is your facility a reverse distributor?	☐ Yes ☒ No

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01945	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Millstone Medical Outsourcing, LLC

Physical Address: 8836 Polk Lane, Suite 100

City: Olive Branch State: MS Zip: 38654

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 662-892-3612 Website: www.millstonemedical.com

Name of Designated Representative (DR): Michael Scott Jones

Licensing Company Email: victoria.hughes@millstonemedical.com DR Email: scott.jones@millstonemedical.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: Distributors and Clinics	☒ Others: Durable Medical Equipment

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

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 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: _____

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: Massachusetts

Parent Company (if any): Taunton Buyer II LLC

Corporation/Organization Name: Millstone Medical Outsourcing, LLC

Mailing Address: 580 Commerce Drive

City: Fall River State: MA Zip: 02720

Telephone: 662-892-3612 Email: victoria.hughes@millstonemedical.com

Contact Person Name: Victoria Hughes

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 See Attachment B 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		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment I 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/. Attachment J		

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 **6 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 - sole owner is an entity		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **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 H	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **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.

Karl Neuberger, CEO of Millstone Medical Outsourcing, LLC

Print Name of Authorized Person Submitting Application

Karl Neuberger

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

1-10-2022

Date

Board Use Only	Date Received: _____	Amount: 500 CHECK # 75310

1/14/22

NABP ACCREDITED
DRUG DISTRIBUTOR

Millstone Medical Outsourcing, LLC

located at

8836 Polk Ln, Ste 100, Olive Branch, MS 38654

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

7/23/2020 - 7/22/2023
Period of Accreditation

Verified 1/31/22
MS

TRAVELERS

Colleen Bishop
PO Box 2950
Hartford, CT 06104-2950

Phone: (781) 817-8449

Email: CBISHOP@travelers.com

December 27, 2021

GALLAGHER\A J\RMS (0G6782)
470 ATLANTIC AVE FL 13
BOSTON, MA 02210

This is an Agency Billed Policy.

This is the Renewal for: MILLSTONE MEDICAL OUTSOURCING LLC
8836 POLK LANE
OLIVE BRANCH, MS 38654

Bond Number:	107327427
Type of Bond:	Pharmaceutical Wholesaler Bond ($25,000)
Obligee Name:	Nevada State Board of Pharmacy
Obligee Address:	985 Damonte Ranch Pkwy, Suite 206
Obligee City, State & Zip:	RENO, NV 89521 USA
Transaction Effective Date:	November 01, 2021
Premium Effective Date:	November 01, 2021
Premium Expiry Date:	November 01, 2022
Bond Limit:	$25,000.00
Bond Premium:	$350.00
Commission - Percentage:	20%
Special Commission:	$0.00
Countersignature Branch:	
Countersignature Commission:	$0.00
State Tax:	$0.00
State Surcharge:	$0.00
TOTAL PREMIUM:	$350.00

Comments:

Thank you for placing your business with us.

Producer Name: Broker

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. 107327427

Application/License No. WH01945

Millstone Medical Outsourcing, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8836 Polk Lane, Olive Branch MS 38654 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (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 One Tower Sq, Hartford Connecticut 06183 (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 November 1, 2020 (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) The 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 12 day of October, 20 20.

APPLICANT/PRINCIPAL

Brian Heath

Authorized Representative

SURETY COMPANY

Laura MacMaster

Surety Company's Representative

Laura MacMaster, Attorney-in-fact

print name

SIGNED and SEALED in the presence of

Witness

Witness

SIGNED and SEALED in the presence of

Witness

Kyle Moore

Witness

Countersigned by

Nevada Resident Agent

TRAVELERS

Colleen Bishop
PO Box 2950
Hartford, CT 06104-2950

Phone: (781) 817-8449

Email: CBISHOP@travelers.com

December 27, 2021

GALLAGHER\A J\RMS (0G6782)
470 ATLANTIC AVE FL 13
BOSTON, MA 02210

This is an Agency Billed Policy.

This is the Renewal for: MILLSTONE MEDICAL OUTSOURCING LLC
8836 POLK LANE
OLIVE BRANCH, MS 38654

Bond Number:	**107327427**
Type of Bond:	**Pharmaceutical Wholesaler Bond ($25,000)**
Obligee Name:	**Nevada State Board of Pharmacy**
Obligee Address:	**985 Damonte Ranch Pkwy, Suite 206**
Obligee City, State & Zip:	**RENO, NV 89521 USA**
Transaction Effective Date:	**November 01, 2021**
Premium Effective Date:	**November 01, 2021**
Premium Expiry Date:	**November 01, 2022**
Bond Limit:	**$25,000.00**
Bond Premium:	**$350.00**
Commission - Percentage:	**20%**
Special Commission:	**$0.00**
Countersignature Branch:	
Countersignature Commission:	**$0.00**
State Tax:	**$0.00**
State Surcharge:	**$0.00**
TOTAL PREMIUM:	**$350.00**

Comments:

Thank you for placing your business with us.

Producer Name: **Broker**

Attachment D

Ownership Information

Sole Owner, Sole Manager, and Parent Company

Name	Address	FEIN	State of Incorporation	Percent Ownership
Taunton Buyer II LLC	5425 Wisconsin Ave., Suite 200, Chevy Chase, MD 20815	87-3014002	Delaware	100%

Officers

Name	Date of Birth	Address	Social Security Number
Karl Neuberger, CEO	8/17/1961	580 Commerce Dr, Fall River, MA 02720	008-60-3003
Brian Heath, VP and Secretary	5/28/1962	580 Commerce Dr, Fall River, MA 02720	030-54-2711
Victoria Hughes, VP of QA / RA	8/29/1972	580 Commerce Dr, Fall River, MA 02720	029-54-5285
Michael S. Jones, General Manager	10/3/1975	8863 Polk Lane, Suite 100, Olive Branch, MS 38654	425-63-6439

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

November 17, 2021

TO WHOM IT MAY CONCERN:

I hereby certify that a certificate of organization of a Limited Liability Company was filed in this office by

MILLSTONE MEDICAL OUTSOURCING, LLC

in accordance with the provisions of Massachusetts General Laws Chapter 156C on **August 16, 2004.**

I further certify that said Limited Liability Company has filed all annual reports due and paid all fees with respect to such reports; that said Limited Liability Company has not filed a certificate of cancellation; that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156C, § 70 for said Limited Liability Company's dissolution; and that said Limited Liability Company is in good standing with this office.

I also certify that the names of all managers listed in the most recent filing are: **NONE**

I further certify, the names of all persons authorized to execute documents filed with this office and listed in the most recent filing are: **KARL NEUBERGER, BRIAN J HEATH**

The names of all persons authorized to act with respect to real property listed in the most recent filing are: **KARL NEUBERGER, BRIAN J HEATH**

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Processed By:BOD

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: Millstone Medical Outsourcing, LLC

Physical Address: 8836 Polk Lane

City: Olive Branch State: MS Zip: 38654

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 662-892-3612 Website: www.millstonemedical.com

Licensing Company Email: victoria.hughes@millstonemedical.com

Section 2: Personal Information

First: Michael Middle: Scott Last: Jones

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

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

Mailing Address: [redacted] Southern Ridge Trail

City: Olive Branch State: MS Zip: 38654

Telephone: 662-892-3612 x 1830 Email: scott.jones@millstonemedical.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: N/A to: N/A

Military Occupation/Specialty: N/A

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: MSJ

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)	
Mississippi State University		08/2007 - 05/2009	
Address	City	State	Zip
75 B. S. Hood Rd.	Mississippi State	MS	39762
Diploma/Degree obtained, if any			
Masters of Science			

School Name		From - To (MM/YY – MM/YY)	
Blue Mountain College		01/1999 - 05/2000	
Address	City	State	Zip
201 W Main St	Blue Mountain	MS	38610
Diploma/Degree obtained, if any			
Bachelor of Science in Biology / Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Booneville High School		08/1990 - 05/1994	
Address	City	State	Zip
300 W George E Allen Drive	Booneville	MS	38829
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
01/2020 - 01/2022	[redacted] Southern Ridge Trail	Olive Branch	MS	38654
01/2010 - 01/2020	9312 Mitchell's Corner Rd N	Olive Branch	MS	38654
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)
Millstone Medical Outsourcing, LLC			03/20 - Present
Business Address	**City**	**State**	**Zip**
8836 Polk Lane, Suite 100	Olive Branch	MS	38654
Phone	**Title**		**Number of Employed Hours**
662-892-3612	General Manager		4,160 hours
Description of Duties			
Management of all systems, operations, and resources within the Olive Branch distribution facility.			

Business Name			From - To (MM/YY – MM/YY)
Millstone Medical Outsourcing, LLC			01/16 - 03/20
Business Address	**City**	**State**	**Zip**
8836 Polk Lane, Suite 100	Olive Branch	MS	38654
Phone	**Title**		**Number of Employed Hours**
662-892-3612	Director of Quality		8,320 hours
Description of Duties			
Establish company-wide goals for the distributor; perform quality system audits, packaging, and warehouse sites; organize and promote company-wide quality improvement efforts; and ensure FDA and other regulatory 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			

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:

Michael Scott Gore

Original Signature (electronic, copies or stamps not accepted)

1/5/22

Date

Applicant's initials MSJ

I, Michael Scott Jones, **certify that as the designated representative for**

Millstone Medical Outsourcing, 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

Michael Jones

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/22

Date

Applicant's initials MSJ

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 Jones

Print Name (First, Last)

Michael Jones — 1/5/22

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

---

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

State of Mississippi, ss. County of DeSoto

I, Michael Scott 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.

Michael Jones — 1/5/22

Original Signature — **Date**

Subscribed and Sworn to before me this 5th day of January 2022

Notary Public Signature

TARSHIA BARBEE
STATE OF TENNESSEE
NOTARY PUBLIC
(Seal)
SHELBY COUNTY
MY COMMISSION EXPIRES 2-8-2023

Applicant's initials MSJ

Attachment G

List of Employees and Lenders of the Applicant

Employee Name	Position Title
Agnew, Javion	Shipper/Receiver II
Alcantara, Evelyn	Inventory Associate I
ALSTON, JORDAN	Customer Service
Anderson, Danielle	Returns Clerk
ANDERSON, KAYLA	Loaner Set Associate II
Anderson, Lekeisha	Training Specialist
Ashford, Latoya	Inventory Associate I
ATKINS, SHUNDA	Inventory Associate II
Austin, Jasmine	Returns Clerk
BAKER, MONICA	Receiving Associate I
BALDWIN, NECOLE	Receiver/Insp/Shipper III
Barbee, Tarshia	Sr. Manager QA Operations
Barnes, Kenshayla M.	Receiver/Insp/Ship I
BARR, CHER	NCR Coordinator I
Barr, Jeremy	Shipping Associate I
Barrios, Maria	Returns Clerk
BAUSLEY, VAKELA	Lead Operations Associate
BEAN, KATHY	Inventory Associate II
Beason, Linnea	Loaner Set Associate I
BEDFORD, KEIANDRA S.	Associate Program Manager
Berry, Jeffery	Loaner Set Associate I
Black, Morgan	Loaner Set Associate I
Botello, Jocabeth R.	Shipper/Receiver I
Bracey, Anquanette	Quality Associate
Brooks Jr., Otis	Lead Operations Associate
Brooks, Andrea	Loaner Set Associate I
Brown, Ashley	Receiving Associate I
BROWN, CARLTON	Inventory Associate III
Bueford, Shundra	Returns Clerk
Bull, James	NCR Coordinator I
BURNS, SHAWN B.	Document Control Clerk
BURNSIDE, TONY	Shipper/Receiver III
Bush, Darian	Decontamin Assoc I
Buso, Carlos	IT Business Analyst
BYERS, AKILAH	Production Planner
CALVIN, AUDBRY	Document Control Clerk
Campbell, Keisean M.	Decontamination Assoc II
CARLISLE, SAMANTHA	Inventory Associate II
Cera Quezada, Itzel	Loaner Set Associate I
CHANDLER, SANDRA	Inventory Associate III
Clayton, April	Doc Control Spec
COATS, JAZZ	Shipper/Receiver II
Collins, Anthony	Senior Operations Manager
Collins, Jermaine	Shipping Associate I
Connard, Romone	Shipping Associate I
Conway-Martin, Chevetta	Lead Operations Associate
Cox, Daniel	Shipping Associate I
COX, MARILYN	Returns Clerk
Davis, Akeyia	Returns Clerk
Davis, Alysia	Returns Clerk
DAVIS, LEONIA	Operations Manager
DEAN, CATRINA	Mechanical Inspector II
DIALLO, ALPHA	Senior Operations Manager
Dixon, Linda	Loaner Set Associate I
Dockery, Errister	Shipping Associate I
Dorris, Tiara	Customer Service
DOTSON, JERONE	Program Manager
DuBose, C'Asia	Receiving Associate I
EDDINS, MARY	Inventory Associate III
Edgeston, Mae W.	Document Control Clerk
Farris, Snookie D.	Returns Clerk Inspector I
Force, Lisa	Loaner Set Associate I
Fowler, Anna	Process Engineering Tech
Franklin, Terrance	Loaner Set Associate I
FULLER, DONALD	Quality Engineer II

Gaston, Andreia	Mechanical Inspector I
Gause, Elva R.	Loaner Set Associate I
Gibson, Shalle'	Loaner Set Associate I
Gordon, Patricia	Shipper/Receiver I
GRANDBERRY, KEITH	Program Manager
GREEN, MONESHA	Inventory Control Sup
Greene, Cassandra D.	Returns Clerk Inspector I
GRISANTI, CODY	Sales Engineer
Grooms, Enoch R.	Engineer Associate II
GROOVER, RICHARD A.	Process Engineer
Guy, Giorgio	Decontamin Assoc I
GUYSE, JAMES MARTY	Facilities Manager
Hall, Rochelle A.	Shipper/Receiver II
Hall, Tamara	Inventory Associate I
Hampton, Gregory	Shipping Associate I
HAMPTON-RAY, ASHLEY	Loaner Set Associate III
Harris, Anthony	Engineer Associate
Harris, Jermaine	Operations Supervisor I
Harris, Shundolyn	Loaner Set Associate I
Harris, Soundra	Receiving Associate I
HICKMAN, MEREDITH	Quality Assurance Assoc
Hinkle II, Robert	Quality Engineer
Hodges, Lagarius	Mechanical Inspector I
Hodges, Natasha	Shipper/Receiver I
HOUSE, ASHLEY	Loaner Set Associate I
House, Atonya	Inventory Associate I
HOUSE, SHAQUIA	Receiver/Insp/Shipper III
HOWARD, CHERYL	Returns Clerk Inspec III
Hoye, Debra	Returns Clerk
HOYLE, REBA	Customer Service
Hudson, Angela	Mechanical Inspector I
JACKSON, KAELYN	Supply Chain Analyst
JAMES, ALEXANDER	NCR Coordinator I
JOHNSON, BRADFORD	Customer Service Manager
Johnson, Jovan M.	Help Desk Technician
JOHNSON, MARGARET R.	Loaner Set Associate I
JOHNSON, PATRICIA E.	Lead Operations Associate
JONES, ALICIA	Lead Operations Associate
Jones, Keidron	Lead Operations Associate
Jones, Kim	HR Generalist
JONES, MICHAEL	General Manager
Jones, Regina	Shipping Associate I
King, Kamaria	Document Control Clerk
Knowles, Alexander	Process Engineering Tech
LaFaver, Ksenija	Shipping Associate I
LANE, CHRISTINE	Program Manager
LAUDERDALE, RENITA	Continuous Improvement Sp
Ledesma, Rosalinda	Shipping Associate I
Leson, Aundretta	Mechanical Inspector I
Lockhart, Shantrelle	Shipping Associate I
LOMAX, REGENIA	Returns Clerk Inspector I
Lopez, Carolina	Receiver/Insp/Ship I
LOPEZ, MIGUEL	Program Manager
LOVE, JIMMY	Operations Manager
LUELLEN, LEVITTA	Quality Associate
Malone, Damanda	Returns Clerk
MALONE, DINESHA	Operations Supervisor I
Mansour, Aya	Quality Associate
MARSHALL, CHELSEY	Inventory Associate II
Martin, Marcie	Mechanical Inspector I
MARTIN, SUSAN	Lead Operations Associate
MCNEAL, REKIRIA	Lead Operations Associate
MCNEIL, ANTHONY	Operations Manager
Meeks, Jakyra	Shipping Associate I
Merriwether, Adriana	Returns Clerk
MIRON, THERESA	NCR Coordinator I

Molina, Yelixa	Returns Clerk
MOORE, LADRIC	Lead Operations Associate
MOSS, CARRIE	Inventory Associate III
Moss, Deveiur	Returns Clerk
MOSS, MARISA	Program Manager
MULL, LAKEISHA L.	Loaner Set Associate II
NESBY, EVELEANA	Customer Service
Ortiz, Maria C.	Loaner Set Associate I
OU, SAROUN	Receiver/Insp/Shipper III
PARKER, VINCENT O.	Shipper/Receiver III
PAYNE, DAVID A.	Shipper/Receiver II
Petties- Ramsey, Shemeka	Mechanical Inspector I
Petties, Shaster	Receiving Associate I
Pierce, Kendall	Returns Clerk Inspector I
POLK, MARTHA	QA Reviewer II
POWELL, ANWAR	Program Manager
QUINN, DEBRACA	Loaner Set Associate I
Ramirez, Blanca	Shipper/Receiver I
Rayford, LaShonda	Inventory Associate I
REDDIPALLI, MAHINDRA	Oracle E-Bus Analyst II
Renix, Tammy	Returns Clerk Inspector I
Richards, Layneisha	Returns Clerk
Roberts, Antasia	Mechanical Inspector I
ROBINSON, TRACY	Loaner Set Associate II
Rucker, Chiquilla	Returns Clerk
Ruffin, Mykeshia	Lead Operations Associate
Rutherford, Anita Y.	Human Resources Manager
Sanders, Kayla L.	Customer Service
Sanders, Trent	Loaner Set Associate I
Scales, Tamaira	Returns Clerk Inspector I
Shaw, Taijah	Mechanical Inspector I
Shelton, Nikki L.	Shipping Associate I
Shields Sr., Rydell	Janitor I
Sidle, Devon	Returns Clerk
Sinkfield, Ja'Tia	Mechanical Inspector I
Smith Jr., Victor	Shipping Associate I
Smith, Kevin	Shipping Associate I
SRITSATHIT, NONGKRAN J.	Doc Control Spec
Steward, Artazia	Loaner Set Associate I
Street, Te'Erica	Lead Operations Associate
TAYLOR, LESLIE	Lead Operations Associate
TAYLOR, MEREDEE	Sr Del Mgr II Oracle
Thavva, Sasanka Reddy	IT Business Analyst
THOMAS, JENNIFER J.	Inventory Associate II
Tidwell, Catherine	Shipping Associate I
Toles, Tamakia	Returns Clerk
TOWNSEND, CALOM	Program Manager
TRAVIS, AMANDA	Loaner Set Associate II
Triplett, Lakeya	Receiving Clerk
Wade, Cherelle	Receiving Associate I
Wallera, Roselyne	Mechanical Inspector I
Wallerah, Eunice	Returns Clerk
WARE, MYLA K.	Loaner Set Associate I
Warford, Erika	Loaner Set Inspector
WARREN, LATOYA	Loaner Set Associate II
Warrick, Alisha	Mechanical Inspector I
Washington, Carlisha	Returns Clerk
Watson, Anthony	Shipping Associate I
Watson, Bianca	Loaner Set Associate I
WATTS, SYLVESTER	Inventory Associate III
WEARY, DENISE	Operations Supervisor I
Weathersby, Wanda	Returns Clerk
WEBB, TIFFANIE	Document Control Clerk
WEST, KEVIN	Sr Mechanical Inspector
White, Debbie	Loaner Set Associate I
Wicks, Caitlin	Shipping Associate I

Wilkins, Shelly	Returns Clerk Inspector I
Wilks, Jessica	Loaner Set Associate I
Williams, Jakyla	Mechanical Inspector I
Williams, Juanita	NCR Coordinator I
Williams, Shunterica	Loaner Set Associate I
Williams, Tarceana	Loaner Set Associate I
Williams, Tatyana	Loaner Set Associate I
Willis, Earnest	Shipping Associate I
Woodard, Danielle	Training Specialist
WRIGHT, CARLA	Loaner Set Associate I
YATES, CASSAUNDRA	Returns Clerk

Lender Name
NXT Capital, LLC
The Private Credit Group of Goldman Sachs Asset Management, L.P.

MISSISSIPPI

Board of Pharmacy

Permit #
15191 / 16.3

Drug Facility

3rd Party Logistics (In-State)

Millstone Medical Outsourcing, LLC

Permit Holder:
Michael S Jones

8836 Polk Lane
Ste 100
Olive Branch, MS 38654
DeSoto

This permit is not transferable or assignable.

Issued: 03/01/2017
Renewed: 12/03/2021
Expires: 12/31/2022

Susa McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Millstone Medical Outsourcing LLC
8836 Polk Lane
Suite 100
Olive Branch, MS 38654
Registration Number: 3010097171
FEI Number*: 3010097171
Status: Active
Date Of Registration Status: 2022

Verified 1/31/22
MS

Owner/Operator:
MILLSTONE MEDICAL OUTSOURCING LLC.[6]
580 Commerce Drive
Fall River, MA US 02720
Owner/Operator Number: 9042927[7]

Official Correspondent:
Kelly J Lucenti
580 Commerce Drive
Fall River, MA 02720
Phone: 508-6798384-2026

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 01/31/2022

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U.S. FOOD & DRUG ADMINISTRATION

eHCTERS - Registration Information

Submitted Registration Information

This information has been submitted to the FDA
Please Remember Your Confirmation Number to Reference this registration submission
YOUR CONFIRMATION NUMBER IS: 54049
Please print this document and maintain as confirmation of your submission.
This application is no longer accessible using your pre-confirmation number.

FEI: 3007499718

Other FDA Registrations

- ☐ Blood
- ☑ Devices 3010097171
- ☐ Drug

Reason for Submission

- ☐ Initial Registration/Listing
- ☑ Annual Registration/Listing
- ☐ Change in Information
- ☐ In-Activate Registration

Physical Location

Legal Name: Millstone Medical Outsourcing
Street Address: 8836 Polk Lane
Suite 100
City: Olive Branch
State: Mississippi
Postal Code: 38654
Country: UNITED STATES
Phone: 508-679-8384 ext.

Reporting Official Information

First Name: Kelly J.
Last Name: Lucenti
Title: President
Phone: 508-679-8384 Ext.2026
E-Mail Address: klucenti@millstonemedical.com

Mailing Address of Reporting Official

Institution Name: Millstone Medical Outsourcing
Street Address: 580 Commerce Drive
City: Fall River
State: Massachusetts
Postal Code: 02720
Country: UNITED STATES

HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane	X			BioFix; Amniofix; CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; Amnioflo; Flower AmnioPatch; FlowerPatch; AMNIOGRAFT;

				AMNIOGUARD; CLARIX 100; CLARIX CORD; CLARIX FLO; NEOX 100; NEOX CORD; NEOX FLO; NEOX RT; TAG-Triple Layer Amniotic Graft
Blood Vessel				
Bone	X			Osteoamp; Purebone; Exponent; Allograft Bone Wedge; SeaSpine Capistrano Cervical Spacer; SeaSpine PLIF Allograft; SeaSpine Compressible Bone Matrix; SeaSpine Cervical Allograft; Laminoplasty Cortical Allograft; LESBiologics; DBMForm; FacetFuse; Allo-Span; Allogenix DBM; Bonus CC Matrix; Bonus II DMB; Cellentra Advanced Allograft; EquivaBone; FiberStack DBM; Fortis ALIF, Composite, Cortical, PLIF, TLIF; Indux Cortical or Cancellous; InterGro DBM; PrimaGen Advanced Allograft; Osteostim Composite; Cortical, ALIF, PLIF; StaGraft Cancellous; StaGraft DBM; StaGraft Fiber; Trinnect; Puros; Puros-S; Fortitude; Bonus Triad; Copios; FIBERFORM; FIBER BOAT; FIBER ANCHOR; FIBER BULLETS; FIBERFORM+; FIBERFORM SYRINGE; FIBERFORM, OSTEOAMP SELECT Flowable, FlowerGRAFT; FibreX Demineralized Bone Fibers; Bigfoot; BioAdapt; BioReady; BioSet; Elemax
Cardiac Tissue - non-valved				
Cartilage				
Cornea				
Dura Mater				
Embryo				
Fascia				
Heart Valve				
HPC Apheresis				
HPC Cord Blood				
Ligament	X			
Nerve Tissue				
Oocyte				
Ovarian Tissue				
Pancreatic Islet Cells - autologous				
Parathyroid				
Pericardium				
Peripheral Blood Mononuclear Cells				
Peritoneal Membrane				
Sclera				
Semen				
Skin	X			HuMend; DermaSpan; DermaSpan Mesh; FlowerDerm
Tendon	X			
Testicular Tissue				
Tooth Pulp				
Umbilical Cord Tissue	X			CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; CTM Flow LV

HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane						☑	☑	☑

Blood Vessel								
Bone						☑	☑	☑
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament						☑	☑	☑
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin						☑	☑	☑
Tendon						☑	☑	☑
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue						☑	☑	☑

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

Select New Establishment | CBER On-Line Main Menu

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.13.01
Updated 11/20/2020

FDA information collection OMB Control number: 0910-0543
Expiration Date: 07/31/2023

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FDA / Center for Biologics Evaluation and Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3007499718

Other FDA Registrations:
Blood:
Devices: FEI: 3010097171
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/16/2021
Summary Report Print Date: 12/01/2021

Legal Name and Location:

Millstone Medical Outsourcing
8836 Polk Lane
Suite 100

Olive Branch, Mississippi 38654
USA

Phone: 508-679-8384 **Ext.:**

Reporting Official:

Kelly J Lucenti, President
580 Commerce Drive
Fall River, Massachusetts 02720
USA
Phone: 508-679-8384 Ext. 2026
klucenti@millstonemedical.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X	X	X			***See full text on next page.
Blood Vessel												
Bone							X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X	X	X			***See full text on next page.
Tendon							X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							X	X	X			***See full text on next page.

Additional Information: No additional information provided.

Proprietary Name(s):		
	Amniotic Membrane	BioFix; Amniofix; CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; Amnioflo; Flower AmnioPatch; FlowerPatch; AMNIOGRAFT; AMNIOGUARD; CLARIX 100; CLARIX CORD; CLARIX FLO; NEOX 100; NEOX CORD; NEOX FLO; NEOX RT; TAG- Triple Layer Amniotic Graft
	Bone	Osteoamp; Purebone; Exponent; Allograft Bone Wedge; SeaSpine Capistrano Cervical Spacer; SeaSpine PLIF Allograft; SeaSpine Compressible Bone Matrix; SeaSpine Cervical Allograft; Laminoplasty Cortical Allograft; LESBiologics; DBMForm; FacetFuse; Allo-Span; Allogenix DBM; Bonus CC Matrix; Bonus II DMB; Cellentra Advanced Allograft; EquivaBone; FiberStack DBM; Fortis ALIF, Composite, Cortical, PLIF, TLIF; Indux Cortical or Cancellous; InterGro DBM; PrimaGen Advanced Allograft; Osteostim Composite; Cortical, ALIF, PLIF; StaGraft Cancellous; StaGraft DBM; StaGraft Fiber; Trinnect; Puros; Puros-S; Fortitude; Bonus Triad; Copios; FIBERFORM; FIBER BOAT; FIBER ANCHOR; FIBER BULLETS; FIBERFORM+; FIBERFORM SYRINGE; FIBERFORM, OSTEOAMP SELECT Flowable, FlowerGRAFT; FibraX Demineralized Bone Fibers; Bigfoot; BioAdapt; BioReady; BioSet; Elemax
	Skin	HuMend; DermaSpan; DermaSpan Mesh; FlowerDerm
	Umbilical Cord Tissue	CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; CTM Flow LV

FEI: 3007499718

Legal Name: Millstone Medical Outsourcing

4V

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Y

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: DENTSPLY North America LLC

Physical Address: 1800 Cloister Drive

City: Lancaster State: PA Zip: 17601

Mailing Address (if different from physical address): 221 W. Philadelphia St., Suite 60W

City: York State: PA Zip: 17401

Telephone: 717-845-7511 Website: https://www.dentsplysirona.com/en-us

Name of Designated Representative (DR): Michael Weaver, Quality Manager

Licensing Company Email: michael.weaver@dentsplysirona.c DR Email: michael.weaver@dentsplysirona.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.

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: DENTSPLY LLC
Address: 1301 SMILE WAY City: York State: PA Zip: 17404
Name: N/A - Dentsply North America LLC only distributes products supplied by Dentsply LLC
Address: City: State: Zip:
Name: N/A
Address: City: State: Zip:
Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Dentsply Sirona Inc.
Corporation Name: DENTSPLY North America LLC
Mailing Address: 221 W. Philadelphia St., Suite 60W
City: York State: PA Zip: 17401
Telephone: 717-845-7511 Email: michael.weaver@dentsplysirona.com
Contact Person Name: Michael Weaver, Quality Manager

Date of SEC Registration: 02/29/2016	SEC Registration Number: CIK 0000818479	Stock Exchange Symbol: XRAY

Section 5: Non-Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation 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:		✔
1. Copy of Certification 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 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
• 9A **List of all Officers and Directors.**	✓	✓		
• 9B **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.**			✓	
• 9C **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**	✓	✓	✓	✓
• 9D **Copy of current SEC 10K or 8K**	✓			
• 9E **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.

Daniel P Key

Print Name of Authorized Person Submitting Application

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

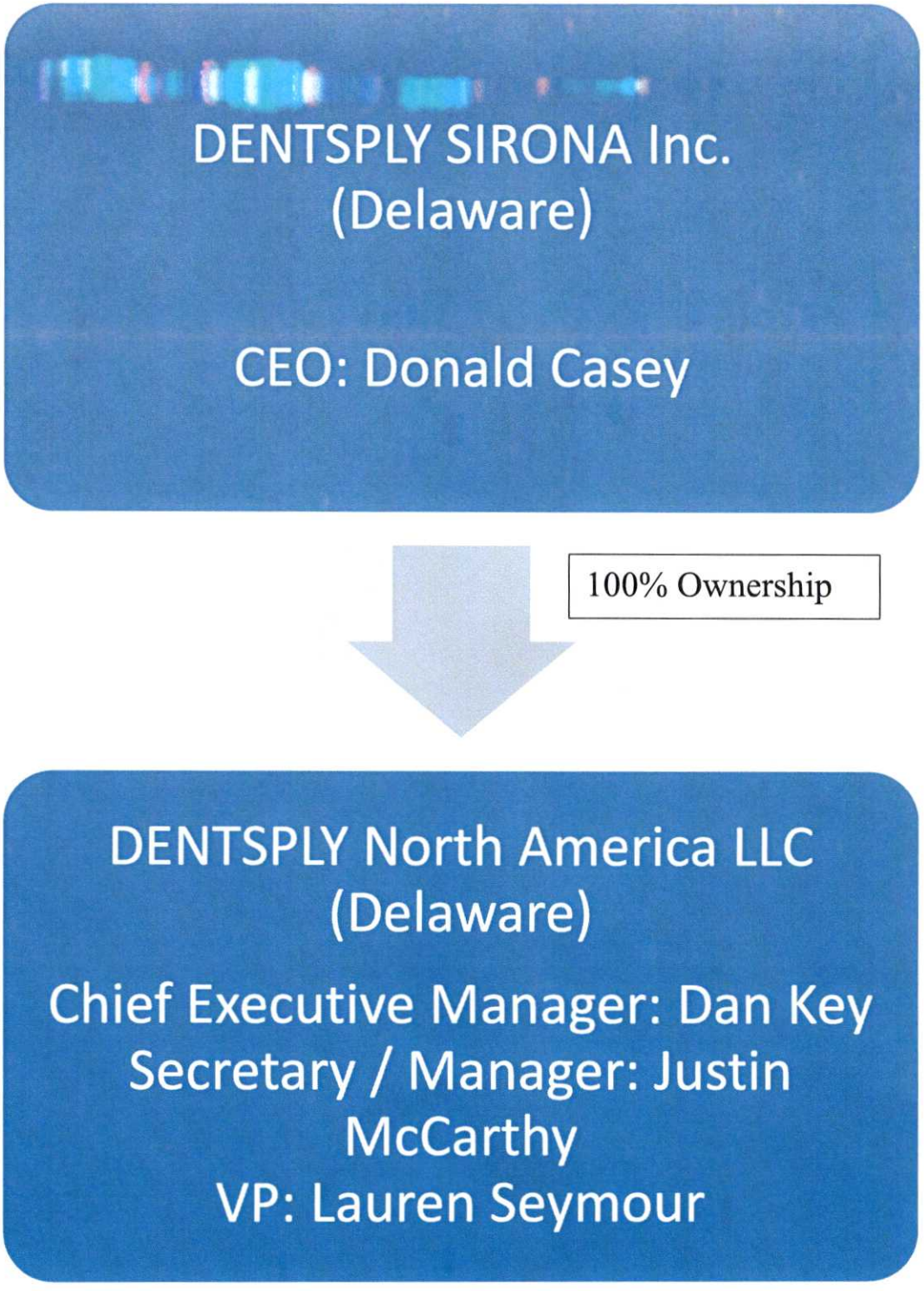
SEPT. 7, 2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Processed 9/22/21

Beneficial Ownership of DENTSPLY North America LLC Chart

DENTSPLY North America LLC is a wholly owned subsidiary of DENTSPLY SIRONA Inc.:



ALL OWNERSHIP PERCENTAGES 100%
CONFIDENTIAL AND PROPRIETARY

DENTSPLY North America LLC
221 W. Philadelphia St., 60W
York, PA 17401
USA

August 30, 2021

Dear Sir or Madam,

Dentsply Sirona Inc., through its various subsidiary companies, is a medical device manufacturer of professional dental solutions that comprise a wide array of medical devices including dental filling and crown materials, implants, imaging devices, dental instruments, orthodontic devices, and the like. Dentsply North America LLC is a wholly owned subsidiary of Dentsply Sirona Inc. While Dentsply North America LLC primarily distributes prescription medical devices, we also make available to our customers a small number of prescription pharmaceutical products for dental use such as Xylocaine, Nupro Fluoride Rinse, and Topex Anesthetic Gel.

On June 8, 2021, we received a letter from the Georgia Board of Pharmacy indicating that Dentsply North America LLC's distribution of prescription pharmaceutical products triggered a requirement to possess a Drug Wholesale Distribution License in the State of Georgia. After receiving the letter from the Georgia Board of Pharmacy, Dentsply North America LLC placed all product shipment to the State of Georgia on hold and prepared our application for the State of Georgia's Drug Wholesale Distribution License. We submitted the application on June 17, 2021. Dentsply North America LLC also signed a Voluntary Cease and Desist Order dated July 6, 2021, (Docket No. 2021-0051) stating that we will voluntarily stop any practice requiring a Georgia license until licensed. The original letter and Order are attached.

On August 19, 2021, the State of Georgia Board of Pharmacy granted Dentsply North America LLC a license, Wholesaler Pharmacy License No. PHWH005100.

We made every effort to remedy this situation as soon as it was brought to our attention. We are not aware of any disciplinary or further action under consideration related to this lapse in licensure. If you have questions, please do not hesitate to call me at 717-585-8190 or email me at Michael.Weaver@dentsplysirona.com.

Sincerely,

Michael Weaver
Quality Assurance Manager

GEORGIA BOARD OF PHARMACY

GOVERNOR
Brian P. Kemp

EXECUTIVE DIRECTOR
Eric R. Lacefield

2 Peachtree St. N.W., 6th Floor • Atlanta, Georgia 30303 • Tel: 404.651.8000 • Fax 470.386.6137
www.gbp.georgia.gov

May 25, 2021

RECEIVED
JUN - 8 2021
DENTSPLY SIRONA LEGAL DEPT.

Sent via Certified Mail: 7018 1830 0000 6103 6419

Dentsply North America, LLC
221 W. Philadelphia St., Ste. 60W
York, PA 17401

Re: Voluntary Cease and Desist

Dear Agent of Dentsply North America, LLC:

The Georgia Board of Pharmacy ("Board") has been made aware that Dentsply North America, LLC has shipped prescription drugs into Georgia without obtaining proper licensure to conduct such business. See O.C.G.A. §§ 16-13-35, 16-13-72, 26-4-110(a), 26-4-113, and 26-4-115. Shipping drugs into Georgia without proper licensure is a criminal offense. To date the Board has not received an application for licensure.

Please find enclosed a Voluntary Cease and Desist from the Georgia Board of Pharmacy. This document should be reviewed by Dentsply North America, LLC's independent counsel, signed by a representative with the authority to do so, and returned to the Board. If Dentsply North America, LLC chooses not to sign the cease and desist voluntarily, please respond with a statement to the Board containing an explanation so next steps can be determined.

Please return the signed form or explanation statement by June 25, 2021.

If you have any questions regarding this matter or any other matter related to the practice of pharmacy in Georgia, please contact the staff at the Board's office at your convenience: (404) 651-8000.

Sincerely,

Georgia State Board of Pharmacy

Enclosures

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

STATE OF GEORGIA

IN THE MATTER OF:	*
	*
Dentsply North America, LLC	*
	*
Respondent.	*

VOLUNTARY CEASE AND DESIST ORDER

Respondent, Dentsply North America, LLC, operating at 221 W. Philadelphia Street, Suite 60W, York, PA 17401,

is not licensed to engage in the distribution of drugs or devices in the State of Georgia, pursuant to the Official Code of Georgia Annotated (O.C.G.A.) T. 26, Ch. 4 or T. 16, Ch. 13, as amended. Potential violations of O.C.G.A. T. 26, Ch. 4 and T. 16, Ch. 13 having been called to Respondent's attention, Respondent, through the signing agent, hereby agrees to voluntarily cease and desist from any practice that would require licensure under O.C.G.A. T. 26, Ch. 4, or T. 16, Ch. 13, as amended, until such time as Respondent may become properly licensed or registered by the Georgia State Board of Pharmacy ("Board"). Respondent, through the signing agent, agrees that this includes distribution or delivery of drugs or devices to or receipt of drugs or devices from any person or firm in this state other than intracompany transfers to or from a licensed firm in this state under common ownership.

The Agent of Respondent understands that he/she has a right to a hearing in this matter, and hereby freely, knowingly, and voluntarily waives such right. The Agent of Respondent also understands that should he/she apply for licensure with the Board, the Board shall have access to this Order and to the entire investigative file on this matter.

This Order shall become effective immediately upon acceptance thereof and docketing by the Georgia State Board of Pharmacy and shall remain in effect until such time as the

Respondent becomes licensed with the Board, or until further order. The Agent of Respondent understands that this document will be considered to be a public record entered as the final disposition of any injunction or cease and desist proceedings presently pending or which could be brought against Respondent by the Board, and that this action shall be considered to be and may be recorded as a final order of the Board. **This Order is not intended and shall not be construed as prohibiting the prosecution of Respondent by any other state or federal agency for Respondent's conduct nor shall it be construed as limiting the Board's authority to subsequently impose a fine or conditions upon licensure with the Board.**

Any violation of this Order shall subject the Respondent to a fine not to exceed $500.00 for each transaction constituting a violation thereof, pursuant to O.C.G.A. § 43-1-20.1.

CONSENTED TO:

_____ (Signature)

_____ (Print)
Agent of Respondent

AS TO SIGNATURE OF RESPONDENT ONLY
Sworn to and subscribed before me this _____ day of _____, 20___.

_____
NOTARY PUBLIC
My commission expires:

This voluntary cease and desist is hereby accepted this ___ day of _____, 20___.

GEORGIA STATE BOARD OF PHARMACY

BY:_____
MICHAEL BRINSON, R.Ph.
President

ATTEST:_____
ERIC R. LACEFIELD
Executive Director

(Board Seal)

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

STATE OF GEORGIA

GEORGIA STATE BOARD OF PHARMACY
JUL 06 2021
DOCKET NO. 2021-0051

IN THE MATTER OF: *

*

Dentsply North America, LLC *

*

Respondent. *

VOLUNTARY CEASE AND DESIST ORDER

Respondent, Dentsply North America, LLC, operating at 221 W. Philadelphia Street, Suite 60W, York, PA 17401,

is not licensed to engage in the distribution of drugs or devices in the State of Georgia, pursuant to the Official Code of Georgia Annotated (O.C.G.A.) T. 26, Ch. 4 or T. 16, Ch. 13, as amended. Potential violations of O.C.G.A. T. 26, Ch. 4 and T. 16, Ch. 13 having been called to Respondent's attention, Respondent, through the signing agent, hereby agrees to voluntarily cease and desist from any practice that would require licensure under O.C.G.A. T. 26, Ch. 4, or T. 16, Ch. 13, as amended, until such time as Respondent may become properly licensed or registered by the Georgia State Board of Pharmacy ("Board"). Respondent, through the signing agent, agrees that this includes distribution or delivery of drugs or devices to or receipt of drugs or devices from any person or firm in this state other than intracompany transfers to or from a licensed firm in this state under common ownership.

The Agent of Respondent understands that he/she has a right to a hearing in this matter, and hereby freely, knowingly, and voluntarily waives such right. The Agent of Respondent also understands that should he/she apply for licensure with the Board, the Board shall have access to this Order and to the entire investigative file on this matter.

This Order shall become effective immediately upon acceptance thereof and docketing by the Georgia State Board of Pharmacy and shall remain in effect until such time as the

Respondent becomes licensed with the Board, or until further order. The Agent of Respondent understands that this document will be considered to be a public record entered as the final disposition of any injunction or cease and desist proceedings presently pending or which could be brought against Respondent by the Board, and that this action shall be considered to be and may be recorded as a final order of the Board. **This Order is not intended and shall not be construed as prohibiting the prosecution of Respondent by any other state or federal agency for Respondent's conduct nor shall it be construed as limiting the Board's authority to subsequently impose a fine or conditions upon licensure with the Board.**

Any violation of this Order shall subject the Respondent to a fine not to exceed $500.00 for each transaction constituting a violation thereof, pursuant to O.C.G.A. § 43-1-20.1.

CONSENTED TO:

_____ (Signature)

DANIEL P. KEY (Print)

Agent of Respondent

AS TO SIGNATURE OF RESPONDENT ONLY

Sworn to and subscribed before me this 24th **day of** June, **20**21.

L. D. Nathan

NOTARY PUBLIC

My commission expires:

L DENISE NATHAN NOTARY PUBLIC MECKLENBURG COUNTY, NC My Commission Expires 11-07-2024

This voluntary cease and desist is hereby accepted this 6th day of July, 2021.

GEORGIA STATE BOARD OF PHARMACY

BY: Michael Brinson
MICHAEL BRINSON, R.Ph.
President

with express permission by
Eric Lacefield, Executive Director

ATTEST: E. R. Lacefield
ERIC R. LACEFIELD
Executive Director

(Board Seal)

Certificate of Licensure

Certificate No. 8000001923
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

DENTSPLY NORTH AMERICA LLC
1800 CLOISTER DRIVE
LANCASTER, PA 17601

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: January 11, 2008
Expiration Date: The Last Day of February, 2022

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Alison V. Beam
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

881

Certificate of Registration

Certificate No. 3000008248
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

Category:

Distributor (Prescription)

DENTSPLY NORTH AMERICA LLC
1800 CLOISTER DRIVE
LANCASTER, PA 17601

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: January 11, 2008
Expiration Date: The Last Day of February, 2022

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Alison V. Beam
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005100 Status: Active

Dentsply Sirona
221 W Philadelphia Street Ste 60W
York PA 17401

Expires: 06/30/2023
Issued: 08/19/2021

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005100 Status: Active
Dentsply Sirona
221 W Philadelphia Street Ste 60W
York PA 17401

Expires: 06/30/2023
Issued: 08/19/2021
Real-time license verification is available at gadch.mylicense.com/verification

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
DENTSPLY NORTH AMERICA LLC
1800 Cloister Drive
Lancaster, PA 17601
Registration Number: 3006186796
FEI Number*: 3006186796
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
DENTSPLY SIRONA INC
221 WEST PHILADELPHIA ST.
SUITE 60W
York, PA US 17401
Owner/Operator Number: 2511302

Official Correspondent:
Courtney Clark
221 WEST PHILADELPHIA ST.
SUITE 60W
York, PA 17401
Phone: 248-8954379

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

✓ Verified
M.H 9/17/21

Page Last Updated: 09/06/2021

Attachment 9A

List of Officers and Directors of Dentsply North America LLC.

Daniel Paul Key, Chief Executive Manager (Officer)

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Pinehill Lane, Weddington, NC 28104
- [redacted]
- Daniel.key@dentsplysirona.com

Lauren Gardner Seymour, Vice President

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Sheridan Walk NE, Atlanta, GA 30324
- [redacted]
- Lauren.seymour@dentsplysirona.com

Justin Huntly McCarthy II, Secretary/Manager

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Lindsey Drive, Plano, TX 75093
- [redacted]
- Justin.mccarthy@dentsplysirona.com

Attachment 9B

Top Four Shareholders of Dentsply North America LLC

Stockholder	Stake
Dentsply Sirona Inc.	100 %

Top Four Shareholders of Dentsply Sirona Inc.

Stockholder	Stake
The Vanguard Group, Inc.	10.42%
T. Rowe Price Associates, Inc.	8.39%
Artisan Partners LP	5.19%
Janus Capital Management LLC	4.96%

List of Officers and Managers of Dentsply North America LLC (NOT OWNERS):

Daniel Paul Key, Chief Executive Manager (Officer)

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Pinehill Lane, Weddington, NC 28104
- [redacted]
- Daniel.key@dentsplysirona.com

Lauren Gardner Seymour, Vice President

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Sheridan Walk NE, Atlanta, GA 30324
- [redacted]
- Lauren.seymour@dentsplysirona.com

Justin Huntly McCarthy II, Secretary/Manager

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted] Lindsey Drive, Plano, TX 75093
- [redacted]
- Justin.mccarthy@dentsplysirona.com

List of DENTSPLY SIRONA Inc. Section 16 Officers (NOT OWNERS)

Business address for Corporation and Section 16 Officers:
DENTSPLY SIRONA Inc.
13320-B Ballantyne Corporate Place
Charlotte, NC 28277
Phone: 704-587-0453

Executive Vice President	Ebling, Keith
General Counsel	Ebling, Keith
Secretary	Ebling, Keith
Chief Human Resources Officer	Yankie, Lisa
Senior Vice President	Yankie, Lisa
Chief Financial Officer	Gomez, Jorge
Executive Vice President	Gomez, Jorge
Chief Executive Officer	Casey Jr., Donald M.
Chief Accounting Officer	Chadha, Ranjit S.
Senior Vice President	Petersohn, Walter
Chief Commercial Officer	Petersohn, Walter
Senior Vice President	Key, Daniel P.
Chief Supply Chain Officer	Key, Daniel P.
Senior Vice President	Staehler, Cord
Chief Technology Officer	Staehler, Cord
Senior Vice President	Chidambaram, Chidam
Chief Digital Officer	Chidambaram, Chidam
Senior Vice President, Business Development & Strategy	Coggin, Matthew

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DENTSPLY 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 TWENTIETH DAY OF OCTOBER, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DENTSPLY NORTH AMERICA LLC" WAS FORMED ON THE FOURTH DAY OF MAY, A.D. 2000.

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

Jeffrey W. Bullock, Secretary of State

3223012 8300

SR# 20213566519

Authentication: 204463851

Date: 10-20-21

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

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF AUTHORIZATION

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

DENTSPLY SIRONA INC.

a corporation organized under the laws of Delaware was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on the 5th day of April, 2006.

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 30th day of August, 2021.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 111123282-1 Reference# 17724398- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

Attachment 9C

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF AUTHORIZATION
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

DENTSPLY NORTH AMERICA LLC

is a limited liability company formed under the laws of Delaware as Dentsply North America LLC and was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on 27th day of July, 2018.

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company has not withdrawn from the State of North Carolina, (ii) the said limited liability company's certificate of authority has not been suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively revoked for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial revocation, withdrawal, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 19th day of August, 2021.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 111077868-1 Reference# 17707662- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

Attachment 9D

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

August 5, 2021 (August 5, 2021)
Date of Report (date of earliest event reported)

DENTSPLY SIRONA Inc.

(Exact name of registrant as specified in its charter)

Delaware	**0-16211**	**39-1434669**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

13320 Ballantyne Corporate Place,	**Charlotte**	**North Carolina**	**28277-3607**
(Address of Principal Executive Offices)			(Zip Code)

(844) 848-0137
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 (see General Instruction A.2. below):

☐ 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, par value $0.01 per share	XRAY	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.

o

Item 2.02. - Results of Operations and Financial Condition

The following information is furnished pursuant to Item 2.02, "Results of Operations and Financial Condition."

On August 5, 2021, DENTSPLY SIRONA Inc. issued the attached press release announcing its net sales and earnings for the second quarter ended June 30, 2021. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	DENTSPLY SIRONA Inc. Second Quarter earnings release issued August 5, 2021, as referenced in Item 2.02.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DENTSPLY SIRONA Inc.

By: */s/ Keith J. Ebling*
Keith J. Ebling,
Executive Vice President,
General Counsel and
Secretary

Date: August 5, 2021

Dentsply Sirona

THE DENTAL SOLUTIONS COMPANY™

Dentsply Sirona Reports Second Quarter 2021 Results

- **Revenue increased 117.3% to $1,067 million. Organic revenue increased 104.6%**
- **GAAP EPS increased to $0.45 vs loss of ($0.44) in 2020**
- **Non-GAAP EPS increased to $0.71 vs loss of ($0.18) in 2020**
- **GAAP operating income increased to $155 million vs loss of ($104) million in 2020**
- **Non-GAAP operating income increased to $219 million vs loss of ($42) million in 2020**
- **Operating cash flows increased to $214 million vs $175 million in 2020**
- **Reaffirm FY21 Non-GAAP EPS outlook of $2.75 to $2.90**

Charlotte, N.C., August 5, 2021 - DENTSPLY SIRONA Inc. ("Dentsply Sirona" or the "Company") (Nasdaq: XRAY) today announced its financial results for the second quarter of 2021.

Second quarter net sales of $1,067 million increased 117.3%, compared to $491 million in the second quarter of 2020. Net income for the second quarter of 2021 was $99 million, or $0.45 per diluted share, compared to a net loss of ($95) million, or ($0.44) per diluted share in the second quarter of 2020. Non-GAAP net earnings per diluted share increased to $0.71 compared to ($0.18) in the second quarter of 2020. A reconciliation of the Non-GAAP measures to earnings per share calculated on a GAAP basis is provided in the attached table.

"Our second-quarter performance closes out a strong first half of the fiscal year," said Dentsply Sirona Chief Executive Officer Don Casey. "Our financial results reflect the resilience of the dental market and demonstrate our team's ability to execute operationally and financially. As we turn our attention to investing for future growth, we are confident that the underlying fundamentals of our business are strong and that we are well positioned. Additionally, we remain committed to completing our restructuring goals on time and on budget."

Q2 21 Summary Results (GAAP)

(in millions, except per share amount and percentages)	Q2 21	Q2 20	YoY
Net Sales	1,067	491	*117.3%*
Operating Income (loss)	155	(104)	*NM*
Operating Income (loss) %	*14.5%*	*(21.2%)*	
Diluted EPS	0.45	(0.44)	*NM*

NM - not meaningful

Q2 21 Summary Results (Non-GAAP)[1]

(in millions, except per share amount and percentages)	Q2 21	Q2 20	YoY
Net Sales	1,067	491	*117.3%*
Organic Sales Growth %			*104.6%*
Operating Income	219	(42)	*NM*
Operating Income %	*20.5%*	*(8.6%)*	
Diluted EPS	0.71	(0.18)	*NM*

[1] Organic sales growth, Non-GAAP operating income, and Non-GAAP EPS are Non-GAAP financial measures which exclude certain items. Please refer to "Non-GAAP Financial Measures" below for a description of these measures and to the tables at the end of this release for a reconciliation between GAAP and Non-GAAP measures.

Segment Results

Consumables

Second quarter 2021 net sales were $445 million, up 138.0% versus prior year. On an organic basis, net sales increased by 135.3% as compared to prior year. Currency favorably impacted sales by 11.2%, while divestitures and discontinued products negatively impacted sales by 8.5%. Sales across all product categories rebounded in the quarter.

Technologies & Equipment

Second quarter 2021 net sales were $622 million, up 104.6% versus prior year. On an organic basis, net sales increased by 85.2% as compared to prior year. Currency favorably impacted sales by 10.4%, acquisitions increased sales by 19.0%, and divestitures and discontinued products negatively impacted sales by 10.0%. Sales across all product categories rebounded in the quarter.

Cash Flow and Liquidity

Operating cash flows in the second quarter of 2021 were $214 million, as compared to $175 million in the prior year. In the second quarter, the Company paid $22 million in dividends, resulting in a total of $134 million returned to shareholders in the first six months of 2021. During the second quarter, the Company also funded the Propel Orthodontics acquisition for $132 million. At June 30, 2021, the Company had $332 million of cash available on its balance sheet.

Fiscal Year 2021 Outlook

Based on the results of the second quarter and the continued gradual recovery of the global dental market, we are reaffirming the fiscal year 2021 outlook. We expect revenues to be in the $4.1B to $4.3B range, up approximately 23-28% on a reported basis and 18-25% on an organic basis. Our Non-GAAP EPS outlook for FY2021 is $2.75 to $2.90 and we expect to be at the upper end of the range.

A list of the 2021 planning assumptions are included in the Q2 FY2021 Earnings Presentation posted in the investor relations section of the Dentsply Sirona web site at www.dentsplysirona.com. The Company does not provide forward-looking estimates on a GAAP basis as certain information is not available and cannot be reasonably estimated.

Recent Announcements & Additional Highlights

- **Quarterly Cash Dividend Declared -** Dentsply Sirona's Board of Directors declared a quarterly cash dividend of $0.11 per share of common stock. The dividend is payable on October 8, 2021 to holders of record as of September 24, 2021.
- **Share Repurchase Program Authorization** - On July 28, 2021, Dentsply Sirona's Board of Directors authorized an increase to the share repurchase program bringing the total to $1 billion.
- **Environmental, Social and Governance ("ESG") Impact -** As a global leader in the dental health sector, we are striving to become an ESG leader. In April 2021, we launched our Sustainability web site and published our Environmental Scorecard and Sustainability Fact Sheet. In May 2021 we announced our partnership with FDI World Dental Federation as one of five industry founding partners to lead the new Sustainability in Dentistry initiative. In Q3 2021, we plan to publish our inaugural Sustainability Report. Further information on our ESG efforts can be found on our Sustainability website located in the investor relations section of www.dentsplysirona.com.
- **Dentsply Sirona World 2021 -** After a successful virtual DS World in 2020, the "Ultimate Dental Experience" will once again welcome guests in Las Vegas, Nevada. The event will take place September 23-25, 2021, at Caesars Forum and will also include a virtual option. This year's meeting will feature educational tracks with pertinent information to help attendees navigate current challenges and prepare to take advantage of the opportunities that digital dentistry offers.

Conference Call/Webcast Information
Dentsply Sirona's management team will host an investor conference call and live webcast on August 5, 2021 at 8:30 am ET. A presentation related to the call will be available on the Investors section of the Company's website at https://investor.dentsplysirona.com.

Investors can access the live webcast on the Investors section of the Company's website at https://investor.dentsplysirona.com. For those planning to participate on the call, please dial +1-877-370-7637 for domestic calls, or +1-629-228-0723 for international calls. The conference ID # is 4184820. A replay of the conference call will be available on the Investors section of the Company's website at https://investor.dentsplysirona.com, and a dial-in replay will be available for one week following the call at +1-855-859-2056 (for domestic calls) or +1-404-537-3406 (for international calls), replay conference ID # 4184820.

About Dentsply Sirona
Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 134-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. The Company's shares of common stock are listed in the United States on Nasdaq under the symbol XRAY. Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.

Contact Information:
Investors:
Andrea Daley
Vice President, Investor Relations
+1-704-805-1293
InvestorRelations@dentsplysirona.com

Forward-Looking Statements and Associated Risks

All statements in this press release that do not directly and exclusively relate to historical facts constitute "forward-looking statements." These statements represent current expectations and beliefs, and no assurance can be given that the results described in such statements will be achieved. Such statements are subject to numerous assumptions, risks, uncertainties and other factors that could cause actual results to differ materially from those described in such statements, many of which are outside of our control. Furthermore, many of these risks and uncertainties are currently amplified by and may continue to be amplified by or may, in the future, be amplified by, the novel coronavirus ("COVID-19") pandemic and the impact of varying private and governmental responses that affect our customers, employees, vendors and the economies and communities where they operate. For a written description of these factors, see the section titled "Risk Factors" in Dentsply Sirona's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and any updating information in subsequent SEC filings including the Company's Quarterly Report on Form 10-Q for the quarterly period ending June 30, 2021. No assurance can be given that any expectation, belief, goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

DENTSPLY SIRONA INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
(In millions, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net sales	$ 1,067	$ 491	$ 2,094	$ 1,365
Cost of products sold	469	315	917	721
Gross profit	598	176	1,177	644
Selling, general, and administrative expenses	398	261	783	620
Research and development expenses	40	18	77	52
Goodwill impairment	—	—	—	157
Restructuring and other costs	5	1	8	44
Operating income (loss)	155	(104)	309	(229)
Net interest and other expense (income), net	21	16	26	21
Income (loss) before income taxes	134	(120)	283	(250)
Provision (benefit) for income taxes	35	(24)	67	(14)
Net income (loss)	99	(96)	216	(236)
Less: Net loss attributable to noncontrolling interest	—	(1)	—	(1)
Net income (loss) attributable to Dentsply Sirona	$ 99	$ (95)	$ 216	$ (235)
Net income (loss) per common share attributable to Dentsply Sirona:				
Basic	$ 0.45	$ (0.44)	$ 0.99	$ (1.07)
Diluted	$ 0.45	$ (0.44)	$ 0.98	$ (1.07)
Weighted average common shares outstanding:				
Basic	218.4	218.7	218.6	219.8
Diluted	220.7	218.7	220.8	219.8

DENTSPLY SIRONA INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
(In millions)

	June 30, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 332	$ 438
Accounts and notes receivables-trade, net	678	673
Inventories, net	539	466
Prepaid expenses and other current assets	236	214
Total Current Assets	1,785	1,791
Property, plant, and equipment	769	791
Operating lease right-of-use assets, net	184	176
Identifiable intangible assets, net	2,488	2,504
Goodwill	4,033	3,986
Other noncurrent assets	119	94
Total Assets	$ 9,378	$ 9,342
Liabilities and Equity		
Current Liabilities:		
Accounts payable	$ 281	$ 305
Accrued liabilities	621	653
Income taxes payable	44	60
Notes payable and current portion of long-term debt	305	299
Total Current Liabilities	1,251	1,317
Long-term debt	1,946	1,978
Operating lease liabilities	139	130
Deferred income taxes	415	393
Other noncurrent liabilities	550	554
Total Liabilities	4,301	4,372
Total Equity	5,077	4,970
Total Liabilities and Equity	$ 9,378	$ 9,342

DENTSPLY SIRONA INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(In millions)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income (loss)	$ 216	$ (236)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	64	65
Amortization of intangible assets	112	94
Deferred income taxes	(6)	(32)
Stock based compensation expense	32	19
Goodwill impairment	—	157
Indefinite-lived intangible asset impairment	—	39
Other non-cash expense	20	4
(Gain) loss on sale of non-strategic businesses and product lines	(13)	—
Changes in operating assets and liabilities, net of acquisitions:		
Accounts and notes receivable-trade, net	(17)	269
Inventories, net	(77)	(1)
Prepaid expenses and other current assets	(22)	33
Other noncurrent assets	(8)	6
Accounts payable	(28)	(89)
Accrued liabilities	(10)	(140)
Income taxes	(8)	(15)
Other noncurrent liabilities	8	(9)
Net cash provided by operating activities	263	164
Cash flows from investing activities:		
Capital expenditures	(66)	(39)
Cash paid for acquisitions of businesses and equity investments, net of cash acquired	(241)	—
Cash received on sale of non-strategic businesses or product lines	27	—
Cash received on derivative contracts	—	58
Proceeds from sale of property, plant, and equipment	1	1
Net cash (used in) provided by investing activities	(279)	20
Cash flows from financing activities:		
Proceeds (repayments) on short-term borrowings, net	6	(1)
Cash paid for treasury stock	(90)	(140)
Cash dividends paid	(44)	(44)
Proceeds from long-term borrowings, net of deferred financing costs	13	1,442
Repayments on long-term borrowings, net	—	(701)
Proceeds from exercised stock options	45	6
Cash paid on derivative contracts	—	(31)
Other financing activities, net	(8)	(3)
Net cash (used in) provided by financing activities	(78)	528
Effect of exchange rate changes on cash and cash equivalents	(12)	(8)
Net (decrease) increase in cash and cash equivalents	(106)	704
Cash and cash equivalents at beginning of period	438	405
Cash and cash equivalents at end of period	$ 332	$ 1,109

Non-GAAP Financial Measures

In addition to results determined in accordance with U.S. generally accepted accounting principles ("US GAAP") the Company provides certain measures in this press release, described below, which are not calculated in accordance with US GAAP and therefore represent Non-GAAP measures. These Non-GAAP measures may differ from those used by other companies and should not be considered in isolation from, or as a substitute for, measures of financial performance prepared in accordance with US GAAP. The Company discloses these measures to allow investors to evaluate the performance of the Company's operations exclusive of certain items that impact the comparability of results from period to period and which may not be indicative of past or future performance of the normal operations of the Company. The Company believes that this information is helpful in understanding underlying operating results including net sales, operating income, and net income.

Organic Sales

The Company defines "organic sales" as the increase or decrease in net sales excluding: (1) net sales from acquired and divested businesses recorded prior to the first anniversary of the acquisition or divestiture, (2) net sales attributable to discontinued product lines in both the current and prior year periods, and (3) the impact of foreign currency translation, which is calculated by translating current period sales using the comparable prior periods currency conversion rates. Organic sales is an important internal measure for the Company. The Company's senior management receives a monthly analysis of operating results that includes organic sales and the performance of the Company is measured on this metric along with other performance metrics.

Adjusted Net Income (Loss) and Adjusted Earnings (Loss) Per Diluted Common Share

The adjusted net income (loss) attributable to Dentsply Sirona consists of net income (loss) attributable to Dentsply Sirona adjusted to exclude the following:

(1) *Business combination related costs and fair value adjustments.* These adjustments include costs related to consummating and integrating acquired businesses, as well as net gains and losses related to the disposed businesses. In addition, this category includes the subsequent impact roll-off to the consolidated statements of operations which results from fair value adjustments related to business combinations, except for amortization expense of purchased intangible assets noted below. Although the Company is regularly engaged in activities to find and act on opportunities for strategic growth and enhancement of product offerings, the costs associated with these activities may vary significantly between periods based on the timing, size and complexity of acquisitions and as such may not be indicative of past and future performance of the Company. They are therefore excluded to allow investors to better understand underlying operating trends.

(2) *Restructuring program related costs and other costs.* These adjustments include costs related to the implementation of restructuring initiatives as well as certain other costs. These costs can include, but are not limited to, severance costs, facility closure costs, lease and contract termination costs and related professional service costs, duplicate facility and labor costs associated with specific restructuring initiatives. Other costs include legal settlements, impairments of assets, and changes in accounting principle recorded within the period. The Company's restructuring programs usually require several years to fully implement and the Company is continually seeking to take actions that could enhance its efficiency. While restructuring charges are recurring, they are subject to significant fluctuations from period to period due to the varying levels of restructuring activity and the inherent imprecision in the estimates used to recognize the impairment of assets and the wide variety of costs and taxes

associated with severance and termination benefits in the countries in which the restructuring actions occur.

(3) *Amortization of purchased intangible assets.* This adjustment excludes the periodic amortization expense related to purchased intangible assets recorded in purchase accounting. Although these costs contribute to revenue generation and will recur in future periods, their amounts are significantly impacted by the timing and size of acquisitions.

(4) *Credit risk and fair value adjustments.* These adjustments include both the cost and income impacts of adjustments in certain assets and liabilities including the Company's pension obligations, that are recorded through net income which are related to the changes in fair value and credit risk. Although this non-service component of pension expense is a recurring item, it is subject to significant fluctuations from period to period due to changes in actuarial assumptions, global financial markets (including stock market returns and interest rate changes), plan changes, settlements, curtailments, and other changes in facts and circumstances. These items can be variable and driven more by market conditions than the Company's operating performance.

(5) *Income tax related adjustments.* These adjustments include both income tax expenses and income tax benefits that are representative of income tax adjustments mostly related to prior periods, as well as the final settlement of income tax audits, and discrete tax items resulting from the implementation of restructuring initiatives and the vesting and exercise of employee share-based compensation. Income tax related adjustments may also include the impact to adjust the interim effective income tax rate to the expected annual effective tax rate. These adjustments are irregular in timing the variability in amounts may not be indicative of past and future performance of the Company and therefore are excluded for comparability purposes.

Both adjusted net income (loss) and adjusted EPS are important internal measures for the Company. The Company's senior management receives a monthly analysis of operating results that includes adjusted net income (loss) and adjusted EPS. The performance of the Company is measured on these metrics along with other performance metrics.

Adjusted Operating Income (Loss) and Margin

In addition to reporting operating income (loss) in accordance with US GAAP, the Company provides adjusted operating income (loss) and margin. The Company defines "adjusted operating income (loss)" as operating income (loss) in accordance with US GAAP excluding certain items noted above which are excluded on a pre-tax basis to arrive at adjusted operating income (loss), a Non-GAAP measure. The adjusted operating margin is calculated by dividing adjusted operating income (loss) by net sales. Both adjusted operating income (loss) and adjusted operating margin are important internal measures for the Company. The Company's senior management receives a monthly analysis of operating results that includes adjusted operating income (loss) and margin. The performance of the Company is measured on these metrics along with the adjusted net income (loss) and adjusted EPS metrics noted above as well as other performance metrics.

DENTSPLY SIRONA INC. AND SUBSIDIARIES
(In millions, except percentages)
(unaudited)

A reconciliation of reported net sales to organic sales by segment is as follows:

(in millions, except percentages)	Three Months Ended June 30, 2021			Q2 2021 Change			Three Months Ended June 30, 2020		
	Technologies & Equipment	Consumables	Total	Technologies & Equipment	Consumables	Total	Technologies & Equipment	Consumables	Total
Net sales	$ 622	$ 445	$ 1,067	104.6%	138.0%	117.3%	$ 304	$ 187	$ 491
Foreign exchange impact				10.4%	11.2%	10.7%			
Acquisitions				19.0%	—%	11.9%			
Divestitures and discontinued products				(10.0%)	(8.5%)	(9.9%)			
Organic sales				**85.2%**	**135.3%**	**104.6%**			

A reconciliation of reported net sales to organic sales by geographic region is as follows:

(in millions, except percentages)	Three Months Ended June 30, 2021				Q2 2021 Change				Three Months Ended June 30, 2020			
	U.S.	Europe	ROW	Total	U.S.	Europe	ROW	Total	U.S.	Europe	ROW	Total
Net sales	$ 366	$ 431	$ 270	$ 1,067	179.4 %	99.5 %	87.5 %	117.3 %	$ 131	$ 216	$ 144	$ 491
Foreign exchange impact					1.8 %	15.6 %	11.4 %	10.7 %				
Acquisitions					43.6 %	— %	0.8 %	11.9 %				
Divestitures and discontinued products					(11.8 %)	(7.9 %)	(10.9 %)	(9.9 %)				
Organic sales					**145.8 %**	**91.8 %**	**86.2 %**	**104.6 %**				

DENTSPLY SIRONA INC. AND SUBSIDIARIES
(In millions, except percentages)
(unaudited)

For the three months ended June 30, 2021, a reconciliation of selected items as reported in the Condensed Consolidated Statements of Operations to adjusted Non-GAAP items is as follows:

(in millions, except per share amounts and percentages)	GAAP Three Months Ended June 30, 2021	Amortization of Purchased Intangible Assets	Restructuring Program Related Costs and Other Costs	Business Combination Related Costs and Fair Value Adjustments	Credit Risk and Fair Value Adjustments	Tax Impact of Non-GAAP Adjustments	Income Tax Related Adjustments	Total Non-GAAP Adjustments	ADJUSTED NON-GAAP Three Months Ended June 30, 2021
GROSS PROFIT	$ 598	32	(5)	1	—	—	—	$ 28	$ 626
% OF NET SALES	56.0 %								58.7 %
SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES	398	(24)	(4)	(3)	—	—	—	(31)	367
% OF NET SALES	37.3 %								34.4 %
RESEARCH AND DEVELOPMENT EXPENSES	40	—	—	—	—	—	—	—	40
RESTRUCTURING AND OTHER COSTS	5	—	(5)	—	—	—	—	(5)	—
OPERATING INCOME	155	56	4	4	—	—	—	64	219
% OF NET SALES	14.5 %								20.5 %
OTHER INCOME AND EXPENSE	21	—	—	(4)	(3)	—	—	(7)	14
INCOME BEFORE INCOME TAXES	134	56	4	8	3	—	—	71	205
PROVISION FOR INCOME TAXES	35	—	—	—	—	17	(3)	14	49
% OF PRE-TAX INCOME	26.1 %								23.9 %
LESS: NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS	—							—	—
NET INCOME ATTRIBUTABLE TO DENTSPLY SIRONA	$ 99							$ 57	$ 156
% OF NET SALES	9.3 %								14.6 %
EARNINGS PER SHARE - DILUTED	$ 0.45							$ 0.26	$ 0.71

For the three months ended June 30, 2021, the following table presents the details of the "Restructuring program related costs and other costs" column in the above table and the affected line item in the Consolidated Statements of Operations:

(in millions)	Separation costs related to executives	Costs related to restructuring plans	Professional services costs	Other	Total
Cost of products sold	$ —	$ (1)	$ —	$ (4)	$ (5)
Selling, general, and administrative expenses	3	—	1	—	4
Restructuring and other costs	—	5	—	—	5
Total	$ 3	$ 4	$ 1	$ (4)	$ 4

DENTSPLY SIRONA INC. AND SUBSIDIARIES
(In millions, except percentages)
(unaudited)

For the three months ended June 30, 2020, a reconciliation of selected items as reported in the Condensed Consolidated Statements of Operations to adjusted Non-GAAP items is as follows:

(in millions, except per share amounts and percentages)	GAAP Three Months Ended June 30, 2020	Amortization of Purchased Intangible Assets	Restructuring Program Related Costs and Other Costs	Business Combination Related Costs and Fair Value Adjustments	Tax Impact of Non-GAAP Adjustments	Income Tax Related Adjustments	Total Non-GAAP Adjustments	ADJUSTED NON-GAAP Three Months Ended June 30, 2020
GROSS PROFIT	$ 176	29	1	1	—	—	$ 31	$ 207
% OF NET SALES	35.8 %							42.2 %
SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES	261	(18)	(12)	—	—	—	(30)	231
% OF NET SALES	53.2 %							47.0 %
RESEARCH AND DEVELOPMENT EXPENSES	18	—	—	—	—	—	—	18
RESTRUCTURING AND OTHER COSTS	1	—	(1)	—	—	—	(1)	—
OPERATING (LOSS) INCOME	(104)	47	14	1	—	—	62	(42)
% OF NET SALES	(21.2 %)							(8.6 %)
OTHER INCOME AND EXPENSE	16	—	—	—	—	—	(2)	14
(LOSS) INCOME BEFORE INCOME TAXES	(120)	47	14	1	—	—	64	(56)
PROVISION FOR INCOME TAXES	(24)	—	—	—	17	(8)	9	(15)
% OF PRE-TAX (LOSS) INCOME	20.0 %							26.8 %
LESS: NET (LOSS) INCOME ATTRIBUTABLE TO NON-CONTROLLING INTERESTS	(1)						—	(1.0)
NET (LOSS) INCOME ATTRIBUTABLE TO DENTSPLY SIRONA	$ (95)						$ 55	$ (40)
% OF NET SALES	(19.3 %)							(8.1 %)
EARNINGS PER SHARE - DILUTED	$ (0.44)						$ 0.26	$ (0.18)
Weighted average common shares outstanding used in calculating diluted GAAP net loss per common share								218.7
Weighted average common shares outstanding used in calculating diluted Non-GAAP net income per common share								218.7

For the three months ended June 30, 2020, the following table presents the details of the "Restructuring program related costs and other costs" column in the above table and the affected line item in the Consolidated Statements of Operations:

(in millions)	Costs related to restructuring plans	Professional services costs	Total
Cost of products sold	$ 1	$ —	$ 1
Selling, general, and administrative expenses	—	12	12
Restructuring and other costs	1	—	1
Total	$ 2	$ 12	$ 14

Attachment 9E

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Dentsply North America LLC (DNA), as a wholly owned subsidiary of Dentsply Sirona Inc., does not have any lenders or holders of indebtedness specific to DNA. Dentsply Sirona Inc., the public parent company, has incurred debt from various lenders in the normal course of business. Information on current and long-term debt of Dentsply Sirona Inc. can be found in its most recent Form 10-K for the year ended December 31, 2020: https://www.sec.gov/ix?doc=/Archives/edgar/data/818479/000081847921000007/xray-20201231.htm

A list of Dentsply North America LLC employees, contractors, etc. is attached.

DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

Employee ID	Last Name	First Name
2004184	ABRAHAM	RICHARD
1006037	ADAMS	HALEY
1000530	AGLOW	JUSTIN
2003599	AKEMAN	LAUREN
2004461	ALBA	JILLIAN
1010043	ALLEN	CHRISTOPHER
2002741	ALLEN	JEFFREY
177996	ALLINSON	MATT
2003940	ALMEIDA	NICHOLAS
1020363	ALMOND	TIMOTHY
2002041	AMARA	ANDREW
1020092	AMBROSIO	BERNADETTE
177861	AMSTUTZ	BRIAN
174092	ANDREGG	STEVEN
2004662	ANDREWS	JOSHUA
2050379	APHING-KOUASSI	JEAN FRANCOIS
1010109	ARDIZZONI	MARIA
1020216	ARMONAS	MANTAS
2003146	ARMSTRONG	REBECCA
905040	ARRINGTON	ERIK
2023556	ARTL	JOSEPH
2005039	ASAMOAH	JERRY
2004726	Aagesen	Bret
2050501	Adams	Anhi
2050392	Ahmedi	Insiyah
2004890	Akdemir	Phillip
1006105	Almy	Shannon
177790	Altman	Russell
2003906	Aluise	Eric
2004811	Alwran	Joshua
2050479	Amalfitano	Carlos
2025681	Anderson	Matthew
2003642	Anderson	Ryan
2024739	Angelova	Nadejda
2025719	Antonelli	Jonathan
2024266	Arena	Thomas
1006171	Audino	Erin
2023443	Ayscue	Cynthia
2002044	BAKER	MATTHEW
2004960	BALDWIN	DANELLA
2023297	BANDURSKI	STEVEN
2050415	BANKSON	CHELSEY
1010114	BARGHI	CLINT
2000738	BARGIEL	JUSTIN
2001980	BARKOW	DAVID
2005085	BARNASH	SHANNON

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2000562	BARRETT	RYAN
2002253	BARWELL	PETER
1010373	BATE	THOMAS
177426	BAUX	BRENT
2005024	BEACH	JENNIFER
177928	BEALS	LARRY
2005067	BEASON	JESSICA
2004695	BECKER	DANIELLE
2004467	BEITZEL	ZACHARY
2001292	BELO	ELISABETH
2002935	BELTRAN	JENNIFER
177812	BENARROUS	DAVID
2004454	BENDIX	JASON
2023461	BENNETT	TIMOTHY
2002767	BENZ	NATALIE
2003006	BERN	BLAKE
177972	BERNAUER	JO5EPH
2000275	BERO	JEANINE
905094	BERRETT	MELISSA
2004896	BERRY	DIANE
2004568	BERSE	NATALIE
2002444	BERTHON	JESSICA
2005345	BILE5	STEVEN
2004678	BILOTTO	ANTHONY
905113	BIRNBAUM	ROBERT
2005135	BLACK	CIRON
2022711	BLACK	MELVIN
1020315	BLASCHKA	ERIKS
1010053	BLOCCHI	CATHY
177980	BOOTH	AARON
1020388	BOWE	BRYAN
2004481	BRANCH	JAMES
2002867	BRANDT	ROBERT
2004868	BRENNAN	TARA
2002394	BRICKMAN	JOSH
2003503	BRIGHT	WESLEY
2004927	BROOKS	HEATHER
2005185	BROWNE	SHANNON
2004795	BRUNO	ERIC
2023534	BRUNO	JOSEPH
2003704	BRYANT	MELISSA
2000363	BUBENICEK	ERIC
2003004	BUCCIONE	MICHELLE
905176	BURKHALTER	MICHAEL
2005238	BUSTOS	JUAN
1010238	BYRNE	CHRISTOPHER
2005829	Baba	Tarek

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2001370	Baier	Jessica
1010103	Baldwin	Casey
2024804	Ballou	Andrea
2025355	Bastoe	Heath
2004158	Baugh	Nicholas
2002271	Baughman	Kristen
2002143	Bautista	Alan
902960	Bearbower	Grant
1010294	Bedwell	William
2050461	Belfi	Ashlee
2025190	Bentz	Kelly
2050498	Berger	Scott
2003826	Bergstrom	Adam
2024553	Bijl	Jennifer
2004823	Biringer	Jenifer
2004334	Blankenship	Leah
2025889	Bloomquist	John
2004542	Blunk	Joshua
2002692	Boehner	Caitlin
2004854	Bohnhoff	Rick
2003773	Bowie	Elizabeth
177608	Braden	Audra
2024211	Bradley	Mack
2025022	Braham	Gregory
1030004	Bridgman	Edward
1002504	Britt	William
2025759	Brown	Danielle
2024737	Brown	Randolph
2024802	Buck	Shane
2025361	Buser	Kelley
2002466	CALVERT	KYLE
2003830	CAMBRIA	JOHN
2000476	CAMPBELL	LEROY
2004200	CAPPICCILLE	THEA
1020788	CARBO GONZALEZ	CARLOS
2005036	CAREY	BRAD
905096	CARMOLA	MICHAEL
177781	CAROON	CALLIE
2023363	CARPENTER	SHAWN
1006192	CASTANON	ALEXANDRA
2005070	CERZA	BENJAMIN
2000899	CHAN	ERICA
2004905	CHANG	JEAN-PIERRE
2003398	CHAPMAN	DANIEL
2050418	CHAPMAN	JOANNA
901071	CHAVARRIA	HENRY
2004666	CHAVEZ	GERARDO

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List of Employees, Contractors, Etc.

902868	CHECK	JACQUELYNE
2023603	CHENEY	ROBERT
039220	CHENEY	SHAWN
20502981	CHOU	PATRICIA
2023552	CHOW	GLORIA
2002093	CHRISTOPHER	MICHAEL
2002433	CHRYSSOFOS	COSTA
902903	CIULLA	KENNETH
2000889	CIUNCI	CHRISTOPHER
2004208	CLANCY	SCOTT
2005107	CLARK	KENDREA
2005319	CLARKE	GEOFFREY
2004209	CLICK	AMANDA
2001721	CLIFFORD	SEAN
1020038	COFFEY	GREGORY
072053	COLEMAN	JASON
1010146	COLEMAN	JULIA
2004865	COLOMBI	CASEY
2023486	COMEAU	DANIELLE
2005254	CONDOR	O5CAR
2017630	CONNELLY	JACK
1030006	CONNELLY	JENNIFER
2001566	CONNERS	ROBERT
177637	CONTRERAS	MARC
2004990	CONWAY	ALEXANDER
2023301	COOK	SAMANTHA
2004970	COOPER	ASHLEY
2004341	COOPER	JAYME
2003121	CORBETT	DONAL
2005130	CORNISH	STEFANIE
2005128	COSTA	ROBERT
2004962	COX	CORY
2004906	CRAMP	DAVID
2023445	CRANDALL	RICHARD
280458	CRAWFORD	ARVILLE
1001039	CREGGER	AMANDA
2004635	CROSS	NATHANIEL
2004934	CROWL	SPENCER
905151	CULLUM	SAMUEL
2000869	CUZA	JEROD
177716	Callahan	Cindy
2050451	Cameron	Kyle
2025660	Carollo	Jennifer
2004702	Carril	Myrna
2025387	Casas	Alejandra
1000533	Centa	Lori
2025946	Cheeks	Travis

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1020435	Chirgwin	Andrew
280420	Cicerone	Harold
2003746	Cisco	James
905129	Cisowski	Steven
2023678	Clark	Colin
2001311	Coffey	Mathew
2024414	Cohen	Jared
2025720	Cohen	Matthew
2002914	Collins	Stephen
2002343	Collins	Timothy
1020512	Colwell	Clark
2025733	Comppen	Amber
2024875	Conner	Maegan
2025042	Conrey	Jonathan
2025888	Cooper	Marlena
1030008	Cooper	Scott
2025267	Cortes	Carly
2050499	Couch	Marc
2000570	Crain	Jordan
1020976	Creath	Adam
177984	Crider	David
2004986	Cullinan	EMILY
1010086	Curry	Valerie
2004765	D'AMBROSIO	DEREK
1010151	DALTON	ROBERT
2023464	DANBURG	SARAH
2004922	DANENBERG	DREW
2023444	DANNA	COURTNEY
1030009	DARK	JASON
1010092	DASKALON	GREGG
2023507	DAVENPORT	MICHAEL
2004350	DAVIS	BRENT
1030010	DAVIS	JONATHON
2004639	DAVIS	LINDA
2004291	DAVIS	MARY
2000430	DAWSON	ELAINE
2004892	DE LA PENA	ERICK
1020491	DEAN	BRADLEY
2000284	DEAN	NIKKI
1020291	DEANGELIS	JEFFREY
2002797	DEBERRY	RICHARD
2001772	DEHNE	LAUREN
905219	DELAWDER	MEAGAN
2005110	DELLER	JOHN
901038	DEMARCO	RANDY
039334	DENERO-FLORIO	SUZANNE
2004504	DENTON	ANDREA

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2005237	DEPETRO	CHELSEA
2001113	DERTINGER	JAMES
2004562	DEVLIN	JOSEPH
2004239	DEW	CYNTHIA
2004883	DIBELLA	MICHAEL
902849	DIETERICH	JEFFREY
174023	DILLEY	ANDREW
905137	DIMOND	TRACEY
2002337	DISIMONE	SALVATORE
2003706	DOBKOWSKI	RACHEL
177985	DODD	DOUG
2004472	DOVER	KELLY
2003655	DRADUL	DORJE
2001617	DRAY	KRISTIN
2001442	DRUCKER	KIRSTEN
177890	DUFFEL	BRADLEY
2005082	DUFFY	KELLY
2001207	DUFFY	RUAIRI
2002536	DUGAN	JOHN
2001760	DUGAN	PATRICK
2000686	DUNCAN	ERIC
2004331	DUNN	JEFFREY
2000114	DUNN	RICHARD
2003481	DUNN	THOMAS
907791	DUPLOOY	LESLIE
2001607	DURANCE	LAURA
2004907	DWYER	MOLLY
2002992	DYBVIG	ALEXANDRA
2024270	Dannberg	Frida
2004628	Davis	Morgan
2024562	Davis	Stacy
1001001	DeGroote	Brandon
2023657	Deschamps	Floyd
2025731	DiPoalo	Giovanni
2002424	Dilworth	Pauline
2050462	Doepel	Adam
2024945	Doughty	Heather
177999	Downs	Kevin
2004583	Doyle	Tyler
2002476	Drain	Jeff
2050453	Dunkin	Amanda
2020735	Duvall	Katie
2004234	EASON SINGER	SARA
902839	EASTERLING	KENNETH
016351	EBBERT	CHARLES
2004147	EHRASTOM	BENJAMIN
1020559	EHRENSTROM	MATTHEW

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

177480	EIDSON	JASON
1001055	EIDSON	JENNIFER
2005058	ELEFTHERIOU	PETER
2003179	ELLIOTT	MARY
1010056	ELLSWORTH	MARLENE
2004456	EMBRY	JAMIE
2000501	ENGEL	LISA
2003596	ENNIS	BRUCE
2004259	EPPERLY	BROOKE
2003963	ESPINOZA	CHRISTOPHER
2003036	Eastman	Seth
2025045	Eaton	Nicholas
2050489	Eggett	Jamee
2001978	Eichler	Craig
2003925	Elfreth	David
2004050	Ellenwood	Lindsey
2024264	Elmore	Robert
2024222	Emry	Troy
2024986	Emsing	Cullen
1020501	Erickson	Thomas
2025717	Eskeland	Rebecca
2003781	Eversole	Joel
2023532	FADOOL	RYAN
1010124	FAIN	KERRY
1030012	FALEN	GREGORY
2004439	FALLER	CANADA
907788	FARNHAM	BARRETT
177948	FEE	CHARLES
2002047	FELDMAN	DENNIS
177956	FELTS	CHARLES
2001214	FERGUSON	SEAN
2004487	FINDLEY	SCOTT
2004834	FINDLEY	TAMMY
1001048	FIORITO	JASON
2000929	FIUMANI	ANTHONY
2050381	FLANNERY	MEGHAN
905191	FLEMING	LAURA
2050349	FLETCHER	RICHARD
2005012	FLOOR	WILLIAM
1020548	FLORES	QUENTIN
2023296	FORSYTH	DANA
2001596	FORTH	AIMEE
2004848	FORTUNA	KRISTIE
1010076	FOX	ANGELA
2003288	FRADELLA	MICHAEL
018788	FRIDAY	JOHN
1020273	FRIEDMAN	SCOTT

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List of Employees, Contractors, Etc.

905143	FURGERSON	JEFFREY
2025934	Fabre de Roussac	Adria
2002537	Fairman	Kyle
2025359	Fawcett	Michele
2025793	Fay	Brian
2024554	Fisher	Mackenzie
2024214	Fleming	Harrison
2024212	Florek	Nicolas
2001706	Forgach	Nicole
2002270	Freeman	Danielle
2024254	Fritz	Stephen
905051	GAGICH	JEFFREY
2002780	GALICHIO	ROBERT
2004450	GALLAGHER	NEAL
902934	GALLEGOS	ERIN
905134	GARD	TODD
905014	GARFF	BRADLEY
177872	GARLAND	BRIAN
1020007	GAVIN	PETER
2000882	GEESEY	JANEL
1020104	GEHRINGER	LINDA
2050348	GIBSON	APRIL
2023656	GILES	JEREMY
2004680	GILLAM	MICHAEL
2004428	GINGRAS	TREVOR
2023314	GIROD	KIMBERLY
2003700	GIZINSKI	SCOTT
2005037	GLADDING	KENNETH
902930	GLADSTONE	KEVIN
2002673	GOGONIS	EVAN
2050340	GONZALEZ	ENEIDA
2004772	GOODWIN	COREY
905163	GOSLEE	BRIAN
017254	GOSNEY	MARK
1006213	GOUDIE	THERESA
1001525	GRAHAM	RENEE
2004530	GRAVES	COURTNEY
20502970	GRAVES	ERICKA
2001336	GRECSI	MONICA
2003162	GREGORY	BRAD
2004935	GRISHABER	HEIDI
908132	GRONERT	DONALD
2003989	GUERIN	THOMAS
2005051	GUILLEN	FRANCISCO
2002781	GUILLEN	SUSANA
2024810	Garner	Cole
177848	Garrett	James

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2002327	Gates	Barrett
2024352	Genter	Jeffrey
2004758	Gielens	Kris
2050475	Gifford	Lance
290175	Godfrey	Joseph
1035028	Golicher	Joseph
2003758	Gonzales	AMBUR
2025942	Granillo	Raul
2025038	Green	Blake
2004317	Guichard	Nicholas
908569	Gunnet	Susan
1020333	HADLEY	MARIA
908386	HAGARMAN	ANGELA
1010441	HAINE5	JAMIE
2004703	HAINES	RHONDA
2004957	HALL	CODY
2004667	HALL	JEREMY
2003774	HALLORAN	AMELIA
1006106	HALSEY	JASON
2004361	HALVATZIS	SUSAN
1020328	HAMDAN	MOHAMAD
2002844	HAMRICK	SHARA
902965	HARPER	KEITH
905164	HARRELL	ROBERT
1020529	HARRIS	CHRISTOPHER
901015	HARRIS	KELLY
2002998	HARRISON	NICHOLAS
2000205	HARTLEY	LYDA
2004869	HARTLEY	SCOTT
2004813	HARTNESS	WILLIAM
2003388	HARWELL	DEREK
2003919	HAYDE	MARK
2002378	HEINZLER	JOSEPH
2003199	HEMPHILL	BENJAMIN
1006087	HERRERA	LUIS
2005059	HERRICK	KEVIN
2020239	HIGH	JENNIFER
2050314	HILL	HALLE
2005249	HODGE	CARL
2004787	HOLLNAGEL	DAVID
2004844	HOLLY	EUN
1007021	HOLM	NICHOLAS
2001039	HOMOLKA	GARY
2004390	HONEYCUTT	JESSICA
905105	HOOVER	NEIL
2004760	HORTON	SHANNON
2000085	HORVATH	BRIAN

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2003767	HORVITZ	EILEEN
2003735	HOVEY	JAMES
1001090	HOVLAND	SCOTT
2003664	HOWELL	MICHAEL
1000546	HOYOS	JOHN
1030017	HUBER	GLEN
2050406	HUNT	SUSANNA
2005189	HUTTENLOCKER	JAMIE
2004727	HUU	CHUCLY
2004881	HUYNH	LISA
2004636	HYNES	JAMES
2002112	Haack	Amy
2023679	Hain	Victoria
2025734	Ham	Brent
2004260	Hansen	Christopher
2025659	Harbeson	Jill
2024965	Hardwick	Maggie
2024816	Haroon	Sharib
2004651	Harper	Jeremy
2024877	Harrell	Charles
2024645	Hathaway	Logan
2024413	Hayes	Franchesca
2050490	Hayes	Ryan
1030016	Hedtler	Nathan
2001989	Hein	Derrick
2024209	Hersey	Matthew
2025349	Hillier	Hilary
177738	Hines	Christopher
2002882	Hofmann	Henry
1020514	Hollenbeck	Ryan
2025252	Houston	Robin
1001011	Howard	Kristina
2025578	Hunt	Kyle
2004943	Hunter	Travis
2025024	Hurd	Saran
2005004	IRVING	PATRICK
2004796	Irwin	Ryan
905082	JACOB	LAURA
2003384	JOHNSTON	CALLIE
2002296	JONES	RYAN
2023503	JUSTIN	LAURA
905136	Jacketti	Anthony
2004509	Jackson	Heather
2024350	Jacques	Alexa
2003593	Jarrett	Noel
2025362	Johnson	Benjamin
2005252	Johnson	Erica

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1010038	Johnson	Kim
2005223	Johnson	William
2024267	Johnston	Lindsey
2004404	Jones	Amy
2025864	Jorgensen	Shelby
2005148	KAHLER	ZACHARY
2003085	KAIN	TYLER
2023546	KALALA	LINA
2003052	KANDALEN	DEIRDRE
1006139	KARTCHNER	BRADLEY
177750	KASH	BRYAN
015857	KEARSE	TALVA
2004351	KEATING	KYLE
2004661	KEEGAN	JAMES
2004627	KEILTY	KIRSTIN
2005303	KELLY	MATTHEW
1030021	KELSCH	ROGER
918799	KERCHNER	KATHERINE
901879	KILGORE	SEAN
2004978	KIM	JASON
2003817	KINDER	ERIN
2004994	KINNEY	KRISTEN
1010127	KLINE	SCOTT
2003254	KLINE	TRENT
2005111	KLOSKEY	JENNIFER
2003708	KLOTZ	ANDREW
2023295	KLUMP	JENNIFER
2003330	KNECHT	ANDREW
177740	KOEHLER	KELLY
2002760	KOEPPEL	JARED
2002282	KOEPSELL	JEFFREY
2004886	KOHLER	JAMES
2023441	KOROSCHETZ	MATTHEW
2005088	KUBIAK	MICHAEL
90S060	KUZEMCHAK	JOHN
2005258	KVICK	JORDAN
1030019	Kasai	Payam
2004007	Keiper	Scott
1001108	Kill	Kevin
2002586	Kiser	Valerie
2002097	Kleber	Amanda
2025104	Knott	Patricia
2025762	Knox	Timothy
2004664	Kolasinski	Zach
2003418	Kosnitzky	Jesse
2004707	Kraft	Spence
2004880	LACHCIK	CHRISTOPHER

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List of Employees, Contractors, Etc.

2002007	LAIRD	REX
2050408	LALA	SUMERA
1010326	LAMODA	JEREMY
2003626	LANIGAN	TAYLOR
905204	LARKIN	DANA
2001274	LARSON	BRENT
1020352	LAW	CHRISTOPHER
2005108	LAWRENCE	ANGELA
2004931	LECHE	CLAUDIA
1006153	LEDBETTER	COLBY
1020982	LEDUC	STEPHANE
2050393	LEE	SINCLAIR
2002408	LEHNERER	KELLY
2005096	LESSARD	JODI
177998	LESSER	ROBERTA
2050335	LI	CHEN
1001057	LIMOGES	JON
2004684	LINDEMANN	ZACHARY
2005246	LINEBERGER	BAILEY
2002999	LIPSKY	ALYSSA
2005068	LITINGER	AMY
2005063	LITTLE	CHRISTOPHER
2001993	LOADMAN	LINDSAY
2003686	LOCASCIO	FRANK
1010075	LOEWENSTEIN	JAMES
2001574	LOONEY	REBECCA
2050410	LOPEZ	JENNICA
2003791	LOPEZ	JUAN
1030023	LOPEZ	LAURA
177697	LORIMER	MATTHEW
2004933	LOUDENSLAGER	NICHOLAS
1006006	LOWE	GARRY
1001072	LUCAS	MICHAEL
2023394	LUCAS MCGURK	ALLISON
902922	LUEHRING	SARAH
177934	LUTJEN	WILLIAM
2002362	LYNGDAL	STEVEN
2002566	Langan	HANNAH
1020353	Lanier	Jeffery
2004979	Larsen	Taren
2004289	Lavin	Daniel
2003646	Lee	Clayton
2024966	Lee	Shawn
2004399	Lemon	Thomas
2005220	Leonard	John
2000953	Leone	Chelsea
1030022	Lerario	James

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List of Employees, Contractors, Etc.

2004545	Lignowski	John
2004789	Lindemann	Jeffrey
2004009	Lis	Adam
2050452	Little	Douglas
1010246	Lockaby	Curtis
2005302	Lopes-Nigro	Katrina
2004014	MABIE	JOSHUA
2050342	MACK	TODD
2004910	MAESTAS	KATHRYN
2023393	MALOY	THOMAS
1020118	MANDIA	JEFFREY
905079	MANGANELLA	KURT
2003740	MARCIN	DIANE
2004673	MARCINKOWSKI	CHRISTINE
2005150	MARIANI	CONNOR
1000554	MARLIN	MELISSA
2003253	MARRA	CELESTE
1010022	MARRON	M. BRIDGET
2000715	MARSH	RACHEL
2000527	MARSHALL	DELMARIE
2003061	MARTIN	PETER
2023602	MARTIN	TODD
2002363	MASON	ASHLEY
2004839	MATHER	KELLEN
2002845	MATHEWS	ANTHONY
2003798	MATTINGLY	THEODORE
2000015	MAYER	DOUG
1010319	MAZEWSKA	ANIA
905148	MCCACHREN	CLARICE
2001151	MCCAULEY	NICHOLAS
2004908	MCCLEARY	JULIA
2002417	MCCLOSKEY	LAWRENCE
1010113	MCCORMICK	STEVEN
2002660	MCDUFF	ELIZABETH
2004790	MCFARLAND	BRADLEY
2002055	MCFARLAND	BRIAN
2004305	MCGARRY	ANDREW
2002199	MCGLEW	MICHELLE
1006186	MCGUIRE	RANDALL
2002944	MCKEE	ALLEN
2050424	MCKNIGHT	ROGER
2003722	MCPHAIL	KRISTEN
2003732	MCPHEE	BRIAN
2023455	MCQUAIDE	MEGAN
2003207	MEADOWS	JAMES
1020327	MERRITT	JONATHAN
2004516	MERRITT	TIMOTHY

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List of Employees, Contractors, Etc.

2003559	MESROPIAN	CHERYL
905019	MILLER	BURKE
2000856	MILLER	DAVID
2005104	MILLER	KEVIN
905218	MILLER	MATTHEW
2001497	MILLER	RACHEL
908288	MILLER	STANLEY
1006238	MILO	GREGORY
2005000	MOCK	LINDSAY
2003389	MOLNAR	PAIGE
2004189	MONTAGUE	ARIELLE
2003947	MONTALVO	LISA
905058	MONTEIRO	JOEL
2003136	MOOK	BRITTANY
2023625	MOORE	WILLIAM
2023362	MORIMOTO	JANNA
2000575	MORIN	BROOKE
2000522	MORKERT	CORY
2003017	MORRIS	CASEY
905081	MORTON	KYLE
1006004	MOSLEY	CHARLES
1030030	MOYAL	HENRY
2000475	MUELLER	DONALD
177964	MULLEN	CHRISTINE
281480	MULLER	KATHLEEN
2002635	MUNSON	JUSTIN
2004463	MURDOCK	RICHARD
2001443	MURNS	DAVID
2001692	MYERS	JONATHAN
2000461	MYERS	KEVIN
2001305	MYERS	ZACHARY
2025256	Mabry	Charles
2025940	Mangan	Marissa
2024415	Mangiere	Richard
2004937	Manzione	Matthew
2024812	Marcellino	Anthony
905231	Martin	Kimberly
2025415	Martinez	Julian
2025667	Mashni	Nicholas
2004816	Mastrota	Lauren
2025658	Mazzie	Linda
1006040	Mazzocco	Gregory
2003878	McDermott	Jonathan
1030026	McDonell	Lauren
2024829	McKernan	Katie
2050365	McLaughlin	Morgan
2000857	Mcclendon	Coley

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List of Employees, Contractors, Etc.

2	Medling	Brandon
2004594	Melancon	Addison
2004911	Mergenmeier	Laura
2004515	Meyer	Melanie
2024735	Miller	Brett
2050502	Miloser	Adam
2024208	Molloy	Sarah
2002061	Monsantofils	Monica
2025468	Montoya	Gwendolyn
2003831	Mooney	Stephen
2004447	Moonitz	Timothy
2025856	Moore	Hiram
2024944	Morrisroe	Kerri
2002648	Munsey	Lisa
2025464	Murphy	Mackenzie
1030031	Murphy	William
2024736	Musgrove	Andrew
2003662	Mutz	Mackenzie
2024369	Myers	Robert
2003743	Myslinski	Michael
2004953	NAJIB	RASHA
2005268	NANGLE	FLANNERY
018702	NEFF	KRISTI
2004002	NEPOMUCENO	KYLE
1001021	NEUFELDT	TIFFANY
2050403	NICHOLLS	CHRISTOPHER
281520	NOLAN	PATRICK
2050441	Nagle	Ryan
2000644	Neitzke	Wendy
2025764	Nelson	Heather
2025579	Nelson	Kyle
2025105	Newberry	Aaron
2004607	Newberry	Austin
2003315	Nganga	Taylor
2005098	Nickell	Cameron
1020275	Novak	James
2002581	Nowling	Stephanie
2005138	Nunes	Scott
2004887	O'BRYAN	ROBBIE
2004841	O'CONNELL	STEPHANIE
2005250	O'LEARY	MICHELE
177761	O'NEILL	CHRISTOPHER
2003360	O'NEILL	JOHN
1020794	OLSON	CAITLIN
2023294	ONOFRE	JENNA
1010293	ORISMA	HUGUES
177796	ORWIG	CHRISTOPHER

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2004236	OWENS	KERRIE
2003373	Odom	Nick
2024573	Oganyan	Pavel
2005261	Olds	Levi
2003699	Olson	Jonathan
2023298	Owen	Ginger
905180	PALADINO	MINITA
1010313	PALAGI	DAVID
2005344	PALKER	KATRINA
905025	PANE	CHRISTOPHER
2004393	PANICO	JEFFREY
177917	PAPAIS	BRANDON
2002245	PARKER	BRYAN
1020540	PARKER	STERLING
2004874	PARQUET	VANIA
2003789	PATE	CHRISTY
2003400	PATTEN	NICOLE
1030034	PATTEN	PAMELA ANN
2004938	PAUL	EDWARD
1001016	PEACHER	YOLANDA
2001242	PEAK	JULIA
2003637	PEDERSEN	BRENT
1030067	PEDRAZA	ISMAEL
905233	PEEK	TIMOTHY
2005296	PELZER	BLAKE
2004923	PESCHL	ALEX
1030035	PETERS	KENNETH
2004997	PETERSON	TIFFANY
1020537	PFERSCHY	DEAN
2003972	PHAM	HELEN
281720	PHELAN	MARI
1020000	PHILLIPS	ALAN
2050412	PICONE	THOMAS
2003421	PIERCE	ROBERT
905089	PIMENTEL	MARK
905059	PLUYMERT	JOEL
2003854	POGOTIS	CLINTON
2003614	POINDEXTER	PAQUITA
1020505	POLICH	MEGGAN
1005043	POLLARD	NICHOLAS
2005160	POLLOCK	GINA
2005181	POTTS	AUGUST
1001102	POULIN	THOMAS
2002879	POWELL	TYLER
177335	PRINGER	CINDY
1006083	PRYNNE	PATRICK
1020033	PUGLISI	GUY

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2050480	Page	Molly
2024511	Palermo	Daniel
177512	Parker	Jonathan
2002262	Parks	Ashley
2024646	Peery	Chase
2024880	Perez	Rebekah
2024803	Petersen	Benjamin
2002395	Petriskie	Mary
2002063	Petrossian	Raffi
2050491	Phillips	Brandon
2002988	Phillips	Bryan
2025363	Phillips	Daniel
1030068	Phillips	Kristina
2002807	Pichardo	Lena
2001009	Pierce	Benjamin
2024943	Plakon	Timothy
2001675	Polsinelli	Stephen
2024634	Poole	Steven
2024220	Proano	Casey
1020263	Pruitt	Jack
2003030	Pullig	David
2000135	Purcell	Jeffrey
1030036	RADELAT	ARMANDO
2004952	RADLE	HALEY
2001095	RAMIREZ	JEFFREY
2004946	RAMOS	MIRIAM
2004902	RAMOS	RODRIGO
2001243	RANDALL	MATT
2000402	RANTZ	JENNIFER
1020290	RATHORE	HARPREET
2002505	RAVINET II	JOSE
062646	REED	SCOTT
2002901	REMKUS	JUSTIN
2003084	RENAUD	RYAN
2002554	RESSLER	RICHARD
2000822	RETTERBUSH	JOHN
2004474	REYNOLDS	CARRIE
2001667	REYNOLDS	JASON
905155	RHINE	KERRI
1002532	RICCIARDI	JEANNE
2004912	RICE-BISHOP	DAVID
2004537	RICH	JOSEPH
2004465	RICHARDSON	ANTONY
2002033	RICHIE	TYSON
2003490	RICHMOND	JORDAN
2004827	RICKS	TABATHA
2002310	RIDER	JESSICA

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List of Employees, Contractors, Etc.

2004940	RIHNER	EVIN
2004669	RISCH	TERESA
2050407	RITENOUR	DORIAN
2001952	RITSCHARD	LAUREN
2003790	ROACH	CYNTHIA
177573	ROADCAP	HARVEY
2023412	ROBINSON	EDWARD
2002732	RODDA	ASHLEY
2004382	RODRIGUEZ	RICHARD
1030038	RODRIGUEZ	WHALKY
1020381	ROGERS	JONATHAN
2023655	ROMANELLI	JENNIFER
290264	ROMOSER	SEAN
1020801	ROSARIO	JORGE
281850	ROSARIO	WAYNE
2004924	ROSSIGNOL	NATHAN
1010129	ROWETT	ROSEANNE
2005021	RUBIO	KARLA
2002260	RUEBEL	ROBERT
2004959	RUGGIERO	MATTHEW
2004605	RUSSO	RICHARD
2004899	RUTHERFORD	NICHOLAS
1001561	RUTKOWSKI	ASHLEY
2025941	Rauterkus	Christine
2000710	Reavy	Neil
2004480	Recor	Michael
2024561	Reed	Asher
2024221	Reed	Nora
2024878	Reimer	Ross
2002841	Rich	Katy
902897	Riley	Brian
2000259	Rivera	Kenneth
177788	Roberts	Matthew
2024368	Robertson	William
2025041	Robinson	Johnathan
2004863	Robinson	Karen
1030039	Rogers	Kevin
2024367	Rogers	Robin
1000571	Rogiokos	George
2004470	Rooney	Cory
2050476	Rush	Brian
2023592	SADLER	CAROLINE
2001297	SANCHEZ	JESUS
2000021	SANSERINO	GREG
2004687	SCARPACE	TODD
2005147	SCHMIDT	JONATHAN
2004246	SCHMIDT	TYLER

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2003108	SCHNUR	JONATHAN
2002865	SCHOBER	ALLISON
2004443	SCHROEDER	NENA
2023468	SCHULTZ	CHRISTOPHER
016024	SCHUMACHER	BRIAN
290058	SCHWAB	ROBERT
1001042	SEE	TONYA
2004893	SEELY	CARY
908824	SELJAAS	AARON
1010133	SENESE	AMANDA
1010187	SENNE	FREDERICK
2050402	SEVERANCE	JENNIFER
1006163	SHALZ	SABRINA
2004532	SHAMOUN	JONATHAN
2023470	SHANKLIN	COURTNEY
2004527	SHAPOVALOV	DAVID
2002151	SHARP	CHARLENE
2005209	SHARP	TRACY
2050400	SHEIN	SYDNEY
177929	SHERMAN	DAVID
2023310	SHIGETA-KOCH	ANNE
2005295	SHOEMAKER	DANIEL
1006025	SHOOK	SANDIE
905213	SHORT	DAVID
2003063	SHULL	ALICIA
177496	SIECH	MATTHEW
2005086	SIGNORELLI	GABRIELLE
2002328	SIMMONS	ELLIOTT
2050396	SIMMONS	JOHN
2003218	SIMS	MICHAEL
2004538	SINATRA	KATHLEEN
019003	SIPPERLY	DAVID
018790	SKIAS	GEORGE
2002861	SLADE	JOSEPH
018264	SMALL	STACEY
2005230	SMEKAL	ZACHARY
2000661	SMITH	ARTHUR
2005294	SMITH	EMILY
902607	SMITH	GREGORY
2003564	SMITH	JOSEPH
2003197	SOMMERS	IAN
2004966	SPARKS	ALEXA
2002526	SPENCER	KATHRYN
2005219	SPERRY	RACHEL
1006216	SPRING	VALERIE
2003733	SPURLOCK	SEAN
1001069	STAERK	ROBERT

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905179	STANDERFER	CHRISTINE
2050376	STAUNING	MOLLY
2004643	STELLING	RYAN
2005102	STENSRUD	SARAH
905127	STEPP	STEPHEN
2002877	STERBA	CHARLES
1020019	STERMER	JAMES
2000937	STOCKTON	BENJAMIN
177453	STOEPPELWERTH	AMY
2005140	STOLTZ	DAVID
2004265	STONE	TYLER
2001627	STORZ	BRIAN
2003483	STRANGE	RONALD
905118	STUMPF	RYAN
2003713	SULLIVAN	TIMOTHY
2000602	SUMMERS	AMANDA
2023395	SUPULSKI	SCOTT
2002754	5UTHERLAND	RYAN
1001025	SWANN	PHILIP
2002555	SWEGER	LINDSEY
2005240	Sagastume	Michael
2024942	Sanderson	Caitlin
1010186	Scaglione	Toby
1030041	Schaeffer	Lawrence
2025495	Schultz	Matthew
2025043	Segovia	Karen
2024951	Seuffert	Chase
2023374	Seymour	Lauren
2002023	5haffer	Jeffrey
905121	5hepard	5cott
2025860	Sheth	Ritesh
2003955	Shipley	Tara
2002216	Siegel	Noah
2025945	Silverthorne	K
290195	Smalley	William
2003783	Smith	Daniel
2003572	Smith	Gregory
2050450	Smith	Kimberly
2004846	5mith	Monica
2024510	Snyder	David
905073	Spatz	Kenneth
2005103	Staley	Terry
2004900	Staton	Francine
2050456	Stavnes-Mattson	Sara
2003712	Stegall	James
2005327	Steiner	Erin
2004928	Steinkamp	Joel

*Dentsply North America LLC, as a wholly owned subsidiary of Dentsply Sirona Inc., does not have any lenders or holders of indebtedness specific to DNA.

DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2005052	Stephens	Destiny
2050481	Stephenson	Cameron
2004533	Stevens	Hannah
2002981	Stevens	Mark
290274	Streicher	Craig
2003849	Studzinski	James
2024633	Swanger	Ashley
1010192	Swanson	Michael
2004733	TARABOCCHIA	NICOLE
2023373	TAYLOR	ALEC
2004773	TAYLOR	STEPHEN
2002034	TETI	ANTHONY
902961	THOMAS	TARA
2001878	THOMPSON	CHRISTOPHER
2002662	THRASHER	JAMES
2004616	TINDALL	CHRISTINA
1020312	TORRENCE	ATIBA
2004690	TOUCHARD	BLAKE
2001594	TOWE	ROBERT
2003014	TRAU	AMANDA
902972	TRAWICK	TODD
2050422	TROTTA	MICHAEL
018488	TURNER	MARK
2003500	TURNEY	MALGORZATA
2004856	TYGART	JAMIE
2024219	Taylor	Adam
2025657	Taylor	Casie
2025048	Thach	Bill
2002071	Thierjung	Clint
1010079	Thomack	Patricia
905032	Thompson	David
2002863	Thrush	Mara
905090	Trimmer	Mark
1020343	Trotter	CAMERON
2025350	Tucker	Nicole
2025324	Tummala	Sasi
2004506	Turner	Samuel
2004657	URIAS	BENJAMIN
2004982	VAN VOORHIS	ROBERT
2000954	VECIO	ERIN
2004988	VELASQUEZ	VINCENT
2004682	VERDUZCO	SHANTAL
071217	VEZMAR	DANIEL
2000314	VICK	DAVID
177878	VILLALOBOS	ONESHI
2023502	VINES	TAMMY
2004596	VITTEK	JEFFREY

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2000323	VREDENBURGH	STEPHEN
905220	VUKOVICH	JESSICA
2025037	Vacchiano	Neil
2050492	Van Buren	Courtney
2025255	VanDyke	Scott
2003760	VandeVeer	Christian
2000606	Vincent	Justin
1005041	Vitone Jr	David
905181	WAIBEL	CELIA
2005308	WALES	MICHELLE
1020469	WALKER	JOHNNY
2000650	WALLEN	CARA
1035081	WALLIS	STACEY
2002528	WANEMACHER	ADAM
2003769	WANIGA	ROSS
2003840	WARD	LAUREN
1006223	WATKINS	DAVE
2002994	WATSON	KELSEY
2004649	WATSON	MARCELLA
2005256	WATT	PAULA
2050414	WATTS	STEPHANIE
2002489	WEAVER	MICHAEL
1020488	WEBB	WILLIAM
178153	WEIS	KEVIN
2005089	WERTZ	JENNIFER
2004915	WHEADON	KEITH
2004675	WHEATLEY	MELISSA
1010138	WHITE	MICHAEL
1005512	WHITESIDE	JONATHAN
2050388	WHITFIELD	SCOTT
2004552	WHITMAN	GRETHE
2004659	WILLENBRINK	GREGORY
1020393	WILLIAMS	CHAD
2001997	WILLIAMS	ELIZABETH
2003477	WINCH	TYLER
2004983	WING	KAITLYN
2004858	WINGERT	CHRISTOPHER
2004571	WINIK	ADAM
2004549	WISE	LANCE
902968	WITHAM	CRISTINA
2000082	WITT	RYAN
2004660	WOMACK	GRANT
2003145	WONG	BRENTON
2002905	WOOD	KATHLEEN
2004855	WOOD	LOGAN
905093	WOODARD	MATTHEW
905027	WRIGHT	CHRISTOPHER

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

1020561	WYLIE	ROBERT
2050435	Wagner	Donna
2024813	Waithe	Frederick
2004423	Walker	Trent
2024825	Wall	Keaton
1001560	Walsh	Christine
2002311	Warby	Lonna
177442	Warren-Kimbro	Amy
2001705	Watkins	Devin
2050311	Watters	Jennifer
2005231	Weaver	Kaitlin
2050427	Wendell	Samantha
2024218	Wesley	Adam
2050482	Wheeler	Scott
2024876	Wicker	Corley
2004484	Wilgosz	Christopher
905157	Wilkie	Benjamin
2002771	Williams	Lisa
2002040	Williamson	Kurtis
1035083	Wilson	Kimberly
2050503	Wilson	Marli
2023645	Winward	James
2003210	Wood	Erin
2000295	YAGER	RICK
2002359	YASAK	JOHN
905068	YELVERTON	JUSTIN
2005047	Yanders	Douglas
2025943	York	Margo
2025046	Young	Sarah
2003356	ZAHNER	MARK
2003159	ZAMANSKY	ALEX
2002945	ZAMORANO	KARINA
908779	ZANOTTI	DANIEL
2005115	ZARKOVACKI	AMY
2003609	ZEGAR	JUSTIN
2002360	ZERVOS	ANASTASIOS
2000708	ZIOGAS	JAMES
2002895	ZUKE	JUSTIN
039320	ZUPKO	GEORGE
2000291	Zazzara	Zackary
2025033	Zilles	Gerald
1020366	Zora	Allison
12418	AARON	HANNAH
2000177	ACOSTA	MANUEL
2050355	ALMEIDA	JENNIFER
2004831	ANAYA-GRACIANI	VALERIE
2001489	ANDREWS	MICHELLE

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2004232	ANDUJAR	ZORAIDA
1020304	AUSTIN	CARLTON
2004961	Arrindell	Shemuel
1020002	Ayer	Christopher
1020334	BAXTER	MARILYN
2004737	BECK	CHRISTINE
1010143	BERCHIE	KENNEDY
280170	BERRY	VANESSA
1010322	BIZIOS	JOHN
2003102	BOOKS	GREGORY
2003978	BOWEN	DANIEL
1020348	BOWMAN	ZACK
2000726	BROOKS	DOUGLASS
2002936	BURD	JESSE
1020376	Basternak	Gabor
1020459	Beadle	Charles
2005298	Bonilla-Lopez	Elizabeth
2005265	Brown	Christopher
1020307	Brown	James
1020382	Buck	Rebecca
177497	CARR	GLENDA
1020331	CARROTHERS	STEPHEN
2005225	CEDENO	JOSE
019008	CHAMBERS	BRANDON
2002162	CHARAIS	STACY
039144	CLASS	KIMBERLY
1020441	COLTS	MENYA
1020528	COWLES	CAROL
2000368	CRITES	JUSTIN
1020799	CRUMES	DONTAE
2002991	CUPIDON	PIERRE
1020221	Campbell	John
2004603	Carmichael	Matthew
2001784	D'ANGELO	JAMES
2004878	DE LA CRUZ RODRIGUEZ	NICOLE
2023604	DELACRUZ	EDITH
018094	DELL	CINDY
1020406	DENNIS	MARK
038911	DICKSON	TYESSE
2000335	DIGIOVANNI	KATHERINE
177770	DONNELL	AMANDA
1020179	DOUMOUYA	ASSAN
2002471	DiCecca	Salvatore
2025191	Dixon	Andrew
2050494	Dodd	Laporchia
2050440	Dubbs	Aaron
2004427	EATON	JENELLE

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2000017	ELLIOTT	LINDSAY
038857	EMIANG	VICTORIA
1010257	ESPOSITO	DONNA
177592	EVANS	THOMAS
2050438	Ernst	Madison
1020177	FAIRFIELD	MATTHEW
2004817	FAULKNER	DEAN
177432	FAUROT	BRENDA
1020804	FELIX	MELVIN
1010371	FOY	CHRISTOPHER
907855	FREY	AMY
2004995	FRIEDHOFEN	KIMBERLY
918432	FUNK	MELISSA
2003220	FUOTI	PEDRO
1020050	Faulkner	Curley
2005340	Fils-Aime	Bellenda
2003736	Forrester	David
1020234	GAMBONY	MARTIN
1010037	GASSNER	CHRISTIAN
2001887	GENTILE	MARIANNE
2002122	GETZAN	CHERYL
1020377	GOODMAN	ANDREW
018677	GWYNN	CHERYL
2025577	Ginter	George
2025664	Gomes	Maria Silvia
2004719	Graybill	Bethany
1020127	HALL	MICHAEL
2004149	HAMILTON	KATHLEEN
2050384	HAMMERSMITH	SUSAN
2003228	HARTNESS	CHAD
2000076	HATTEN	MICHELLE
1020524	HEGSTAD	GERALD
038883	HEISER	KATHY
2004803	HEMINGWAY	MELISSA
1020151	HENRIQUEZ	NOE
1020141	HENRY	NATASHA
2001268	HERMANSKI	KRISTIE
2003518	HILL	KRISTEN
2004696	HINDS	ARLIN
2050401	HINTON	DANNY
067995	HIRSCHHORN	SUSAN
2005079	HOLMES	GREGORY
062754	HOWARD	TINA
2005139	Hagan	Seth
2025107	Harris	Hunter
039212	Holderegger	Tracy
2024664	Holley	Rhushaun

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2004283	JAFFER	FARHAAN
1020073	JEAN	ROBERT
2004150	JOHNSON	JANIEKA
2050372	JONES	DEWAYNE
2004566	JONES	SYIDEAN
1020326	JORDAN	KEENAN
2025682	Jenkins	Steven
2022729	Johnston-Wade	Valerie
2050409	KENNEDY	SHAJUANA
2050317	KILBOURN	KAYLENE
1020423	Kefalas	Vasileios
1020258	Kolessar	John
2003459	Kone	Aida
1020012	LANIER	KARENA
2004352	LANZILLOTTI	MARIA
2002305	LARO	ERIN
2000170	LAU	SHERRY
1030055	LEE	KE-YUANAH
1030056	LIONETTO	MICHAEL
2001896	LOPES	KEVIN
1010084	Leblanc	Jeannine
2005292	Lee	Christopher
2004810	Leon	Zachary
2004001	MACK	JARRAD
1020011	MAGALHAES	PHILLIP
1020243	MALLOY	JAMES
2002387	MANGUS	RYAN
2002193	MELENDES	MARIO
2004864	MESSENGER	DAVID
1020306	MILLER	JEROME
2004859	MUNYAN	YVONNE
039276	MURPHY	CHRISTIE
2001786	Marcucci	Dawn
2001975	Markham	Judd
2024741	McBride	Shane
2025605	Mcknight	Tamicka
2005014	Mensah	Sylvester
1010177	Metcalf	David
2004238	Miller	James
2005183	Morris	John
2005208	Mulder	Scott
1020535	NASTACIO	TALIA
2019246	Neenan	Clara
2019780	Nystrom	Robin
2023472	ORTWOOD	JEREMIAH
2002427	OVERSTREET	NICHOLAS
2001519	Orpin	Pamela

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

1020204	PAGE	KERRY
2004329	PAIKOS	EFTHIMIA
2000065	PALMER	CHARLES
2003351	PARSONS	PAULINE
2001718	PETROWSKI	BRIAN
2004936	PIRO	MARY
178188	POOR	KYLE
2000396	PRIZER	MELISSA
2003340	Paris	Nancy
2003647	Pickens	Christopher
2050354	Pickens	Kevin
1030059	Pierce	Loria Jean
2005291	Powell	Jason
2003933	Powrozek	CarrieAnn
2002949	QUINN	CAROL
2000747	QUINN	LACEY
2002092	ROBLES	MARIO
071240	ROGERS	MICHELLE
2023492	Rush	Steven
1020347	Russell	Richard
2022728	Ryan	Daniel
1020112	SANTACRUZ	ARMANDO
2050386	SANTOS	ZANE
2003453	SANTOYO	MELISSA
2004975	SCHWEITZER	ADAM
1020080	SEYE	ELHADJI
2005260	SHIREY	JORDAN
2001992	SHOPE	THERESA
1020103	SIDEY	THOMAS
2001466	SMITH	KEVIN
2004745	SMITH	MICHELE
017749	SMITH	SABRINA
1001559	SPONSELLER	NINA
2003880	SPOON	JORDAN
2005226	STEVENS	AUSTIN
2023454	STIFFLER	PATRICK
2020008	Samara	Ruby
2023584	Seibles	Britnee
2050442	Shields	Mackenzie
2003271	Smith	Donnie
2025861	Snell	Lynn
2003250	Sprague	Erik
2025576	Stechmann	Michael
2019929	Stevens	Justin
2025108	Swasy	Joy
1020254	TATE	LELAND
2002710	THOMPSON	JAY

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DENTSPLY NORTH AMERICA LLC
List of Employees, Contractors, Etc.

2004479	THOMPSON	SONIA
2002717	TILTON	ANDREA
1010259	VACHERESSE	MICHELLE
1020116	VARGAS	WILLIAM
2050428	VAUGHN	JOHN
2002013	VAZQUEZ	MARGARITA
2004617	VELA	RAIDEL
1030064	VITTORIOSO	EILEEN
1020001	WOODWARD	DAVID
1020490	WORKMAN	LELIAN
2025694	Walker-Griggs	Valinda
2019689	Wheeler	Brenda
2050426	Williamson	Rebekah
1020519	YANG	TOU LEE
1020731	YANG	VA
177775	YATES	MARY

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☒ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: CARDIO PARTNERS, INC.

Physical Address: 1800 U.S. HIGHWAY 51 N

City: WOODRUFF State: WI Zip: 54568

Mailing Address (if different from physical address): 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Website: AED.COM

Name of Designated Representative (DR): NIRAJ PATEL

Licensing Company Email: REGULATORY@SARNOVA.COM DR Email: REGULATORY@SARNOVA.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)?		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

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 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: IMS Limited
Address: 11570 Sixth Street City: Rancho Cucamonga State: CA Zip: 91730

Name: Fresenius
Address: 1501 E Woodfield Rd. Ste. 300 E City: Schaumburg State: IL Zip: 60173

Name: Pfizer
Address: 235 E 42nd Street City: New York State: NY Zip: 10017

Name: Cardinal Health
Address: 7000 Cardinal Place City: Dublin State: OH Zip: 43017

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: OH
Parent Company (if any): SARNOVA HC, LLC
Corporation Name: CARDIO PARTNERS, INC.
Mailing Address: 5000 TUTTLE CROSSING BLVD
City: DUBLIN State: OH Zip: 43016
Telephone: 614-760-5000 Email: REGULATORY@SARNOVA.COM
Contact Person Name: JILL VENNEKOTTER

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		X
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		X
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/.		X

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**	✓			
• **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.

DARRELL HUGHES, SECRETARY

Print Name of Authorized Person Submitting Application

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

9/3/21

Date

Board Use Only	Date Received: _____	Amount: 500 check # 012766

Sarnova HC, LLC

(100% Owner of Cardio Partners, Inc.)

PO Box 8023, Dublin, Ohio 43016

State of Organization: DE Date of Organization: 05/01/2008 EIN: 26-2549813
File No. 4540843

Officers	
NAME	**TITLE**
Jeffrey M. Prestel	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

Cardio Partners, Inc.

(Owned 100% by Sarnova HC, LLC)

State of Incorporation: OH Date of Incorporation: 12/03/2012 EIN: 80-0874694
Charter No. 2155064

Officers	
NAME	**TITLE**
Jeffrey M. Prestel	CEO
Brian J. LaDuke	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

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 Cardio Partners, Inc.

Physical Address 1800 U.S. Highway 51 N

City Woodruff State WI Zip 54568

Mailing Address (if different from physical address) 5000 Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone 614-670-5000 Website

Licensing Company Email regulatory@sarnova.com

Section 2: Personal Information

First Niraj Middle Last Patel

Alias(es, nicknames, name changes, etc.) N/A

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

Mailing Address [redacted] Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone [redacted] Email regulatory@sarnova.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.)		
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 N.P.

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: The University of North Carolina at Chapel Hill		From - To (MM/YY – MM/YY)	
Address: UNC-Chapel Hill Ste. 3100, SASB North CB# 2100	City: Chapel Hill	State: NC	Zip: 27599
Diploma/Degree obtained, if any: Masters in Business Administration			
School Name: Florida Institute of Technology		From - To (MM/YY – MM/YY)	
Address: 150 W University Blvd.	City: Melbourne	State: FL	Zip: 32901
Diploma/Degree obtained, if any: B.S. Mechanical Engineering			
School Name: Kisumu Senior Academy		From - To (MM/YY – MM/YY)	
Address:	City: Kisumu	State: Kenya	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
10/2015-Present	[redacted]Loures Lane	League City	TX	77573
02/2015-10/2015	1800 South Egret Bay Blvd.	League City	TX	77573
01/2012-02/2015	261 Crocker Park	Westlake	OH	44145

Applicant's initials N.P.

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)	
Sarnova HC, LLC			04/2018-Present	
Business Address		City	State	Zip
5000 Tuttle Crossing Blvd.		Dublin	OH	43016
Phone	Title		Number of Employed Hours	
614-760-5000	VP of Operations		29,000 approx.	
Description of Duties				

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

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

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

Niraj

Original Signature (electronic, copies or stamps not accepted)

10/29/2024

Date

Applicant's initials N.P.

I, Niraj Patel, **certify that as the designated representative for** Cardiv Partners, 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

Niraj, Patel
Print Name (First, Last)

Niraj
Original Signature (electronic, copies or stamps not accepted)

10/29/2021
Date

Applicant's initials N.P.

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.

Niraj, Patel

Print Name (First, Last)

Niraj

Original Signature (electronic, copies or stamps not accepted)

9/21/2021

Date

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

State of _____, ss. County of _____

I, Niraj Patel, 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.

Niraj

Original Signature

9/21/2021

Date

Subscribed and Sworn to before me this 30th day of September

Deena Raucstadt

Notary Public Signature

DEENA RAUCSTADT
Notary Public, State of Texas
Comm. Expires 08-05-2025
Notary ID 128001375

(Seal)

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Position Description

Position Title:	VP of Distribution Center Operations	Department:	Distribution
Travel Required:	Choose an item.	Location:	Remote
Education:	Bachelors Degree	Reports To:	Sr VP of Operations

Position Description

Summary:

The VP of DC Operations will direct and oversee Sarnova's operational policies, objectives, and initiatives. They are responsible for analyzing current systems and identifying and proposing solutions to problems with distribution center operations. They will implement changes as necessary and lead the warehouses with the goal of delivering accurate and timely customer orders in a safe, compliant manner.

Organizational Impact:

Essential Duties and Responsibilities:

- Direct and lead all distribution requirements (receiving, inventory management, order fulfillment, safety, and compliance) for multiple warehouses.
- Develop and adhere to service and financial metrics, including staffing, capital and expense targets for each warehouse.
- Develop distribution plans in regard to mergers and acquisitions.
- Represent Sarnova in transportation carrier negotiations.
- Assist in the development and negotiations of facility leases and renewals.
- Design and enhance distribution and facility layout.
- Conduct budget adherence meetings with Operation Managers and Supervisors to ensure proper utilization with the Assistant Director of Operations.
- Collaborate with Sales, Customer Service, Regulatory, and Supply Chain to ensure optimal distribution performance.
- Develop and ensure compliance policies and procedures with current federal, state and local regulations (DOT, DOH, OSHA, DEA, BOP, FDA and VAWD).
- Develop and ensure supply chain initiatives and/or project teams; i.e. facility relocations, facility expansions, mergers and acquisitions.
- Develop and monitor the Safety Program.

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Skills/Experience Required:

- High-level problem-solver.
- Strong leadership capabilities; ability to project a positive example for others to follow.
- Strong managerial and conflict resolution skills. Able to effectively train, coach and mentor associates; provide current, direct, complete, and "actionable" positive and constructive feedback to team members.
- Ability to think tactically and strategically at a high level.
- Strong analytical skills (ability to define problems, collect data, establish facts, and draw valid conclusions).
- Knowledgeable in current and possible future laws, policies, practices, industry trends and information affecting the organization.
- Able to make recommendations to effectively resolve problems or issues, by using judgment that is consistent with standards, policies, procedures, regulation or government law.
- Experience developing and implementing processes and procedures.
- Organized and efficient. Able to organize, prioritize and delegate work.
- Strong communication skills, including ability to influence and communicate at all levels, through verbal and written means. Able to effectively present information and respond to questions from groups of managers, clients, customers, and the general public.

Physical Requirements:

- Ability to stand for long continuous periods of time.
- See and be able to read, write, and interpret text
- May engage in some repetitive motion.
- May engage in frequent bending, stooping, pushing and pulling of parts and part containers.
- Due to the open environment of the warehouse, must be able to work in various weather and temperature conditions to include extreme heat, humidity and cold.
- Ability to continuously lift and/or move objects up to 10 pounds, frequently lift and/or move objects up to 25 pounds, and occasionally lift and/or move objects that weigh 50+ pounds.
- Specific vision abilities required include close vision, distance vision, color vision, peripheral vision, depth perception and ability to adjust focus.

The above statements are intended to describe the nature and level of work being performed by people assigned to this job. They are not intended to be an exhaustive list of all responsibilities, duties and skills required of staff members so classified.

Work environment characteristics described here are representative of those that must be met by an employee to successfully perform the essential function of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

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While performing this job, the employee is exposed to weather conditions prevalent at the time. This may include warm, hot or cold temperatures. The noise level in the work environment is moderate.

Work Schedule: Employee will be required to work a minimum of forty (40) hours of per week or as many hours as it may take to perform above job duties. Schedule may vary based on business demands and will require a combination of office hours as well as work performed after hours and/or weekends.

Sarnova is an Equal Opportunity Employer. We offer a competitive salary, commensurate with experience, along with a comprehensive benefits package, including 401(k) Plan.
EEO/M/F/Veterans/Disabled

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 Cardio Partners, Inc.

Physical Address 1800 U.S. Highway 51 N

City Woodruff State WI Zip 54568

Mailing Address (if different from physical address) 5000 Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone 614-760-5199 Website

Licensing Company Email regulatory@sarnova.com

Section 2: Personal Information

First Darrell Middle Last Hughes

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

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

Mailing Address [redacted]Tuttle Crossing Blvd.

City Dubln State Ohio Zip 43016

Telephone [redacted] Email regulatory@sarnova.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?		X

Applicant's initials DAH

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)	
Capital University Law School		08/1996 - 05/1999	
Address	City	State	Zip
303 East Broad Street	Columbus	OH	43215
Diploma/Degree obtained, if any			
J.D.			

School Name		From - To (MM/YY – MM/YY)	
Indiana University, Bloomington		08/1991 - 05/1995	
Address	City	State	Zip
107 S Indiana Ave.	Bloomington	IN	47405
Diploma/Degree obtained, if any			
B.A. in Psychology			

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
2003 to current	[redacted] Lytham Road	Upper Arlington	Ohio	43220
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DAH

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)
Please see attached.			
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.)		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)

9/3/21
Date

Applicant's initials DAH

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.

Darrell, Hughes
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/2021
Date

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

State of OHIO, ss. County of FRANKLIN

I, DARRELL HUGHES, 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

9/3/2021
Date

Subscribed and Sworn to before me this 3RD day of SEPTEMBER

Notary Public Signature

MICHAEL P. COOKE
Attorney At Law
NOTARY PUBLIC
STATE OF OHIO
My Commission Has
No Expiration Date
Section 147.03 O.R.C.

(Seal)

Applicant's initials DAH

Darrell A. Hughes, Esq.

[redacted] Lytham Road
Columbus, Ohio 43220

Home Phone: [redacted]
Cell Phone: [redacted]
E-mail: [redacted]

SUMMARY

Versatile professional with diverse experience in private and public sector legal work. Known for creativity, resourcefulness, innovation, and timely completion of major projects. Skilled negotiator with a reputation for consistently achieving win-win outcomes. Successful at mitigating legal risk while achieving core corporate objectives. Legal experience includes technology and other corporate related transactions, compliance and risk management, labor and employment law, human resource and personnel problem solving, civil litigation, appellate practice and public sector law.

COMPETENCIES

- Corporate Transactional Support
- Complex Contract Creation and Negotiation
- Letters of Intent
- Confidentiality Agreements
- Outsourcing Contract Negotiations
- Contract Administration
- Technology Related Transactions
- Corporate/Commercial Law
- Risk Management and Oversight of Compliance Matters
- Corporate Governance
- M&A Due Diligence
- Insurance Policies
- Data Security
- Privacy Laws
- ERISA/COBRA
- Litigation Management (e-discovery)
- Labor/Employment Law
- EEOC and OCRC Cases
- Operations Support
- Government Investigations
- Mediation

LEGAL EXPERIENCE

Sequent, Inc., Columbus, Ohio (August 2004 – Present)
General Counsel
Serve as General Counsel for Columbus-based consulting and outsourcing company. Responsible for monitoring and overseeing compliance with all laws and regulations relating to company's operations. Advise Board of Directors and senior executives on compliance, risk avoidance, new business strategies/ventures and other general management issues. Ensure adherence with corporate governance processes, policies and ethics. Protect company's intellectual property. Identify preventable measures aimed at mitigating liability and risk. Review, draft and negotiate agreements for a variety of commercial transactions including lease agreements, software licenses, technology-related transactions, and the acquisition of goods and services for corporate use. Assist in establishing, drafting, and implementing corporate policy. Perform due diligence for and assist in document review and preparation relating to merger and acquisition activities. Responsible for advising on matters relating to data security and privacy laws. Provide legal representation on labor and employment matters. Standardize and oversee

Sequent, Inc., Columbus, Ohio (Continued)
General Counsel
company's corporate contracting process. Monitor and respond to legislative developments and governmental enforcement activities impacting company's operations. Responsible for registration and licensing requirements for the approximately thirty-two states where company conducts business. Supervise and manage outside counsel retained for intellectual property, ERISA, and other specialized matters. Manage all litigation, including coordination with and oversight of outside counsel and applicable insurance carriers. Assist in the securing of General Liability, E&O, D&O, EPLI, Fiduciary Liability, Cyber and other insurance policies. Authored guest columns for *Business First*, a weekly Columbus, Ohio, business publication, and for the NAPEO *PEO Insider*.

Downes, Hurst & Fishel, Columbus, Ohio (August 2000 – August 2004)
Labor and Employment Law - Attorney
Represented private and public sector employers in labor and management related disputes before arbitrators, administrative agencies, trial courts, and appellate courts. Successfully argued before the 6th Circuit Court of Appeals and the 10th District Court of Appeals. Defended employers in all phases of employment discrimination claims, including state and local agency investigations and fact-finding conferences, EEOC and OCRC investigations on the basis of race, sex, age, religion, national origin, ancestry, and disability. Advised clients on issues relating to the ADEA, FMLA, ADA, FLSA, Title VII, drug testing, policy manuals, discipline, layoffs and other general management issues. Drafted and assisted in the implementation of policy manuals and other operating procedures. Identified preventative measures to minimize employment disputes. Reviewed employment contracts and non-compete agreements. Experienced in collective bargaining, with responsibilities ranging from advising on negotiation strategies to conducting negotiation sessions on behalf of management. Assisted employers with union elections, unfair labor practice proceedings, arbitrations, contract grievances, and enjoining work stoppages and picketing. Provided legal advice to municipalities and other political subdivisions on civil service law, the Public Records Act and the Open Meetings Act. Conducted lectures at employment-related seminars. Defended clients in audits conducted by governmental regulatory agencies. Wrote articles for state-wide publications (*Ohio Lawyer* and *Ohio Ready Mix Concrete Connection*).

Bank One Corporation, Columbus, Ohio (May 1998 - August 2000)
Law Department (Technology and Contracts National Practice Group - Law Clerk); and
Technology Acquisition Department (Technology One Alliance Group - Contracts Specialist)
Supported the bank's telecommunication outsourcing and web hosting initiatives with AT&T. Assisted in the consolidation of the bank's telecommunication platforms. Reviewed, drafted and negotiated lease agreements, software licenses, and contracts for technology related transactions and for the acquisition of goods and services for corporate use. Participated in multi-million dollar contract negotiations. Drafted corporate confidentiality agreements. Performed due diligence for contract negotiations, including the sale of a bank subsidiary. Conducted legal research involving issues relating to national banks.

Attorney General of Ohio, Columbus, Ohio (May 1997 - August 1997)
Legal Intern in the Education Section
Researched issues dealing primarily with colleges and universities. Drafted legal memoranda and documents for client use. Assisted in negotiating settlements to lawsuits.

City Attorney's Office, Columbus, Ohio (July 1996 - March 1997)
Intake Counselor in the Prosecutor's Division
Conducted interviews and screened complaints from private citizens regarding misdemeanor criminal cases. Evaluated cases and directed them to prosecution or mediation. Performed background checks to determine whether complainants had warrants for their arrest. Drafted temporary restraining orders.

NON-PROFIT INVOLVEMENT

Columbus State Community College, Columbus, Ohio (2008 - Present)
Member of Advisory Board for Business Management Department
Provide input to the Business Management Department on curriculum to better prepare students for the business world upon graduation. Includes identifying current business trends and needs, potential changes to core courses and/or elective courses, and student leadership skills.

Indiana Invaders, Inc., Indianapolis, Indiana (November 2011 - Present)
Non-Profit - Pro Bono Services
Provide pro bono legal services to non-profit running club that serves elite and elite development athletes. Services include research relating to corporate governance, United States Olympic Committee, United States Track and Field, and the Ted Stevens Olympic and Amateur Sports Act. Provide advice relating to marketing and sponsorship mandates imposed on athletes by the sport's national governing body.

Kayla 5K Run, Granville, Ohio (March 2004 - Present)
President and Race Director
Assisted in the creation of the Kayla 5K Run, which is a non-profit organization whose objective is to raise college scholarships for female athletes graduating from a high school located in Licking County, Ohio. Provided oversight for all facets of raising monies for the scholarship fund, including coordinating vendors, securing sponsors, managing volunteers, organizing events. Have raised in excess of $80,000 for the scholarship fund, which is managed by the Licking County Foundation.

PROFESSIONAL PROFILE

Academic:

Capital University Law School, Columbus, Ohio; May 1999
Doctor of Jurisprudence

Indiana University, Bloomington, December 1995
Bachelor of Arts in Psychology

NCAA All-American for Indiana University in Track and Field.

Received the *Sid Robinson Athletic Scholarship* that is awarded for leadership, excellence in track and field, and academic achievement.

Academic: (Continued)

Balfour Award Recipient 1994, 1995 (Given to best athlete in each sport for Indiana University).

Elected Captain for Indiana University's cross country and track teams (1995-96).

Big Ten Scholar Athlete for eight consecutive semesters.

Admissions:

Supreme Court of Ohio and all subordinate courts
U.S. Court of Appeals, 6th Circuit
U.S. District Court for the Southern District of Ohio

Activities:

- Adjunct Professor for Franklin University – Business Law (2006- Present).
- Coach for Northwest Kiwanis Soccer League (2010 - Present).
- Member of Sequent's S.W.A.T. Committee (2008 – 2010).
- Organized Community Forum on Economic Dev. for Upper Arlington (2004).
- Organized and co-hosted CLE Health Care Seminar (2004).
- Member of Order of the Curia (National Honorary Legal Fraternity).

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 Cardio Partners, Inc.

Physical Address 1800 U.S. Highway 51 N

City Woodruff State WI Zip 54568

Mailing Address (if different from physical address) 5000 Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone 614-760-5000 Website

Licensing Company Email regulatory@sarnova.com

Section 2: Personal Information

First Brian Middle J. Last LaDuke

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

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

Mailing Address [redacted]Tuttle Crossing Blvd.

City Dublin State Zip 43016

Telephone [redacted] Email regulatory@sarnova.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?		X

Applicant's initials BL

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)	
Xavier University		08/2009 - 05/2011	
Address	City	State	Zip
3000 Victory Pkwy	Cincinnati	OH	45207
Diploma/Degree obtained, if any			
MBA, Business			

School Name		From - To (MM/YY – MM/YY)	
Point Loma Nazarene University		08/1994 - 05/2000	
Address	City	State	Zip
3900 Loaland	San Diego	CA	92106
Diploma/Degree obtained, if any			
B.A., Business Communications			

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
07/18 – Present	[redacted] WINTERBERRY DRIVE	PLAIN City	OH	43064
06/13 - 07/18	14236 CALDERDALE LANE	STRONGSVILLE	OH	44136
07/06 - 07/13	8445 EAGLE RIDGE DRIVE WEST	CHESTER	OH	45069
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)	
Please see attached.			
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.)		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:

B.H

Original Signature (electronic, copies or stamps not accepted)

10/08/2021

Date

Applicant's initials BL

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.

Brian, LaDuke

Print Name (First, Last)

B. L

Original Signature (electronic, copies or stamps not accepted)

9/2/2021

Date

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

State of OHIO, ss. County of FRANKLIN

I, Type text here BRIAN LADUKE, 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.

B. L

Original Signature

9/2/2021

Date

Subscribed and Sworn to before me this 21st day of SEPTEMBER.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

MICHAEL P. COOKE
Attorney At Law
NOTARY PUBLIC
STATE OF OHIO
My Commission Has
No Expiration Date
Section 147.03 O.R.C.

(Seal)

Applicant's initials BL

Brian LaDuke

Cleveland/Akron, Ohio Area

Senior Executive Leader | Delivering Strategic Vision, Serving as Catalyst for Business Turnarounds and Growth

Summary

Specialties:

Strategic Sales Planning & Execution | P&L Management | Corporate Strategy
Revenue Growth | Profit Growth | Distribution & Channel Management
Cost Control | Market Growth & Expansion | Change Management

Experience

President, Emergency Preparedness at Samova
October 2017 - Present (2 years 4 months)

VP, Rehab Division | VP, Home & Long Term Care | VP, Respiratory Division & Marketing at Invacare
January 2013 - September 2017 (4 years 9 months)

- Led multiple divisions for the North American Market with oversight of Marketing, Sales, and Operations.

Senior Director of Marketing North America at Formica Corporation
February 2011 - January 2013 (2 years)

- Implemented integrated digital strategy including website and Salesforce.com integration driving increase in website traffic and dramatic spike in customer leads.
- Identified and led technology acquisition and launched new product at Lowe's and Home Depot.

North America Director of Business Development at Formica Corporation
April 2010 - February 2011 (11 months)

- Partnered with Booz Hamilton and evaluated potential acquisitions and developed Playbook for distributors to drive sales and revenue through improved accountability of partners.

Director of OEM/Fabrication at Formica Corporation
April 2008 - April 2010 (2 years 1 month)

- Obtained 17% increase in revenue through development of service initiative addressing 24 key accounts.
- Created "industry-first" paper samples that became most successful product launch in company history.

National Sales Manager | Commercial Market Segment Manager | Territory Manager at Formica Corporation

February 2003 - April 2008 (5 years 3 months)

- Promoted Multiple Times from Territory Manager to National Sales Manager – Landed 7 of the Top 10 Builders Producing over millions in Annual Revenue and attained as much as 188% of Sales Targets.

Education

Xavier University
MBA, Business, 2009 - 2011
Activities and Societies: Graduated Beta Gamma Sigma
Point Loma Nazarene University
B.A., Business Communications, 1994 - 2000

Brian LaDuke

Cleveland/Akron, Ohio Area

Senior Executive Leader | Delivering Strategic Vision, Serving as Catalyst for Business Turnarounds and Growth

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LinkedIn

Profile Notes and Activity (1)

1/7/2020—View by Greg Brame

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 Cardio Partners, Inc.

Physical Address 1800 U.S. Highway 51 N

City Woodruff State WI Zip 54568

Mailing Address (if different from physical address) 5000 Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone 614-760-5199 Website

Licensing Company Email regulatory@sarnova.com

Section 2: Personal Information

First Shawn Middle Last Saylor

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

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

Mailing Address [redacted]Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone [redacted] Email regulatory@sarnova.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?		X

Applicant's initials SPS

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 Ohio State University		08/2002 - 05/2004	
Address	City	State	Zip
281 W Lane Ave.	Columbus	OH	43210
Diploma/Degree obtained, if any			
Masters of Accounting/CPA			

School Name		From - To (MM/YY – MM/YY)	
Ohio University			
Address	City	State	Zip
1 Ohio University	Athens	OH	45701
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
03/2008-09/21	[redacted] Brentwood Ct	Powell	OH	43065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 SBS

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)
Please see attached.			
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.)		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)

9/1/2021
Date

Applicant's initials SPS

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.

Shawn, Saylor

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/1/2021

Date

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

State of Ohio, ss. County of Franklin

I, SHAWN SAYLOR, 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

9/1/2021

Date

Subscribed and Sworn to before me this 1st day of SEPTEMBER.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

MICHAEL P. COOKE
Attorney At Law
NOTARY PUBLIC
STATE OF OHIO
My Commission Has
No Expiration Date
Section 147.03 O.R.C.

(Seal)

Applicant's initials SS

Shawn Saylor

[redacted] Brentwood Ct.
Powell, OH 43065
[redacted]

EDUCATION

Certified Public Accountant (CPA Designation), Accountancy Board of Ohio

- **Date of certification is September 2005 (Active)**
- Member of the American Institute of Certified Public Accountants (AICPA)
- Member of the Ohio Society of Certified Public Accountants

THE OHIO STATE UNIVERSITY FISHER COLLEGE OF BUSINESS, Columbus, Ohio

- **Masters of Accounting, June 2004**
- MAcc Professional Committee
- Stuchell Accounting Scholarship

OHIO UNIVERSITY, Athens, Ohio

- **Bachelor of Business Administration, June 2003**
- Majors: Accounting & Finance
- Dean's List, Beta Alpha Psi, Real Estate Technology Cluster

WORK EXPERIENCE

JPMorgan Chase & Co., Columbus, Ohio **July 2013 – Present**
Vice President, Corporate Controller

- Financial oversight responsibilities for Corporate Lines of Businesses: Digital Solutions (Chase.com), Enterprise Solutions, Infrastructure and Architecture, Strategic Investments, Corporate Tax, Compliance & Legal, Executive (Office of Chairman), Human Resources & Benefit Plans, Oversight & Control, Corporate Strategy, Corporate Responsibility, JPMorgan Chase Foundation, Office of Regulatory Affairs, Communications, Arts & Archives
- Manage monthly close processes related to cash, investments, revenue and receivables, purchasing and payables (accrued liabilities), fixed assets and taxation
- Coach and mentor Corporate Controllers (6 direct reports and 14 total team members)
- Develop accounting policies and procedures related to relevant business risks identified to ensure compliance with applicable Generally Accepted Accounting Principles
- Perform domestic and international balance sheet reviews (certification and substantiation of 10,000+ accounts)
- Coordinate regulatory reporting matters related to areas supported (Call Reports (FDIC), SEC filings, etc.)
- Prepare and review monthly Controller Review Books and Schedules (internal financial statements, cash flow analysis, investment summaries, etc.)
- Preparation of JPMorgan Chase Foundation Form 990 and tax supporting schedules
- Accounting for corporate strategic investments (capital calls, investment outlook, fair value, quarterly impairment analysis, etc.)
- Financial reporting responsibilities for external financial statements for the JPMorgan Chase Foundation
- Coordinate external audit of JPMorgan Chase Foundation performed by PricewaterhouseCoopers
- Lead various Corporate Controller cross training sessions

PricewaterhouseCoopers, Columbus, Ohio **July 2004 – June 2013**
Assurance Manager

- Perform reviews, audits, and agreed upon procedures for both private clients and publicly held companies (domestic and international registrants).
- Service clients in the distribution, manufacturing, retail and service related industries.
- Design and implementation of control processes and procedures.
- Trusted business advisor on complex accounting matters and reorganizations:
  - Deferred and stock compensation plans
  - Initial public offerings
  - Mergers and acquisitions
  - Equity restructurings
  - Leveraged recapitalizations
- Supervise engagement teams throughout the assurance process.
- Management responsibilities for the Ohio, Kentucky and Indiana Private Company Services Group.
- Financial statement preparation and review.
- Lead instructor for Assurance Senior Associate Training.
- Advanced International Financial Reporting Standards (IFRS) Certification

Dominion Homes, Inc., Dublin, Ohio **Summer 2003**
Summer Accounting Internship

- Worked in the accounting department processing vendor related transactions.

Babcock & Wilcox, Barberton, Ohio **Summer 2002**
Summer Accounting Internship

- Worked as a cost analyst in the accounting department utilizing my computer knowledge and managerial accounting skills through analytical business writing.

Global Competitiveness Program, Pecs, Hungary **Summer 2001**
International Business-Consulting Project

- Worked with a team of three Hungarian and two Ohio University business students to formulate a marketing and fundraising plan.

UNITED STATES ARMY, Savannah, Georgia **1995-1999**
Ranger Team Leader

- Served under the United States Special Operations Command as a member of the 75th Ranger Regiment.
- This experience emphasized teamwork skills, communication skills, and a commitment to excellence.
- Army Commendation Medal (1999), Ranger Tab Award (1998), Army Achievement Medal (1998), Army Good Conduct Medal (1998), Airborne Wings (1995)

COMPUTER SKILLS

SAP, Essbase, Business Objects (Crystal Reports), Peopiesoft, CyberGrants, Microsoft Office, Microsoft Visio, Lotus Notes

RIDER

To be attached to and form part of:

Bond Number 107403303

dated November 24, 2021

issued by the TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

in the amount of $ 100,000.00

on behalf of CARDIO PARTNERS, INC.
(Principal)

and in favor of THE STATE OF NEVADA
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The Principal Address shall be amended:

FROM: 5000 Tuttle Crossing Blvd., Dublin, OH 43016

TO: 1800 US Highway 51 N, Woodruff, WI 54568

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 24th day of November, 2021.

Signed, Sealed & Dated this 8th day of December, 2021.

CARDIO PARTNERS, INC.
(Principal)

By: _____ 12/8/21

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
(Surety)

By: _____
Rachel Fore, Attorney-in-Fact

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF MCHENRY

On this 8th day of December, 2021, before me, Bartlomiej Siepierski, a Notary Public, within and for said County and State, personally appeared Rachel Fore to me personally known to be the Attorney-in-Fact of and for Travelers Casualty and Surety Company of America and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

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.

Notary Public in the State of Illinois
County of MCHENRY

OFFICIAL SEAL
BARTLOMIEJ SIEPIERSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MCHENRY COUNTY
MY COMMISSION EXPIRES 03/10/2026

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. 107403303

Application/License No. _____

CARDIO PARTNERS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5000 Turtle Crossing Blvd. Dublin, OH 43016 (Address of Applicant/Principal), as PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA (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 Tower Square Hartford, CT 06183 (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 November 24, 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 24th day of November, 2021.

APPLICANT/PRINCIPAL
CARDIO PARTNERS, INC.

COMPANY

Authorized Representative

SURETY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

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 Rachel Fore

Witness Ricky Casas

Countersigned by:

Nevada Resident Agent Christopher P. Troha, Non-Resident Agent

Posted February 20, 2020

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 **Derek J Elston** of **CHICAGO**, **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 **24th** day of **November**, **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.

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF MCHENRY

On this 24th day of November, 2021, before me, Bartlomiej Siepierski, a Notary Public, within and for said County and State, personally appeared Derek J. Elston to me personally known to be the Attorney-in-Fact of and for Travelers Casualty and Surety Company of America and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

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.

Notary Public in the State of Illinois
County of MCHENRY

OFFICIAL SEAL
BARTLOMIEJ SIEPIERSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MCHENRY COUNTY
MY COMMISSION EXPIRES 03/10/2025

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. 107403282

Application/License No. _____

CARDIO PARTNERS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1800 U.S. Highway 51 N Woodruff, WI 54568 (Address of Applicant/Principal), as PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA (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 Tower Square Hartford, CT 06183 (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 September 1, 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 1st day of September, 2021.

APPLICANT/PRINCIPAL
CARDIO PARTNERS, INC.

Authorized Representative

SURETY COMPANY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

Surety Company's Representative

Bartlomiej Siepierski, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Rachel Fore

Witness Ricky Casas

Countersigned by:

Christopher P. Troha
Nevada ~~Resident~~ Non-Resident Agent

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 **BARTLOMIEJ SIEPIERSKI** of **CHICAGO**, **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 **1st** day of **September**, **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.

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF COOK

On this 1st day of September, 2021, before me, Derek Elston, a Notary Public, within and for said County and State, personally appeared Bartlomiej Siepierski to me personally known to be the Attorney-in-Fact of and for Travelers Casualty and Surety Company of America and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

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.

Notary Public in the State of Illinois
County of Cook

OFFICIAL SEAL
DEREK ELSTON
NOTARY PUBLIC, STATE OF ILLINOIS
COOK
MY COMMISSION EXPIRES 09/08/2022

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. 107268498

Application/License No. _____

CARDIO PARTNERS, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
5000 Tuttle Crossing Blvd., Dublin, OH 43016, as
Address of Applicant/Principal
PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, a
Surety Company
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 Tower Square, Hartford, CT 06183 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 9/1/2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statu[illegible] Nevada Administrative Code (NAC) 639.5937 require th[illegible] or have on file with the Nevada State Board of Pharm[illegible] $25,000.00 payable to the Nevada State Boar[illegible] executed and tendered in accordance therewith. [illegible] any administrative fines imposed by the Board pursua[illegible] any costs incurred by the Board regarding the license of App[illegible] are impose pursuant to NRS 622.400 or 622.410 which the App[illegible] fails to pay.

Need look! Pl. issues! emailed 11/23! Ask for emp. list!

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 end said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, ere jointly end 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 Boerd 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 et 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 September, 2020.

APPLICANT/PRINCIPAL
CARDIO PARTNERS, INC.

Authorized Representative

SURETY COMPANY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

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 Paul M Allen

Witness Rachel Fore

Countersigned by:

Nevada Resident Agent
Christopher P. Troha, Non-Resident Agent

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 **Derek J. Elston of Chicago, 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 **21st** day of **September**, **2020**

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.

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF COOK

On this 21st day of September, 2020, before me, Bartlomiej Siepierski, a Notary Public, within and for said County and State, personally appeared Derek J. Elston to me personally known to be the Attorney-in-Fact of and for Travelers Casualty and Surety Company of America and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

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.

Notary Public in the State of Illinois
County of Cook

OFFICIAL SEAL
BARTLOMIEJ SIEPIERSKI
NOTARY PUBLIC, STATE OF ILLINOIS
COOK COUNTY
MY COMMISSION EXPIRES 09/16/2023

Y

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 Cardio Partners, Inc.

Physical Address 1800 U.S. Highway 51 N

City Woodruff State WI Zip 54568

Mailing Address (if different from physical address) 5000 Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone 614-760-5000 Website

Licensing Company Email regulatory@sarnova.com

Section 2: Personal Information

First Jeffrey Middle Last Prestel

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

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

Mailing Address [redacted] Tuttle Crossing Blvd.

City Dublin State OH Zip 43016

Telephone [redacted] Email regulatory@sarnova.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?		X

Applicant's initials _____

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)	
Fisher College of Business, The Ohio State University		06/1989	
Address	**City**	**State**	**Zip**
281 W Lane Avenue	Columbus	OH	43210
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Wright State University		06/1987	
Address	**City**	**State**	**Zip**
3640 Colonel Glenn Hwy.	Dayton	OH	45435
Diploma/Degree obtained, if any			
B.S. Business Administration, minior in Marketing			

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
1995 –	[redacted] Melbury Drive	Columbus	OH	43221
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
Please see attached.			
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.

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.)	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

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:

Please see attached.

Original Signature (electronic, copies or stamps not accepted)

10/16/21

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.

Jeffrey, Prestel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09-01-2021

Date

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

State of OHIO, ss. County of FRANKLIN

I, JEFFREY PRESTEL, 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

SEP 20, 2021

Date

Subscribed and Sworn to before me this 12th day of SEPTEMBER.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

MICHAEL P. COOKE
Attorney At Law
NOTARY PUBLIC
STATE OF OHIO
My Commission Has
No Expiration Date
Section 147.03 O.R.C.

(Seal)

Applicant's initials

Cardio Partners

Date: September 3, 2021
To: Nevada State Board of Pharmacy
From: Regulatory Affairs
Re: Cardio Partners, Inc., 1800 U.S. Highway 51 N, Woodruff, WI 54568

To Whom It May Concern:

It is my understanding the following information is needed in order to complete the above referred application:

- In 1982, I was cited for possession of marijuana and pled no contest; and
- In 1983, I was cited for possession of liquor in a public park and pled no contest.

I do not recall the specific dates of these incidences given how far back in time these occurred. Additionally, I have not been able to locate any records relating to either case.

To date, there are no other reportable incidences.

Sincerely,

Jeffrey M. Prestel, CEO
Cardio Partners, Inc.

JEFFREY M. PRESTEL
[redacted] Melbury Drive
Columbus, Ohio 43221
[redacted]

EMPLOYMENT EXPERIENCE

BT Conferencing — **June 2008 to Present**
Denver, Colorado and Quincy, Massachusetts

CEO and General Manager — *June 2008 to Present*

Responsibilities:
Responsible for leading a team of seven hundred associates delivering over $297 million in revenue and $58 million in EBITDA. Primary duties include managing and directing company resources and providing industry-leading audio conferencing, video conferencing, web conferencing and streaming solutions.

Key functions:
- Setting company direction
- Business planning and financial management
- Strategic planning
- Human resource management
- Coordinating activities and resources including performance management

Major Accomplishments:
- Grew revenue 8% in 2009/2010 while the market declined 1%; grew EBITDA 12.5% while improving working capital by $2.6 million
- Oversaw the successful merger of Wire One Communications and BT Conferencing realizing 5% year over year revenue growth in 2008/2009
- Became #1 provider of Cisco TelePresence while maintaining position of top reseller for both Polycom and TANDBERG products
- Leading provider of managed video services; grew revenue 76% year over year in 2009/2010

Wire One Communications, Inc — **February 2004 to June 2008**
Denver, Colorado

Sr. Vice President of Sales and Marketing — *February 2004 to June 2008*

Responsibilities:
Responsible for managing a team of one hundred and twenty-five associates in the United States and Europe delivering over $139.5 million in profitable revenue. Primary duties include directing sales executives responsible for selling video and collaboration solutions direct to commercial and public sector customers and indirect through key channel partners such as telecommunication providers.

Key functions:
- Solution selling
- Demand creation and presales support
- Strategic alliance planning and management
- Sales operations and discipline
- Contract negotiation and execution

Major Accompliahments:
- Planned and executed the successful turnaround of an unprofitable company in less than five months
- Achieved year-over-year revenue growth, from $79.3M in 2004 to $139.5M in 2008, while improving overall gross margin by 7%
- Actively positioned and sold Wire One Communications to BT Conferencing in June, 2008
- Successful acquisition of VSPAN – a leader in managed video and collaboration services

NCR Corporation — June 1989 to February 2004
Dayton, Ohio

Vice President of Alliances — *August 2002 to February 2004*

Responsibilities:
Responsible for directing a team of one hundred thirty associates worldwide, delivering $420 million in revenue in 2003 selling IT Infrastructure Solutions to, through and with Original Equipment Manufacturers, Telecommunications Providers, Systems Integrators and Value-Add Resellers alliance partnerships. Also responsible for selecting and managing suppliers who fill gaps in NCR's service delivery capabilities.

Key functions:
- Strategic alliance planning and implementation
- Solutions sales and marketing
- Contract negotiation and execution
- Demand creation and presales support
- Financial analysis and planning
- Supplier selection and supplier management

Major Accomplishments:
- 100% of revenue plan; 89% of cost plan
- Completed Sun Global Reseller Agreement
- Implemented ten new service suppliers

Sales Vice President (interim) — *April 2002 to August 2002*

Responsibilities:
Responsible for directing a team of one hundred fifty associates in Europe, Middle East, and Africa, delivering $310 million in revenue in 2002 selling IT Infrastructure Solutions to End Users, Telecommunications Providers, Original Equipment Manufacturers, and Systems Integrators - selling maintenance, implementation, integration, networking and

technology solutions.

Key functions:
- Solution sales and marketing
- Demand creation
- Account planning
- Sales management discipline

Major Accomplishments:
- Profitably grew orders from $32M in Q1-02, to $60M in Q2-02, to $78M in Q3-02
- Successfully transitioned to permanent Sales Vice President

Assistant Vice President and General Manager *November 1999 to April 2002*

Responsibilities:
Responsible for directing a team of sixty-five associates assigned to the worldwide business relationship with Sun Microsystems - selling and delivering maintenance, implementation, integration, networking and technology solutions.

Key functions:
- Service sales and marketing
- Strategic account planning
- Demand creation
- Capital budgeting
- Account support management

Major Accomplishments:
- Profitably grew revenue from $13.45M to $51.2M – a 382% increase
- Sold and implemented second largest order ($50M) for NCR Worldwide Customer Services – Sun Remote Services
- Recognized for outstanding performance and qualifying for Century Point Club two out of two years
- NCR 2000 Chairman's Award winner in $25M quota category

National Sales Director *April 1997 to November 1999*

Responsibilities:
Responsible for directing a team of seven sales associates selling multi-vendor service solutions to Original Equipment Manufacturers, Systems Integrators, and Value-Added Resellers.

Key functions:
- Demand creation
- Strategic account planning
- Sales associate mentoring

Major Accomplishments:
- Attained 127% of 1997 objective, 212% of 1998 objective, and 115% of 1999 objective
- Successfully established new account relationships with Dell, Sun Microsystems, Intel,

Sequent, Bull, and EDS
- Recognized for outstanding performance and qualifying for Century Point Club four out of four years
- NCR 1998 Top Team Award winner in $25M quota category

EDUCATION

Master of Business Administration (June, 1989)
Fisher College of Business, The Ohio State University, Columbus, Ohio.
Emphasis in Marketing and Finance.

Bachelor of Science – Business Administration (June, 1987)
Wright State University, Dayton, Ohio
Emphasis in Marketing.

PERSONAL ASSOCIATIONS & AFFILIATIONS

American Marketing Association
National Management Association
Fisher College of Business – Alumni Board of Directors
Evolution Theater Company – Board of Directors

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 CARDIO PARTNERS, INC., an Ohio corporation, Charter No. 2155064, having its principal location in Dublin, County of Franklin, was incorporated on December 3, 2012 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 9th day of August, A.D. 2021.

Ohio Secretary of State

Validation Number: 202122103846

Cardio Partners, Inc.

Employee List

First Name	Last Name	Department - Current	Job Title	Supervisor	Work Location
Maria	Almazan	107 - Sales	Account Executive	Hagene, Anthony	Remote Worker - N/A
Paul	Behrens	104 - IT	IT Infrastructure Specialist	Kassien, Jared	Remote Worker - N/A
Robert	Beja	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Lauren	Blatt	107 - Sales	Account Executive	Hagene, Anthony	Remote
James	Boelman	104 - IT	Front End Web Developer	Splinter, Mitchell	Remote
Jennifer	Bradley	112 - Service Operations	Training Account Manager	Wagoner, Wesley	Remote
Mallory	Castro	103 - Customer Care	Sr Customer Care	Jacquest, Bryan	Remote
Dennis	Chars	104 - IT	Full Stack Developer	Edgell, Kristopher	Remote
Emilia	Choate	102 - CCU Acct Mgmt	Account Manager	Trapp, Emily	Remote
Melynda	Coleman	109 - Warehouse	DC Coordinator	Strejc, Steve	Woodruff
Daniel	Craig	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Brittany	Curtis	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Thomas	Dahlk	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Eileen	Daniel	105 - Marketing	Marketing Manager	Gonzalez, Lisa	Woodruff
Cali	Dankovich	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Cynthia	Dunbar	103 - Customer Care	Director of Customer Care	LaDuke, Brian	Woodruff
Kathleen	Dunham	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Kristopher	Edgell	104 - IT	Software Manager	Kassien, Jared	Remote
Steve	Emmel	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Carla	Fermann	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Remote
Adam	Flasch	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Elmer	Foley	109 - Warehouse	Distribution Center	McCormack, Kevin	Woodruff
Will	Foss	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Cara	Fox	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Michael	Gallo	112 - Service Operations	Field Service	Hernandez, Christian	Remote
Samantha	Gillich	107 - Sales	AED Sales Consultant	Olson, Sara	Woodruff
Megan	Goessl	102 - CCU Acct Mgmt	Account Manager	Trapp, Emily	Woodruff
Natalie	Grass	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Anthony	Hagene	107 - Sales	Inside Sales Manager	Cinquemani, Rob	Remote
Angelique	Harman	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Candice	Helgeson	102 - CCU Acct Mgmt	Account Manager	Trapp, Emily	Woodruff
Sara	Henn	103 - Customer Care	Customer Care	Dunbar, Cynthia	Woodruff
Amy	Herring	105 - Marketing	Senior Product Manager	Patel, Niraj	Remote

Todd	Hirsch	109 - Warehouse	DC Coordinator	Strejc, Steve	Woodruff
Dan	Hoehn	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Margaret	House	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Jennifer	Howard	100 - Accounting	Accounting Specialist	Ross, Cindy	Woodruff
Amber	Hubbard	105 - Marketing	Marketing Manager	Gonzalez, Lisa	Woodruff
Jenna	Hunter	107 - Sales	AED Sales Consultant	Olson, Sara	Woodruff
Jeron	Hunter	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Bryan	Jacquest	103 - Customer Care	Customer Care Team Lead	Dunbar, Cynthia	Woodruff
William	Jelinek	107 - Sales	Account Executive	Hagene, Anthony	Remote
Jared	Kassien	104 - IT	VP, Business Systems	Greene, Rhiannon	Woodruff
Paula	Kettler	100 - Accounting	Administrative Assistant	Ross, Cindy	Woodruff
Danielle	Kutschenreute	111 - Reseller Sales	Sub-Distribution Account	Stargel, Sean	Woodruff
Frank	Lindberg	104 - IT	Product Onboarding	Patel, Niraj	Woodruff
Shannon	Long	107 - Sales	Account Executive	Hagene, Anthony	Remote
Theodore	Ludeman-	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Melissa	Marocco	112 - Service Operations	Key Account Manager	Trapp, Emily	Woodruff
Samantha	McCarty	102 - CCU Acct Mgmt	Customer Care	Trapp, Emily	Woodruff
Kevin	McCormack	106 - Operations	VP of Supply Chain	Ellis, Brian	Remote
Mitchell	Meinhardt	100 - Accounting	Staff Accountant	Ross, Cindy	Woodruff
Ryan	Mobry	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Edgar	Montes	112 - Service Operations	Field Service Technician	Hernandez, Christian	Remote
Scott	Mullenberg	107 - Sales	Account Executive	Hagene, Anthony	Remote
Carter	Olson	104 - IT	Junior Software Developer	Splinter, Mitchell	Remote
Sara	Olson	107 - Sales	Manager, AED Sales Team	Leonard, Brian	Woodruff
Megan	Pagano	105 - Marketing	Product Manager	Patel, Niraj	Remote
Dolores	Ponce	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Remote
Camille	Quade	100 - Accounting	Intern	Ross, Cindy	Woodruff
Jennifer	Quade	100 - Accounting	Accounting Assistant	Ross, Cindy	Woodruff
Patrick	Quinn	107 - Sales	AED Sales Consultant	Olson, Sara	Woodruff
David	Reddy	107 - Sales	Account Executive - TEP	Rubo, Patti	Remote
Sarah	Rio	100 - Accounting	Accounting Assistant	Ross, Cindy	Woodruff
Lillian	Rivera	106 - Operations	Inventory Manager	McCormack, Kevin	Remote
Andy	Roeder	107 - Sales	Enterprise Sales Executive	Leonard, Brian	Remote
Cindy	Ross	100 - Accounting	Director of Finance	Saylor, Shawn	Woodruff
Nathan	Roy	104 - IT	IT Support Specialist	Kassien, Jared	Woodruff
Patti	Rubo	107 - Sales	Manager, Training &	Cinquemani, Rob	Woodruff
Craig	Rundle	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff

Daniel	Rundle	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Rorie	Schmitz	107 - Sales	AED Sales Consultant	Olson, Sara	Woodruff
Elana	Seidler	112 - Service Operations	National Training	Wagoner, Wesley	Woodruff
Erin	Smith	106 - Operations	Purchasing Coordinator	McCormack, Kevin	Woodruff
Stephanie	Sowatzka	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Woodruff
Jacob	Spears	105 - Marketing	Digital Marketing Specialist	Gonzalez, Lisa	Remote
Mitchell	Splinter	104 - IT	Manager, Front-End	Kassien, Jared	Remote
Jon	Stein	105 - Marketing	Graphics	Gonzalez, Lisa	Remote
Steve	Strejc	109 - Warehouse	Distribution Center	Foley, Elmer	Woodruff
David	Sutherland	107 - Sales	Account Executive - TEP	Rubo, Patti	Remote
Virginia	Then	102 - CCU Acct Mgmt	Account Manager	Trapp, Emily	Woodruff
Emily	Trapp	102 - CCU Acct Mgmt	Manager of Account	Dunbar, Cynthia	Woodruff
Jason	Trevizo	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Joseph	Turnquist	109 - Warehouse	DC Associate	Strejc, Steve	Woodruff
Christopher	VanHaren	104 - IT	Senior Full Stack Developer	Edgell, Kristopher	Remote
Anett	Vilchez	103 - Customer Care	Customer Care Specialist	Jacquest, Bryan	Remote
Liza	Vilchez	107 - Sales	Sub-Distribution Account	Stargel, Sean	Remote
Marissa	Vilchez	112 - Service Operations	Service Manager	Hernandez, Christian	Remote
Wesley	Wagoner	112 - Service Operations	Training Department	Hernandez, Christian	Woodruff
Jacqueline	Walters	107 - Sales	AED Sales Consultant	Olson, Sara	Remote
Morgan	Wegner	102 - CCU Acct Mgmt	Key Account Manager	Trapp, Emily	Woodruff
Cassidy	Weinstein	103 - Customer Care	Sr Customer Care	Jacquest, Bryan	Woodruff
Alexandria	Whitaker	103 - Customer Care	Sr Customer Care	Jacquest, Bryan	Woodruff
Jayme	White	111 - Reseller Sales	Sub-distribution Account	Stargel, Sean	Woodruff
Douglas	Wiesbrock	102 - CCU Acct Mgmt	Senior Account Manager	Trapp, Emily	Remote
Lisa	Wilke	101 - Admin	VP of Human Resources	McNabb, Lynn	Remote
Donna	Willome	102 - CCU Acct Mgmt	Senior Account Manager	Trapp, Emily	Remote

State of Wisconsin
Department of Safety and Professional Services

Wholesale Distributor of Prescription Drugs

Additional Resources

Other Forms

Statutes and Administrative Code

Offenses that May Result in Refusal, Bar, or Termination of Licensure

Related Links

Pharmacy Examining Board

Orders and Disciplinary Actions

Conviction Self Report

Professional Assistance Procedure

Monitoring

File a Complaint

Predetermination

Pursuant to 2017 Wisconsin Act 278, beginning August 1, 2018, prior to submitting an application for a credential, an individual may apply to the Department for a determination of whether the individual would be disqualified from obtaining the credential due to his or her conviction record. To apply for a predetermination, please fill out Form #3085 and submit all required documentation specified on the form. Pursuant to Wis. Stat. § 111.335(4)(e), the offenses or kinds of offenses that may result in a refusal, bar, or termination of licensure are published under Additional Resources on the left side of this page.

License Information

Fee Reduction

Pursuant to 2017 Wisconsin Act 319, beginning August 1, 2018, an applicant for an initial credential may apply for a reduction of the initial credential fee that is equal to 10% of the initial fee. Qualification is based on the federal adjusted gross income being at or below 180% of the federal poverty guideline prescribed for the applicant's family household size by the United States Department of Health and Human Services. To determine eligibility please visit the United States Department of Health and Human Services website at https://aspe.hhs.gov/poverty-guidelines, prior to submitting Form 3217.

Per Wisconsin State Statutes 440.08 (2), the required renewal date for the Wholesale Distributor of Prescription Drugs credential is 05/31/even years. Should you receive your initial credential in the months leading up to this date, you are still required to renew your license by the statutorily defined date.

Requirements for Licensure

- A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.
- Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.
- Submit Wholesale Distributor of Prescription Drugs Application (see below), including required documentation and fee(s).

Application Process

- A designated representative must be identified on the application.
- All designated representatives must be fingerprinted as described in the application materials.
- All distributors are required to submit a surety bond (Form #2819) or irrevocable letter of credit (Form #2824) with the application in the amount of $5,000.
- Meet Inspection Requirements (see below).
- Distributors must comply with any applicable federal track and trace pedigree system.
- Register with the Drug Enforcement Administration (if applicable).
- Determination to grant credential.

Prescription Medical Device Distributors

No longer need a wholesale distributor of prescription drug license to ship medical device products into Wisconsin. Print this web page for your records verifying no license is needed.

Prescription Medical Device or Drug Manufacturers

- Need to hold a WI Drug or Device Manufacturer license only if your facility is physically located in the state of WI. Print this web page for your records verifying no license is needed.
- No longer need to hold the Wholesale Distributor of Prescription Drug license. Print this web page for your records verifying no license is needed.
- Manufacturers must maintain a list of distributors of record and update the list monthly.

Inspection Requirements

- Whole sale distributors are advised that they must have an inspection completed before the application is filed.
- An approved inspection must be completed and passed within three years prior to the application date.

Approved Inspections Include:

4X

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

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

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Exel Inc. dba DHL Supply Chain (USA)

Physical Address: 1704 Midpark Road

City: Knoxville State: TN Zip: 37921

Mailing Address (if different from physical address): 360 Westar Blvd, Dept 555

City: Westerville State: OH Zip: 43082

Telephone: 865-330-1173 Website: www.dhl.com

Name of Designated Representative (DR): Mary Thomas

Licensing Company Email: regulatory@dhl.com DR Email: mary.thomas4@dhl.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.

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: GlaxosmithKline Biologicals SA
Address: _____ City: Rixensart, Belgium State: _____ Zip: _____

Name: Glaxo Wellcome Operations
Address: _____ City: Ware Hertfordsh, UK State: _____ Zip: _____

Name: Glax Wellcome Production
Address: _____ City: Evreux Cedex 9, France State: _____ Zip: _____

Name: GlaxoSmithKline
Address: _____ City: Barnard Castle, UK 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: MA
Parent Company (if any): DPWN Holdings (USA) Inc.
Corporation Name: Exel Inc. dba DHL Supply Chain (USA)
Mailing Address: 360 Westar Blvd, Dept 555
City: Westerville State: OH Zip: 43082
Telephone: 614-865-8500 Email: regulatory@dhl.com
Contact Person Name: Mark A. Smolik

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 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 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**	✓			
• **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.

Mark A. Smolik

Print Name of Authorized Person Submitting Application

Mark A. Smolik

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

8/30/21

Date

Board Use Only	Date Received: _____	Amount: $500 Check 642525

Processed 9/13/21

Exel Inc. dba DHL Supply Chain (USA)

Business Description

Exel Inc. dba DHL Supply Chain (USA) has been at the forefront of innovative supply chain solutions for the life sciences and healthcare industries for 20 years. As a trusted global partner we create agile, highly responsive supply chains capable of transporting critical, sensitive and valuable products, even to the world's most rugged and remote locations.

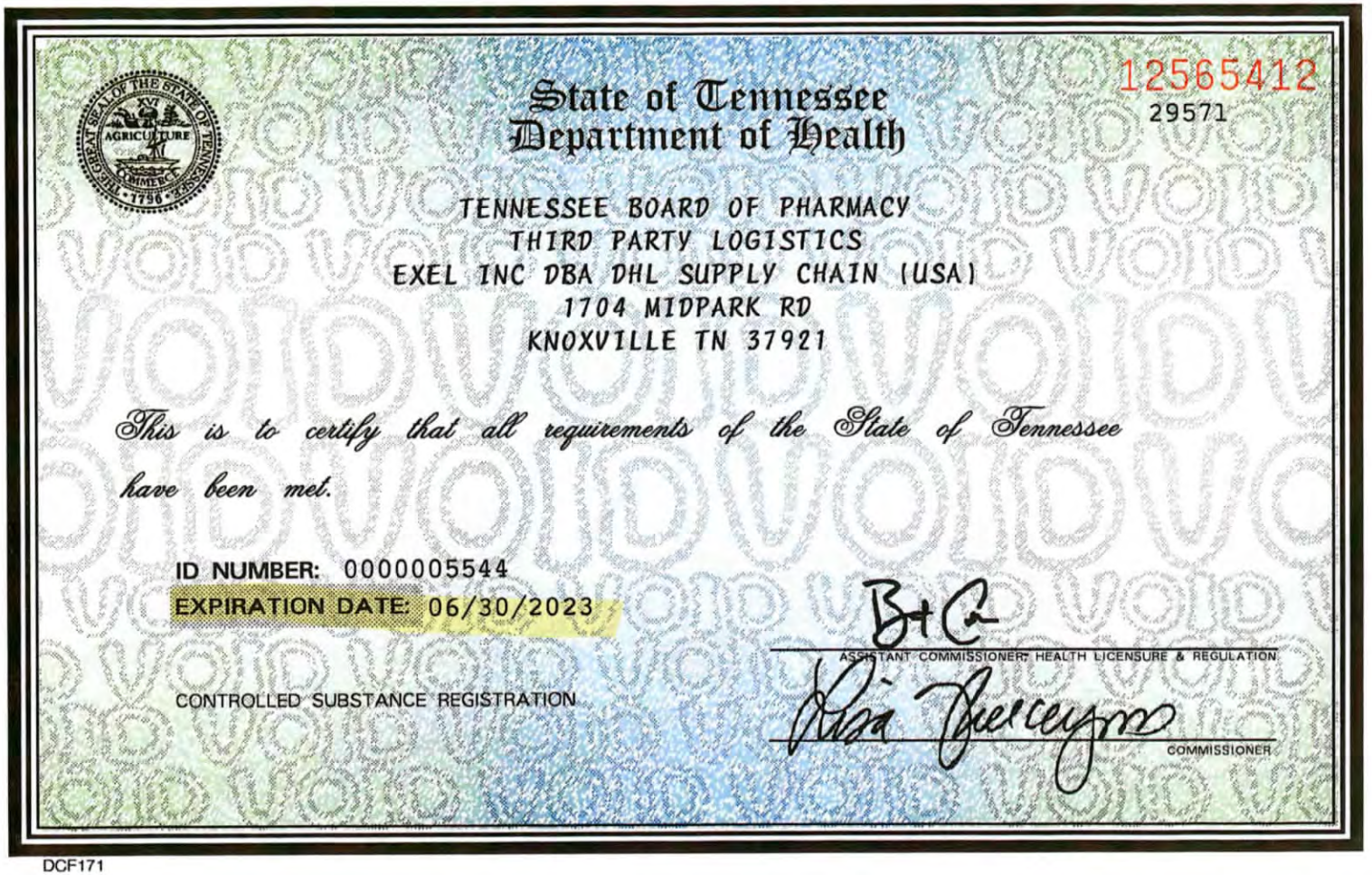
Our extensive experience of supplying logistical solutions to the life sciences and healthcare sector has enabled us to develop specific expertise in the following areas: Vaccines, Generic Pharmaceuticals, Controlled Substances, Over The Counter (OTC) Medication, and Animal Health. For each of these areas we have experts working with our customers to optimize their supply chains.

A connected global footprint and industry expertise
With over 120 sites in 40 countries and 4,500 dedicated healthcare staff, serving 250 life sciences and healthcare customers worldwide, we're always there to offer a safe pair of hands. We have the scale and experience to implement healthcare logistics solutions across the world.

Quality and regulatory compliance
For our customers, deep sector expertise is vital to track, comprehend, and comply with essential and increasing rules and regulations for the storage, transportation and delivery of pharmaceuticals, medical equipment and patient-specific treatments.

With our Global Quality Assurance group of over 100 individuals driving operational consistency and governance we're always up to date with the latest changes in local and international regulations. Our global network provides highly controlled environments and we ensure full GxP (Good Practice) compliance from origin to destination.

Health, safety and security
We help to achieve high standards on health, safety and security through extensive training and timely monitoring. We offer consulting on global safety regulations and conduct regular inspections and process audits of our facilities.



12565412
29571

State of Tennessee
Department of Health

TENNESSEE BOARD OF PHARMACY
THIRD PARTY LOGISTICS
EXEL INC DBA DHL SUPPLY CHAIN (USA)
1704 MIDPARK RD
KNOXVILLE TN 37921

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000005544
EXPIRATION DATE: 06/30/2023

CONTROLLED SUBSTANCE REGISTRATION

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER

DCF171

EXEL INC DBA DHL SUPPLY CHAIN (USA) 1704
Midpark Rd
Knoxville, TN 37921
Attn: Jeff Stanley
865-299-3770

Qualifications
Controlled Subs

Rank: Third Party Logistics

Facility License Number: 00005544
Status: Licensed
Date of Original Licensure: 06/11/2019
Date of Expiration: 06/30/2023
No Disciplinary Actions

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: January 25, 2021

To Whom It May Concern :

I hereby certify that according to the records of this office,

EXEL INC.

is a domestic corporation organized on **June 01, 1983** , under the General Laws of the Commonwealth of Massachusetts. I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156D section 14.21 for said corporation's dissolution; that articles of dissolution have not been filed by said corporation; that, said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 21010950220

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: mas

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RE0557732	08-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 4,5	DISTRIBUTOR	07-28-2021

EXEL INC. DBA DHL SUPPLY CHAIN (USA)
1704 MIDPARK RD
KNOXVILLE, TN 37921-0000

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)

0-1

1020

Corporate Officer Information:

Name:	Kenneth Scott Sureddin	Scot Kevin Hofacker	Mark Andrew Smolik
Title:	Chairman/CEO	VP/CFO	Officer/Secretary
Email	scott.sureddin@dhl.com	scot.hofacker@dhl.com	mark.smolik@dhl.com
Office Address:	360 Westar Blvd, Westerville OH 43082	360 Westar Blvd, Westerville OH 43082	360 Westar Blvd, Westerville OH 43082
Office Phone:	614-865-8500	614-865-8500	614-865-8500
% Ownership	0	0	0

Employee List
SHARIE BAILEY
LOGAN BERRY
MARK BINGHAM
CYNTHIA BRUHIN
DWIGHT CARROLL
KRISTOPHER CASCARELLI
JERRY CATE
KELSEY CHILDRESS
VICKI DAVIS
JAMES DAY
NEWTON DAY
LENNON GLOVER
RICHIE GREENE
TIM GRISWOLD
MARIO GUTIERREZ TUNON
MIKE GUTMAN
NADIA HAMDAN
STAN HAMMEREN
GRACE HAYNES
BRIAN HERRELL
CYNTHIA HOBBS
BRENDA HURST
BRIAN LAMB
JUSTIN LEE

JOE LLEWELLYN
CHRISTI LONG
LISA LOOPE
STEVE LUNSFORD
RODNEY MALONE
EMILY MANER
BETTINA MCKAMEY
MASHAYA NEWMAN
TONYA NEWMAN
CHRISTINE NORTON
JOSH O'CONNOR
DONALD PARTON
CLINT PATTERSON
LORA PATTERSON
ROGER PAYNE
STAN PENNINGTON
JEREMY PRESSLEY
CHRISTIAN SEUS
ORORA SEZENIAS
JEFF STANLEY
ERIC THOMAS
MARY THOMAS
PAULINA TOMASKY
CHERYL TRISH
CHARLENE WADE
STACY WALTON

MICHAEL WARREN
MIKE WESLEY
TONY WEST
KENNETH WILLIAMS
BILL WOODS

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 Exel Inc. dba DHL Supply Chain (USA)

Physical Address 1704 Midpark Road

City Knoxville State TN Zip 37921

Mailing Address (if different from physical address) 360 Westar Blvd, Dept 555

City Westerville State OH Zip 43082

Telephone 865-330-1173 Website www.dhl.com

Licensing Company Email regulatory@dhl.com

Section 2: Personal Information

First Mary Middle Kozel Last Thomas

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

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

Mailing Address [redacted]Westar Blvd, Dept[redacted]

City Westerville State OH Zip 43082

Telephone [redacted] Email Regulatory@dhl.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 MT

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)	
Pellissippi State Technical Community College		08/94- 01/97	
Address	**City**	**State**	**Zip**
10915 Hardin Valley Rd	Knoxville	TN	37932
Diploma/Degree obtained, if any			
Associates			

School Name		From - To (MM/YY – MM/YY)	
Doyle High School		08/87- 05/91	
Address	**City**	**State**	**Zip**
2020 Tipton Station Rd	Knoxville	TN	37920
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
04/99 - Present	[redacted]Jasmine Lane	Maryville	TN	37801
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 MT

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)	
Exel Inc. dba DHL Supply Chain (USA)			05/19 - Present	
Business Address		**City**	**State**	**Zip**
1704 Midpark Road		Knoxville	TN	37921
Phone	**Title**		**Number of Employed Hours**	
865-330-1173	Systems Analyst & Designated Representative		6,240 hours	
Description of Duties				
Maintain Inventory, Support Hardware, Complete monthly reports and assist with testing and trainings.				

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				

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.)	☐	☑
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, Mary Thomas, **certify that as the designated representative for**

Exel Inc. dba DHL Supply Chain (USA),

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

Mary Thomas

Print Name (First, Last)

→ Mary Thomas

Original Signature (electronic, copies or stamps not accepted)

→ 23-Aug-2021

Date

Applicant's initials MT

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.

Mary Thomas

Print Name (First, Last)

→ Mary K Thomas

Original Signature (electronic, copies or stamps not accepted)

→ 23-Aug-2021

Date

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

State of Tennessee, ss. County of Blount

I, Mary 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.

Mary K Thomas

Original Signature

23-Aug-2021

Date

Subscribed and Sworn to before me this 23 day of August, 2021

→ Kelly McCarter

Notary Public Signature

KELLY McCARTER
State of TN
Notary Public
BLOUNT COUNTY

My commission expires
04/23/2025

(Seal)

Applicant's initials _____

Mary K. Thomas

[redacted] Jasmine Lane, Maryville, TN 37801 – [redacted] – mary.thomas4@dhl.com

Experience

Senior Operations Systems Analyst & Designated Representative

DHL Supply Chain, Knoxville, TN

May 20, 2019 - Present

FedEx Supply Chain, Knoxville, TN

April 2015 – May 19, 2019

Kenco Logistics, Inc, Knoxville, TN

January 2008 – March 2015

Maintain inventory control between DCMS and E1

Support hardware (RF's, printers, PC's, etc)

Troubleshoot all aspects of daily operations using DCMS, UNIX, and SQL

Configure data setup in DCMS

Complete monthly report generation for all 3 DCMS instances (DEA ARCOS reports, Vaccine containers shipped, etc)

Work with GSK Legal to complete application renewals for Board of Pharmacy and Controlled Substance licensing

Assist in testing, training, and validating DCMS upgrades and patches, including User Acceptance Testing, creating test cases, and test case execution

Review and update SOP's

Supported CERPS, MERPS & Tech Refresh testing with Trade Relations and IT Groups

Assisted in successful testing, training, and implementation of the new CERPS & MERPS Systems, as well as the complete Tech Refresh project completed EOY 2019

Systems Coordinator/Lead Person

Kenco Logistics, Inc, Knoxville, TN

January 1998 – January 2008

Backup for Systems Manager

Order Processing, including coordinating transportation, requesting export documents, returning Quality Samples to GSK's Cidra Facility, creating destroys orders

Assisted GSK Trade Relations with order discrepancies and customer complaints

Maintained inventory control

Troubleshooting Systems Issues

Data setup for new products

Trained employees on DCMS and CSS

Lead Person over Pick/Pack processing

Working knowledge of every aspect of daily operations (Receiving, Picking, Packing, Shipping, including Vaccines and Controlled Substances)

Assisted GSK QA with system holds, adjustments, Quality Samples

Assisted in testing, training, and successful implementation of the DCMS upgrade

Assisted in testing, training, and successful installation of the new Distribution Management System

Assisted in Best Practices SOP revision project

Administrative Assistant/Materials Handler

Kenco Logistics, Inc, Knoxville, TN

August 1993 – January 1998

Performed daily duties of Administrative Assistant

Backup for Office Manager

Processed Controlled Substance DEA 222 Forms

Processed returned goods

Completed online receiving of Trade products

Performed lot audits of Promotional products

Confirmed Promotional orders

Education

Associates of Arts

Pellissippi State Technical Community College, Knoxville, TN/University of Tennessee Knoxville, TN

January 1997

Business Administration

Mary K. Thomas
[redacted] Jasmine Lane, Maryville, TN 37921 [redacted] mary.thomas4@dht.com

DRIVER LICENSE
Tennessee
THE VOLUNTEER STATE
USA
TN
DL NO [redacted]
DOB [redacted]
EXP 06/01/2026
ISS 06/01/2018
CLASS D
END NONE
REST NONE
SEX F HGT 5'-06" EYES BRO
DD [redacted]
DL
THOMAS
MARY KOZEL
[redacted] JASMINE LN
MARYVILLE, TN 37801-5126

Save Time, Renew Online
www.Tennessee.Gov
[redacted]
Rev 12/02/2011
ENDORSEMENTS:
None
CLASS: D Vehicles <26,000 (Operator)
RESTRICTIONS: None
ORGAN DONOR
I hereby certify that I am 18 or older, of sound mind, and upon my death, wish to make an anatomical gift noted here:
Any Organ/Tissue
Entire Body
Donor Signature
Date
Blood Type
RH Factor
Specific Organ(s)/Tissue
FOR NON-PHOTO
SIGN HERE:

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: Exel Inc. dba DHL Supply Chain (USA)

Physical Address: 1704 Midpark Road

City: Knoxville State: TN Zip: 37921

Mailing Address (if different from physical address): 360 Westar Blvd, Dept 555

City: Westerville State: OH Zip: 43082

Telephone: 865-330-1173 Website: www.dhl.com

Licensing Company Email: regulatory@dhl.com

Section 2: Personal Information

First: Mark Middle: Andrew Last: Smolik

Alias(es, nicknames, name changes, etc.): NA

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

Mailing Address: [redacted] Westar Blvd Dept [redacted]

City: Westerville State: OH Zip: 43082

Telephone: [redacted] Email: regulatory@dhl.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: MT

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 See attached Resume		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
	[redacted] Macneil Drive	Dublin	OH	43017
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 MT

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)
Exel Inc. dba DHL Supply Chain (USA)			04-09 - Present
Business Address	**City**	**State**	**Zip**
360 Westar Blvd Dept 555	Westerville	OH	43082
Phone	**Title**		
614-865-8500	Officer/Secretary		

Description of Duties

Responsible for leading the legal, commercial contracts, compliance and economic development departments throughout America.

Business Name			From - To (MM/YY – MM/YY)
See Attached Resume			
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?	☐	☑

Applicant's initials MT

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 A. Smolik

Print Name (First, Last)

Mark A. Smolik

Original Signature (electronic, copies or stamps not accepted)

8/30/21

Date

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

State of Ohio, ss. County of Delaware

I, Mark Smolik, 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.

Mark A. Smolik

Original Signature

8/30/21

Date

Subscribed and Sworn to before me this 30th day of August.

Lori Hill

Notary Public Signature

LORI HILL
NOTARY PUBLIC • STATE OF OHIO
My commission expires Feb. 7, 2026

(Seal)

Applicant's initials MT

MARK A. SMOLIK

[redacted] Macneil Drive
Dublin, OH 43017
Email: [redacted]
Home: [redacted]
Cell: [redacted]

INTERNATIONAL GENERAL COUNSEL, COMPLIANCE OFFICER

Mergers & Acquisitions • Retail Store Operations • Joint Ventures and Business Start-ups • Corporate Governance and Securities • Commercial Transactions • Corporate Litigation (Trial Experience and Settlement Negotiations) • Vendor and Customer Contract Negotiations and Drafting • General Corporate Law • Government Lobbying • Consumer Product Recalls • Retail Advertising Law

- Entrepreneurial, results oriented Business Executive and General Counsel with rich global and national retail, manufacturing, and logistics experience.
- Background includes 25 years of achievements as General Counsel/Attorney; delivered corporate success during engagements with national and international retail/manufacturing and logistics organizations.
- Successful in directing national and international legal affairs for world's largest logistics provider; a thriving privately held retail/manufacturing service provider; and a Fortune 500 retail/manufacturing business.

Career Highlights:

- Legal Department recipient of Deutsche Post DHL 2012 Global Business Service CEO awards for Provider and Investment of Choice (Americas Region)
- Recognized by Deutsche Post DHL in 2011 & 12 for superior achievements in Active Leadership and Best in Class distinctions for employee engagement, team cooperation, communication and social responsibility
- Finalist, Columbus Business First, 2011 General Counsel award; Nominee 2012
- Nominee, 2011 Excellence in Corporate Practice Award, Association of Corporate Counsel
- Orchestrated numerous M&A and joint venture transactions in the U.S., Canada, Panama, Brazil, Chile, Argentina, Mexico, Italy, Peru, Germany, and Japan
- Successfully defended Safelite Autoglass against federal unfair trade practice litigation challenging company's core business model
- Directed national and international business start-ups and business shut down events; established foreign based legal department for Fortune 500 publicly traded retail/manufacturing company
- Recipient, 7 national awards and State of Ohio Commendation for advancing learning opportunities for children

LEGAL CAREER HISTORY

EXEL INC. (a Deutsche Post DHL company) – Columbus, OH.....April 2009 to Present

VICE PRESIDENT / GENERAL COUNSEL & SECRETARY
CHIEF COMPLIANCE OFFICER

*Staff: 7 **Direct Reports**; 29 **Indirect Reports***

Member of Company's Global Legal Services Board, and Senior Management team, responsible for leading the legal, commercial contracts, compliance, and economic development departments throughout the Americas for this $4.5 billion, 40,000 employee organization. Serve as Corporate Secretary to Board of Directors and on Board Employee Benefits Committee. Oversee budget in excess of $10 million.

Key Accomplishments:

- Completely reengineered legal and commercial contracts departments (consisting of 36 people) to align with business operations and improve service. Designed and rolled-out external counsel performance review program reducing outside counsel spend $1,500,000 comparing 2012 to 2010 despite increased work load. Total cost of Legal department in 2012 below 2010 despite growth and increased investment in department personnel
- Appointed Compliance Officer; partnered with multiple internal disciplines to design and roll-out all elements of corporate compliance program (including risk assessment evaluation process, training, policy evaluation and design); frequent speaker on compliance at national and international conferences
- Established Economic Development & Incentives function; secured $24 million in incentive commitments (2012-YTD) enhancing company's financial performance and competitive offering in support of key business initiatives

- Navigating Board of Directors and key internal stakeholders through multiple U.S. class action lawsuits and complex tax litigation in Brazil seeking damages in excess of $1 billion

BELRON US INC. (formerly Safelite Group, Inc.) – Columbus, OH.....Oct. 2002 to April 2009

SENIOR VICE PRESIDENT / GENERAL COUNSEL & SECRETARY, LEGISLATIVE AFFAIRS / ETHICS OFFICER / HUMAN RESOURCES
*Staff: 4 **Direct Reports**; 8 **Indirect Reports***

Managed all aspects of Legal, Human Resources, Corporate Governance and Government Affairs functions for this $1 billion national retail/manufacturer of vehicle glass and provider of insurance claims management services with nearly 8,000 employees.

Served as Secretary to Board of Directors managing all aspects of governance associated with external board meetings, and key shareholder communications and interactions.

Reorganized Legal department aligning it with business operations and establishing credibility; leveraged legal expertise to win complex federal lawsuit during crisis situation. Founded Safelite Charitable Foundation.

Served as Human Resources Officer responsible for all aspects of design, implementation and management of company's employee health and welfare benefit plans managing a $40 million budget and overseeing day-to-day aspects of HR department.

Member of executive team accountable for state and federal litigation, labor and employment law compliance, consumer product safety issues, legal issues involving retail store operations, and commercial financing activities.

Corporate Litigation	• Won two federal lawsuits when a major competitor and trade group alleged business model violated state and federal laws and demanded $200 million in damages. Filed counter-claims against competitor (Diamond Triumph) that led to an out-of-court settlement when Plaintiff agreed to pay company $3 million. After competitor filed bankruptcy, partnered with executives to acquire their assets for $54 million.
Acquisition Integration	• Following acquisition of Diamond Triumph, led Human Resources Team to integrate existing HR benefit plans, policies, procedures, and 1,400 employees into Belron.
State Legislative Issues	• Founded the Department of Legislative Affairs. Directed activities of Lobbyists in 10 states, and managed staff focusing on legislative activities. Testified before numerous state legislative bodies.
Legal Strategies	• Structured plan to file, and filed, suit against company's general liability insurance carrier to collect nearly 100% of litigation fees and expenses totaling $12 million following litigation with competitor.
Corporate Sale	• Member of executive team that sold company to Belron SA for $365 million. Managed team that handled all legal aspects associated with sale and negotiations with several possible buyers. As HR Executive, led team that integrated HR benefit plans, policies, and employees.
Cost Savings	• Delivered a $2 million annual savings by implementing a more cost-effective and valuable employee benefits program.
Ethics Management	• Selected by Board of Directors to launch and manage the company's first Ethics Office.

THE SHERWIN-WILLIAMS COMPANY – Cleveland, OH .....Jan. 1990 to Oct. 2002

SENIOR CORPORATE COUNSEL / CORPORATE COUNSEL / ATTORNEY
*Staff: 5 **Direct Reports** – Attorneys in the US and South America*

Demanding legal role involved starting-up the company's first Legal Department in South America and directing legal affairs for nearly 1,000 US retail stores producing $2 billion in annual sales. Presided over legal issues concerning the aerosol products business, including domestic and foreign manufacturing operations.

Held significant role in joint ventures, Mergers & Acquisitions, and financing activities across the US, UK, Japan, Germany, Panama, Peru, Mexico, Chile, Brazil, Italy, and Argentina. Advised senior executives on national acquisitions, joint ventures, corporate governance, securities, e-commerce, retail advertising, international and national litigation, and regulatory compliance. Spent significant time working in Brazil, Argentina, Chile, Mexico, Japan, and Italy during tenure.

Legal Department Growth	• Catalyst in expanding the international scope of the legal department from a non-existent state to one that was viewed as a valuable part of this international, public company.
M&A Leadership	• Primary Attorney that negotiated and presided over numerous Merger & Acquisition deals in Brazil worth a collective $145 million. Led M&A deals in Chile, Argentina, Panama, Mexico, and Italy worth a total of $110 million which enabled company to penetrate new markets and industries.
Legal Document Negotiations and Development	• Negotiated and drafted legal documents to support numerous financing programs with an aggregate total of $1.8 billion. As Lead Counsel, negotiated and drafted legal instruments for shelf-registration debt financing arrangements.
Corporate Governance; Securities; Hostile Takeover	• Primarily responsible for managing team that advised management and the Board on all securities, NYSE, and SEC related issues involving public company including preparing all '34 Act filings (including 10K, 10Q, 8K, Schedule 14A); architect of company's insider trading policy and managed related compliance reporting. Served as finance counsel regarding $1 billion hostile takeover of competitor
State Government Negotiations	• Settled litigation with California's Attorney General's Office which desired to enjoin the sale of company's aerosol products. Negotiated favorable terms that avoided injunction.

Earlier Career: 1987 to Jan. 1990, **Attorney**, Ziegler, Metzger & Miller, Cleveland, OH

EDUCATION / BAR ADMISSIONS

Juris Doctor • CLEVELAND MARSHALL COLLEGE OF LAW, Cleveland, OH

Bachelor of Arts, Political Science • JOHN CARROLL UNIVERSITY, University Heights, OH

State of Ohio Bar, 1987 to Present; US District Court, Northern District of Ohio, 1988 to Present

PROFESSIONAL AFFILIATIONS

ASSOCIATION OF CORPORATE COUNSEL, Member: Corporate & Securities Law, International Legal Affairs, Law Department Management Committees

AMERICAN BAR ASSOCIATION, Business and International Law Sections

Bar Associations: State of Ohio, Columbus, Ohio, and Cleveland, Ohio

EXECUTIVE APPOINTMENTS

Board Member, American Cancer Society 2012 - present

Founder and Board Member, SAFELITE CHARITABLE FOUNDATION • 2005 to April 2009

Vice Chairman of the Board and Vice President, SHERWIN-WILLIAMS FEDERAL CREDIT UNION • 1991 to 2002

Vice President, Board Member, Greater Cleveland International Lawyer's Group • 1996 to 2002

PUBLICATIONS

Foreign Corrupt Practices Act Compliance Program Primer (With Sample Language for Use in International Sales, Marketing, Agency and Distribution Agreements), The Lawyer's Brief, Volume 30, Issue No. 8, April 30, 2000

Building a Platform to Achieve the Company's Goals, HR Leadership & Development, Inside the Minds, Aspatore Books, 2005

SPEAKING ENGAGEMENTS -- numerous domestic and international speaking engagements focusing on Best Practices in Corporate Governance, Compliance and Law Department management

RIDER

To be attached to and form part of:

Bond Number 016075066

dated 4/15/2017

issued by the LIBERTY MUTUAL INSURANCE COMPANY

in the amount of $100,000.00

on behalf of EXEL, INC. DBA DHL SUPPLY CHAIN (USA)
(Principal)

and in favor of THE STATE OF NEVADA
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

ADD THE FOLLOWING LOCATION TO THE BOND:

1704 Midpark Road, Knoxville, TN 37921

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 October, 2021.

Signed, Sealed & Dated this 6th day of October, 2021.

EXEL, INC. DBA DHL SUPPLY CHAIN (USA)
(Principal)

By: _____

LIBERTY MUTUAL INSURANCE COMPANY
(Surety)

By: _____
Elizabeth Marrero, Attorney-in-Fact

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8201310-016018

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Claudette Alexander Hunt; Guillermo A. Luis; Elizabeth Marrero

all of the city of Miami state of FL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 24th day of May, 2019.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 24th day of May, 2019 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute 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 have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires March 28, 2021
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 6th day of October, 2021.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co_062018

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

To confirm the validity of this Power of Attorney call 1-610-832-8240 between 9:00 am and 4:30 pm EST on any business day.

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. 016075066

Application/License No. _____

EXEL, INC. DBA DHL SUPPLY CHAIN (USA), doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
570 Polaris Parkway, Dept. 555 Westerville, OH 43082, as
Address of Applicant/Principal
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
Surety Company
corporation organized under the laws of the state of MA
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 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 4/15/2017.
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 17th day of April, 2017.

APPLICANT/PRINCIPAL
EXEL, INC. DBA DHL SUPPLY CHAIN (USA)

_____
Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Claudette Alexander Hunt
Surety Company's Representative

Claudette Alexander Hunt, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Jeannie Reinoso

_____
Witness Camille M. Cruz

Countersigned by:

n/a
Nevada Resident Agent

THIS POWER OF ATTORNEY IS NOT VALID UNLESS IT IS PRINTED ON RED BACKGROUND.
This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Certificate No. 7366328

American Fire and Casualty Company
The Ohio Casualty Insurance Company
Liberty Mutual Insurance Company
West American Insurance Company

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That American Fire & Casualty Company and The Ohio Casualty Insurance Company are corporations duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Camille M. Cruz; Claudette Alexander Hunt; Jacqueline Jordan Hampton

all of the city of Miami, state of FL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 17th day of May, 2016.

American Fire and Casualty Company
The Ohio Casualty Insurance Company
Liberty Mutual Insurance Company
West American Insurance Company

By: David M. Carey
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 17th day of May, 2016, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of American Fire and Casualty Company, Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute 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 have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Plymouth Twp., Montgomery County
My Commission Expires March 28, 2017
Member, Pennsylvania Association of Notaries

By: Teresa Pastella
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS – Section 12. Power of Attorney. Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts – SECTION 5. Surety Bonds and Undertakings. Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Gregory W. Davenport, the undersigned, Assistant Secretary, of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 17 day of April, 2017.

By: Gregory W. Davenport
Gregory W. Davenport, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

To confirm the validity of this Power of Attorney call 1-610-832-8240 between 9:00 am and 4:30 pm EST on any business day.

LMS_12873_122013

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks 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 Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
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 1,2,3,4
- ☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
- ☑ Partnership - Pages 1,2,3,7,8
- ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Organic PoAg LLC DBA My Medical Supply

Physical Address: 800 Westpark Dr. Ste 7

City: Little Rock State: AR Zip Code: 72204

Telephone Number: 501-319-7422 Fax Number: 800-506-4901

Toll Free Number: N/A

E-mail: Laura@mymedicalsupply.com Website: mymedicalsupply.com

Facility Manager: Laura Lusinger

Professional qualifications and experience of facility manager: _____

Types of licensed outlets or authorized persons firm will serve:

- ☑ Pharmacies
- ☑ Practitioners
- ☑ Hospitals
- ☑ Wholesalers
- ☐ Other: _____

Type of Products to be handled or wholesaled by firm:

- ☑ Legend Pharmaceuticals, Supplies or Devices
- ☐ Poisons or Chemicals
- ☐ Controlled Substances (include copy of DEA)
- ☐ Other: _____
- ☐ Hypodermic Devices
- ☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☑
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☑ No ☐
attached list

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.
New Business

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

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 ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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, site 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.

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 pharmacy 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.

Leslie Wilson
Original Signature of Person Authorized to Submit Application, no copies or stamps

Leslie Wilson
Print Name of Authorized Person

05/21/2021
Date

Board Use Only	Date Processed:_____	Amount: 500	Check # 1022 10/12/21

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General _____ Limited ✓

List names of 4 largest partners and percentage of ownership:

Name: Gregory John Rideout %: 33.34

Name: Joseph Pravoot Gira %: 33.33

Name: John Howard McDougall %: 33.33

Name: _____ %: _____

Partnership Name: Organic Prag, LLC dba My Medical Supply

Mailing Address: 1300 Westpark Dr. Ste 7

City, State Zip Code: Little Rock, AR 72204

Telephone Number: 501-319-7422 Fax Number: 800-506-4901

Contact Person: Gregory J. Rideout

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a partnership

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600, Little Rock, Arkansas 72201

2021 - 2022 WHOLESALE DISTRIBUTOR LICENSE

Organic Poag, LLC
DBA: My Medical Supply

located at:

1300 Westpark Drive, Suite 7, Little Rock, AR 72204

License #: WD05473 **Original License Date: 01/20/2021**

This is to certify that the business named above is licensed under the provisions of the Arkansas Pharmacy Practice Act, other Arkansas statutes, and Arkansas Pharmacy Regulations.

License expires: December 31, 2022

This permit is not transferable and must be prominently displayed.

Arkansas State Board of Pharmacy

License #: WD05473 **Facility ID: 108858**

Mailing Address:

Organic Poag, LLC
1300 Westpark Drive
Suite 7
Little Rock, AR 72204

Reason Mailed:

Original License
Replacement Requested

The address above is the mailing address where all correspondence from the board will be sent, including renewal information.
All changes to contact information can be made online at www.pharmacyboard.arkansas.gov under "License Maintenance."
Use the license number and facility ID above to log in.

Organic Poag, LLC, DBA: My Medial Supply
Ownership Info

Gregory Rideout, President
[redacted] St. Thomas Ct.
Little Rock, AR 72211
Office Phone: 501-319-7422
Home Phone: [redacted]
Ownership: 33.3%

Joseph Gira, Partner
[redacted] Claymark Dr.
St Louis, MO 63131
Office & Home Phone: [redacted]
Ownership: 33.4%

John McDougall, Managing Member
[redacted] south Gulfview Blvd, [redacted]
Clearwater, FL 33767
Office and Home Phone: [redacted]
Ownership: 33.3%

Arkansas Secretary of State
John Thurston
State Capitol Building ♦ Little Rock, Arkansas 72201-1094 ♦ 501-682-3409

Certificate of Good Standing

I, John Thurston, Secretary of State of the State of Arkansas, and as such, keeper of the records of domestic and foreign corporations, do hereby certify that the records of this office show

ORGANIC POAG, LLC

authorized to transact business in the State of Arkansas as a Limited Liability Company, filed Articles of Organization in this office April 7, 2021.

Our records reflect that said entity, having complied with all statutory requirements in the State of Arkansas, is qualified to transact business in this State.

In Testimony Whereof, I have hereunto set my hand and affixed my official Seal. Done at my office in the City of Little Rock, this 3rd day of December 2021.

John Thurston
Secretary of State

Online Certificate Authorization Code: 43187758f109414
To verify the Authorization Code, visit sos.arkansas.gov

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, 2021

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

To whom it may concern:

This is to certify that **My Medical Supply** located at **1300 Westpark Drive, Suite 7** in **Little Rock, Arkansas** is licensed as a **Wholesale Distributor** in the state of **Arkansas**. Their Arkansas license number is **WD05473.** Their license is **Active** and in **Good Standing** and has no past disciplinary action, nor any disciplinary action pending. They acquired their license on **01/20/2021** and it will expire **12/31/2022**.

If you have any questions, please feel free to contact me by phone at 501-682-9010 or email me at: Jennifer.m.burgin@arkansas.gov.

Sincerely,

Jennifer M. Burgin

Jennifer M. Burgin
Administrative Analyst

My Medical Supply Employees:

Josh Bond - Executive Vice President
Greg Rideout- President
Mark McAllister- inside sales Rep
Michelle Spicer- inside sales rep
Kelley Rideout- Outside Sales rep
Justin Spicer- contract inside sales rep
Virginia Perkins- lead warehouse associate
Larry smith- warehouse associate
Tiffany Quick- warehouse associate
Laura Lusinger- Director of Operations and Compliance

0Laura E Lusinger
[redacted]**West St.**
Conway, AR 72032
Telephone: [redacted]
Email: [redacted]

Work Objective

To obtain a position from which I will bring my extensive knowledge and sense of responsibility to contribute to a professional work environment.

Summary of Qualifications

- Extensive knowledge of quality and compliance with cGMP regulations, Food and Drug laws and federal and state safety requirements.
- Extensive knowledge of manufacturing operations, GMP's, GDP's, SOPs, auditing, and inspections.
- Excellent customer relations and customer retention skills
- Ability to plan, prioritize workload, organize and coordinate multiple tasks and projects
- Ability to use problem-solving and analytical techniques
- Good critical thinking, deductive reasoning, and decision-making skills
- Strong project management skills
- Strong Management Skills
- Certified Designated Representative in Florida and California

Professional Experience

Director of Operations and Compliance

- Take a lead role to manage and develop company's strategy
- Collaborate and work with the leadership of every department to build a trusted, cooperative, and responsible environment.
- Initiate for better business practices
- Drive employees and lead them to the best performance and workforce
- Ensure the objectives meet customer and business expectations
- Ensure compliance with local, state, and federal laws
- Designated Representative/Manager in Charge
- Create, present and perform Quality training sessions and assist employees to increase knowledge and skills necessary to achieve improved results
- Implement and oversee in the creation/day to day, implementation, revision, and maintenance of documents including SOPs, methods, protocols, and reports
- Lead FDA and State inspections
- Inspects equipment, facility and grounds to ensure property is being properly maintained
- Oversee all warehouse activities ensuring compliance and standards are meet and maintained
- Oversee Inventory management including purchasing material, product, supplies, etc

Quality Assurance and Regulatory Affairs Supervisor

- Generate, design, and implement policy and procedures
- Perform reviews, walkthroughs, audits and inspections
- Provide quick and effective resolution to escalated issues
- Develop and Implement Quality Assurance Program
- Develop and implement quality improvement strategies and Quality Plans
- Provide feedback on quality audit results and make recommendations for improvements
- Create, present and perform Quality training sessions and assist employees to increase knowledge and skills necessary to achieve improved results
- Identify new technology and other resources, to achieve greater efficiency and improved results.
- Follow up on outstanding audit items and recommendations (including those performed by supervised staff) to determine satisfactory disposition in a timely manner
- Provide consulting services in the areas of internal control standards and operational policies and procedures with management, where appropriate
- Assist in the audit planning process
- Oversee in the creation, implementation, revision, and maintenance of documents including SOPs, methods, protocols, and reports
- Oversee Investigation's and implementation of CAPA's, customer complaints, Adverse Events, NCMRs, OOS, DCR's
- Assist with implementation and recommendations for business improvements
- Review and Approve Marketing material, batch records, labels, packaging materials and any other component that requires approval before distribution.
- Oversight of day-to-day distribution activities
- Manage and maintain records directly related to distribution
- Lead FDA and State inspections
- Manage subordinate staff in the day to day performance of their tasks
- Oversee all warehouse activities ensuring compliance and standards are meet and maintained
- Oversee Inventory management including purchasing material, product, supplies, distribution, etc

Quality Assurance and Regulatory Affairs Specialist

- Generate and implement policy and procedures
- Perform reviews, walkthroughs, audits, and inspections
- Provide quick and effective resolution to escalated issues
- Assist with Development and Implementation of Quality Assurance Program
- Assist in the Development and implementation of quality improvement strategies and Quality Plans
- Provide feedback on quality audit results and make recommendations for improvements
- Assist in the audit planning process
- Supports the creation, implementation, revision, and maintenance of documents including SOPs, methods, protocols, and reports
- Investigate and implement CAPA's, customer complaints, Adverse Events, NCMRs, OOS, DCR's
- Assist with implementation and recommendations for business improvements
- Review and Approve Marketing material, batch records, labels, packaging materials and any other component that requires approval before distribution.

- Oversight of day-to-day distribution activities
- Manage and maintain records directly related to distribution
- Oversee all warehouse activities ensuring compliance and standards are meet and maintained
- Oversee Inventory management including purchasing material, product, supplies, etc

Facility and Equipment Coordinator

- Perform Preventative maintenance of equipment, instruments, and other devices used in the manufacturing process
- Inspects equipment, facility and grounds to ensure property is being properly maintained
- Drive reliability performance and support price negotiations with utility service and equipment providers
- Monitor work order submissions and closures
- Implement and maintain equipment SOP's according to cGMP standards
- Assists in the tracking of expenditures on projects and maintains logs and records of work performed and materials used
- Analyzes equipment and facility performance and interpret trends to prevent breakdowns
- Monitor documentation of equipment use, facility certifications and maintenance in accordance with cGMP standards, FDA regulations, and OSHA requirements
- Participate in equipment failure investigations, corrective/preventive actions and equipment release
- Assist in developing new processes and procedures for Preventative maintenance, training, and to decrease deficiencies throughout the manufacturing process
- Drives input for continuous improvement activities (LEAN, 5S) through participation intra and interdepartmentally
- Provide Customer Service/Support to all in house employees, vendors, contractors, etc.
- Manage Maintenance team

Validation Technician

- Maintain and develop expertise in validation activities and compliance for qualification validation.
- Generate and execute all Validation protocols including IQ/OQ/PQ of all site equipment including production equipment and other related systems in compliance with cGMP
- Generate and Execute Validation protocols for sterilization of pharmaceutical drug products
- Resolve all deviations and non-conformances reported during validation/qualification
- Analyze validation results and compile data into summary reports for initial qualifications and re-qualifications
- Coordinate validation schedule with impacted area managers and quality control based on project needs
- Participates in investigation/deviation process related to OOS, OOT and OOE results
- Develops processes for production equipment
- Able to provide cost savings by developing and performing all equipment and process validations

Certified Licensed Pharmacy Technician

- Review and fill prescriptions, and provided customers with information and counseling regarding prescriptions and other medications
- Prepared labels using Rx30 pharmacy management system
- Collections and billing for store accounts and other cashier duties
- Gather all required information to enter into new and existing patient records

- Communication with physicians to verify prescriptions/refills and address insurance issues
- Use of multiple computer applications for filling prescriptions and maintaining prescription inventory
- Maintaining prescription inventory by ordering and receiving the prescriptions daily
- Provide customer service to satisfy customer' s needs to questions, concerns, or complaints on a daily basis

Employment History

Date	Position	Employer
01/2021 - current	Director of Operations and Compliance	Organic Poag, LLC DBA My Medical Supply
07/2020 - 1/2021	Quality Assurance and Regulatory Affairs Supervisor	Focus Laboratories, Inc.
01/2017 – 07/2020	Quality Assurance and Regulatory Affairs Specialist	Focus Laboratories, Inc.
08/2016 - 03/2017	QA Facility and Equipment Coordinator	Central Drug Company, Inc.
04/2014 - 07/2016	QA Facility, Validation, and Equipment Coordinator	US Compounding
08/2013 - 08/2014	Certified Pharmacy Technician	VA Medical Center
05/2006 - 07/2013	Licensed Pharmacy Technician	Woodlands Pharmacy

EDUCATION

High School Diploma, Pine Bluff High School-Pine Bluff, AR, 2000.

Certified Pharmacy Technician 2012

AIU – Bachelor in Business Administration 7/2016 to current

Certified Designated Representative – California 2020

Certified Designated Representative - Florida 2020

TRAINING

Active member of IVT (Institute of Validation Technology)

Actively attends webinars through compliance online

Actively attends webinars through Steris

Extensive Customer service training

NSF GMP training

Active Member of ASQ

REFERENCES

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 Organic Poag, LLC

Physical Address 1300 Westpark Dr. Ste 7

City Little Rock State AR Zip 72204

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 501 319 7422 Website mymedicalsupply.com

Licensing Company Email licensing@mymedicalsupply.com

Section 2: Personal Information

First Laura Middle E. Last Lusinger

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

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

Mailing Address [redacted] Westpark Dr. Ste [redacted]

City Little Rock State AR Zip 72204

Telephone [redacted] Email laura@mymedicalsupply.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 LV

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)	
Pine Bluff High School		2017 - 2000	
Address	City	State	Zip
711 W 11th Ave	Pine Bluff	AR	71601
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
AIU		07/2016 - current	
Address	City	State	Zip
231 N. Martingale Rd	Schaumburg	IL	60173
Diploma/Degree obtained, if any			
pending - Business Admin			

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
04/2021-Current	[redacted] Laura Lane	Conway	AR	72034
03/2020 - 04/2021	2102 West Street	Conway	AR	72032
11/2018 - 03/2020	3 Alfred Cove	Conway	AR	72034
11/2017 - 11/2018	1620 Middle Rd, Apt 1201	Conway	AR	72032
01/2011 - 11/2017	1730 Penny Street	Conway	AR	72034
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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: See Attached Resume			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

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

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

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

Applicant's initials 5

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 LL

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:

Laura E. Lusinyer
Original Signature (electronic, copies or stamps not accepted)

12-30-21
Date

Applicant's initials LL

I, Laura Lusinger, **certify that as the designated representative for** Organic Poag, LLC dba: My Medical Supply, **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

Laura Lusinger
Print Name (First, Last)

Laura E. Lusinger
Original Signature (electronic, copies or stamps not accepted)

12-30-21
Date

Applicant's initials LL

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.

Laura Lusinger
Print Name (First, Last)

Laura E. Lusinger
Original Signature (electronic, copies or stamps not accepted)

12-30-21
Date

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

State of Arkansas, ss. County of Faulkner

I, Laura Lusinger, 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.

Laura E. Lusinger
Original Signature

12-30-21
Date

Subscribed and Sworn to before me this 30 day of December.

Leslie Wilson
Notary Public Signature

STATE OF ARKANSAS NOTARY PUBLIC
LESLIE WILSON
MY COMMISSION # 12384923
EXPIRES: October 31, 2031
(Seal) Faulkner County

Applicant's initials LL

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

1069

Date 3/22/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Wholesale Distributor
Nature of License

My Medical Supply 1300 Westpark Dr. Ste 7, Little Rock, AR 72204
Name and Address of Establishment for Which License Is Requested

Organic Poag, LLC DBA My Medical Supply
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

GIRA, JOSEPH PRAVOOT
Last Name / First Name / Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] CLAYMARK DRIVE, ST. LOUIS, MO. 63131
Present Residence Address-Street or RFD / City / State/Zip

Dates
Present Business Address / City / State/Zip

PHYSICIAN Dates 1995 - present
Occupation

Phone:
Residence .....
Business .....

[redacted] ST. LOUIS, MO
Date of Birth / Place of Birth (City, County, State)

50 [redacted] M
Age / Social Security Number / Sex

BROWN	BLACK		210		6'1"
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No .....

If naturalized, certificate No ..... Date .....

Place ..... (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial JG

A. **Current Marriage** 8-28-1999 (Date) ST. LOUIS, MO (City, County and State)

Spouse's full name (Maiden) MARY KOLY S.S. No [redacted]

Date of Birth [redacted] Place of Birth ST. LOUIS, MO

Resident address [redacted] CLAYMARK DRIVE, ST. LOUIS, MO. 63131
Street City State Zip

Telephone: Residence [redacted] Business

Spouse's employer Occupation HOME MAKER

Address of employer
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
MICHAEL GIRA	[redacted]	ST. LOUIS, MO	[redacted] Claymark, St. Louis MO. 63131
ELIZABETH GIRA	[redacted]	ST. LOUIS, MO.	[redacted] Claymark, St. Louis, MO. 6313

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a 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 initial TG

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name.....

Address.....

Contact person.....

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	PAUL GIRA	[redacted]	[redacted] FRONTENAC WOODS ST. LOUIS, MO. 63131	DECEASED
Mother	BANG-ORN GIRA		same	RETIRED PHYSICIAN
Father-in-Law	JOHN KOLY		[redacted] WILLIAMSBURG ROAD ST. LOUIS, MO. 63141	RETIRED ENGINEER
Mother-in-Law	ARLENE KOLY		same	TEACHER

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	JOHN GIRA	[redacted]	[redacted] ASCOT MANOR ATLANTA, GA. 30327	PHYSICIAN
Spouse	AMY KIM			PHYSICIAN
	OTT GIRA		[redacted] FRONTENAC WOODS ST. LOUIS, MO. 63131	ARCHITECT
Spouse	SAI GIRA			ARCHITECT
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	ROBIN HILL	ST. LOUIS, MO	1976-1980	Yes ☑ No ☐
High School	COUNTRY DAY	ST. LOUIS, MO	1981-1989	Yes ☑ No ☐
College University	UNIV. OF MO - KANSAS CITY		1989-1995	Yes ☑ No ☐
Other	UNIV. OF MO - KC SCHOOL OF MEDICINE		1989-1995	Yes ☒ No ☐

Type of degree obtained, if any BA / M.D.

College or university where obtained UMKC

Applicant's initial JG

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☑ No ☐

County St. Louis State MO Date registered 1989

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒
If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒
If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial JG

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☒ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
1996-1999	7500 KIRBY	HOUSTON,	TEXAS
1999-2000	11511 CRAIG CT	ST. LOUIS,	MO
2000-2010	1 WILLIAMSBURG RD	ST. LOUIS,	MO
2010-present	[redacted] CLAYMARK DR.	ST. LOUIS,	MO

Applicant's initial JG

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JUNE 1999 - present	OPHTHALMOLOGY CONSULTANTS	SELF
Title	**Description of Duties**	**Name of Supervisor**
PHYSICIAN		

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JULY 1996 - JUNE 99	HERMANN EYE CENTER	Graduated
Title	**Description of Duties**	**Name of Supervisor**
MD	RESIDENT PHYSICIAN	RICHARD RUIZ MD

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
July 1995 - June 96	ST JOHNS MERCY HOSPITAL	Graduated
Title	**Description of Duties**	**Name of Supervisor**
Inter	Internship	Chris Veramakis MD

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/89 - 6/95	UMKC Combined BA/MD Program	Graduated
Title	**Description of Duties**	**Name of Supervisor**
	STUDENT	

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial JG

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name STEVE LEE	Home	[redacted]	Pine Terrace, Ballwin, MO. 63021		[redacted]	18
Employer Ophthalmology Consultants	Business	12990 Manchester Road St. Louis, MO 63131				
Name Michael Donahue	Home	[redacted]	Thornhill Drive, Town + Country, MO 63131			22
Employer OC	Business				[redacted]	
Name Cathy Mohr	Home	[redacted]	Foxwood Dr, Maryland Heights, MO 63043			19
Employer OC	Business	12990 Manchester Rd, 63131			636-699-3274	
Name Ranjan Malhotra	Home	[redacted]	Thornhill Ct. 63131		[redacted]	32
Employer Ophthalmology Associated	Business					
Name John Galanis	Home	[redacted]	Aston Ct, Chesterfield, MO. 63005			20
Employer Galanis Eye	Business				[redacted]	

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☒
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

(Liquor)	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
(Doctor)	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐
If yes, state type, where and years held

Liquor - Kansas, Nebraska - 2010-present

Doctor - CA, MO, IL, FL, TX, IN, KY, NC, OH, OK, MI, GA, NJ - 2018-present

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial JG

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

Date of photograph 3-23-21

Applicant's initial JG

STATE OF MISSOURI
ss.
COUNTY OF ST. LOUIS

I, JOSEPH GIRA, 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 case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 22 day of March, 2021

Notary Public

(seal)

JENNY M. WIEMERS
Notary Public – Notary Seal
St Louis County – State of Missouri
Commission Number 13716214
My Commission Expires May 23, 2021

Applicant's initial JG

ADDITIONAL INFORMATION

Applicant's initial_____

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 3/31/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Wholesale Distributor
Nature of License

My Medical Supply 1300 Westpark Dr. STE 7, LR, AR 72204
Name and Address of Establishment for Which License Is Requested

Organic Poag LLC. DBA My Medical Supply
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

McDougall — John — Howard
Last Name — First Name — Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] S Gulfview Blvd Unit 1802 — Clearwater, FL 33767
Present Residence Address-Street or RFD — City — State/Zip

Present Business Address — Dates — City — State/Zip

Retired Optometrist — Dates 1981 – 2017
Occupation

Phone:
Residence
Business

[redacted]
Date of Birth — Place of Birth (City, County, State)

68 — [redacted]
Age — Social Security Number — Sex

Hazel — Brown — 172 — Medium — 5'9"
Color of Eyes — Color of Hair — Complexion — Weight — Build — Height

Scars, tattoos or distinguishing marks and/or characteristics

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial JM

A. **Current Marriage**

Spouse's full name (Maiden) Date Ginny McDougall City, County and State S.S. No 394-68-00-56

Date of Birth 11/7/ Place of Birth

Resident address Same
Street City State Zip

Telephone: Residence Business

Spouse's employer RETIRED Occupation

Address of employer
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
JOANNE	2004	CHICAGO		Springfield IL
MELISA	2016	LAS VEGAS		Tampa, FL

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
JOANNE ~~[illegible]~~	HIBBLEN	QUINCY, IL			
MELISA	MATHAS	TAMPA, FL			

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
CHRISTOPHER	[redacted]	[redacted]	OAKWAY, STL MO
MEGAN			OAK ST. STL, MO
SEAN			ROSCAN STL, MO

B. Child Support Information:

Please mark the appropriate response:

☒ I am not subject to a court order for the support of child.

☒ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☒ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a 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 initial JM

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name .....

Address .....

Contact person .....

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	DECEASED	[redacted]		CITY MANAGER
Mother	DECEASED			HOUSEWIFE
Father-in-Law				
Mother-in-Law				

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
Spouse	TOM McDOWELL		[redacted]	RETIRED
Spouse				
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School				Yes ☒ No ☐
High School	C.C. MONA	SAUK RAPIDS MI		Yes ☒ No ☐
College University	MICHIGAN STATE		1970-1972	Yes ☒ No ☒
Other	IL COLLEGE OF OPTOMETRY			Yes ☒ No ☐

Type of degree obtained, if any OPTOMETRIST

College or university where obtained .....

Applicant's initial JA

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch ..... Date of entry-active service .....

Date of separation ..... Type of discharge .....

Rating at separation ..... Serial number .....

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☒ No ☐

County ..... State MT Date registered 1971

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒
If yes, when? ..... city, county and state .....

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒
If yes when? ..... city, county and state .....

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial JM

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☒ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2018 PRESENT	[redacted] S. GULFVIEW BLVD	CLEARWATER,	FL 33767
	18 HOLLYWOOD DR.	STL, MO	2013 – 2018 ~~2018 – PRESENT~~
	18 Lakeland DR.	QUINCY, IL	1966 – 2000

Applicant's initial JA

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1981 – 2016	SELF	RETIRED
Title	**Description of Duties**	**Name of Supervisor**
OWNER	OPTICIAN. ST	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial JM

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Mark Tre. Bing	Home	Quincy, IL				
Employer Self	Business					
Name Bruce Sundek	Home	Detroit, MI				
Employer Atty	Business					
Name Tim Hantle	Home	Tampa, FL				
Employer	Business					
Name Dutch Schutte	Home	Quincy, IL				
Employer	Business					
Name Pere Lambkin	Home	Slotts Pile, AZ				
Employer	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☒
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☐
If yes, state type, where and years held
optometrist 1976 - 2020

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial JB

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

Date of photograph 3/22/21

Applicant's initial JM

STATE OF ARKansas
ss.

COUNTY OF Saline

I, [signature], 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 case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

[signature]
Original Signature of Applicant

Subscribed and Sworn to before me this 1st day of April, 2021

[signature]
Notary Public

MICHELLE L GREGORY-SPICER
Arkansas - Saline County
Notary Public - Comm# 12385489
My Commission Expires Jan 2, 2022
(seal)

MICHELLE L GREGORY-SPICER
Arkansas - Saline County
Notary Public - Comm# 12385489
My Commission Expires Jan 2, 2022

Applicant's initial JM

ADDITIONAL INFORMATION

Applicant's initial .....

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 3/22/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for WHOLESALE DISTRIBUTOR
Nature of License

ORGANIC ROAD LLC 1300 WESTPARK DR, STE 7, LITTLE ROCK, AR 72204
Name and Address of Establishment for Which License Is Requested

DBA MY MEDICAL SUPPLY
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

RIDEOUT — GREGORY — JOHN
Last Name — First Name — Middle Name

GREG RIDEOUT
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] ST. THOMAS CT. — LITTLE ROCK — AR 72211
Present Residence Address-Street or RFD — City — State/Zip

1300 WESTPARK DR, STE 7 — Dates 2021 — LITTLE ROCK — AR 72204
Present Business Address — City — State/Zip

PRESIDENT — Dates
Occupation

Phone: Residence [redacted]
Business 501-319-7422

[redacted] — CONCORD, NH
Date of Birth — Place of Birth (City, County, State)

54 — [redacted] — MALE
Age — Social Security Number — Sex

BLUE — GREY — FAIR — 195 — SLENDER — 6'4"
Color of Eyes — Color of Hair — Complexion — Weight — Build — Height

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☑ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial GWR

A. **Current Marriage** 8-7-93 (Date) PINE BLUFF, AR (City, County and State)

Spouse's full name (Maiden) KELLEY NELSON RIDEOUT (WRIGHT) S.S. No [redacted]

Date of Birth [redacted] Place of Birth MOBILE, AL

Resident address [redacted] (Street) ST. THOMAS CT. (City) LITTLE ROCK (State) AR (Zip) 72211

Telephone: Residence [redacted] Business

Spouse's employer FOCUS LABORATORIES Occupation SALES

Address of employer 11205 RICHARDSON DR. (Street) NORTH LITTLE ROCK (City) AR (State) 72113 (Zip)

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
KATHRYN L. RIDEOUT	[redacted]	HOMEWOOD, AL	[redacted] S. JABIAD LN, FAYETTEVILLE, AR 72701
CARTER G. RIDEOUT	[redacted]	HOMEWOOD, AL	[redacted] OLIVER ST, CONWAY, AR 72034

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a 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 initial GJR

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name .....

Address .....

Contact person .....

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	ARTHUR E. RIDEOUT	[redacted]	S. 70TH, FORT SMITH, AR 72903	DECEASED
Mother	MILDRED T. RIDEOUT	[redacted]	S. 70TH, FT. SMITH, AR 72903	DECEASED
Father-in-Law	RICHARD S. NELSON	[redacted]	CHERRY RIDGE CT., MOBILE, AL 36609	RETIRED
Mother-in-Law	MARTHA B. LEGROS	[redacted]	NATCHEZ TRAIL CT., MOBILE, AL 36609	RETIRED

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	ARTHUR E. RIDEOUT, JR.	[redacted]		CPA'S
Spouse	LORRAN B. RIDEOUT			TEACHER
	THEODORE B. RIDEOUT			MANUFACTURING
Spouse	BECKY RIDEOUT			REALTOR
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	SUNNYMEADE	FORT SMITH, AR	73-79	Yes ☑ No ☐
High School	NORTHSIDE	FORT SMITH, AR	82-84	Yes ☑ No ☐
College University				Yes ☑ No ☐
Other	UNIVERSITY OF CENTRAL ARKANSAS	CONWAY, AR	84-88	Yes ☐ No ☐

Type of degree obtained, if any BBA MARKETING & MASS COMMUNICATIONS

College or university where obtained UNIVERSITY OF CENTRAL ARKANSAS

Applicant's initial GJR

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch..... Date of entry-active service.....

Date of separation..... Type of discharge.....

Rating at separation..... Serial number.....

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County..... State..... Date registered.....

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when?..... city, county and state.....

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when?..... city, county and state.....

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☑
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial GJR

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
5/03 - PRESENT	[redacted] St. Thomas Ct.,	Little Rock,	AR 72211
8/02 - 5/03	2105 Woodford G.,	Mobile,	AL 36609
8/96 - 8/00	539 Broadway,	Homewood,	AL 35254
6/94 - 8/96	5113 E. Janis Way,	Scottsdale,	AZ 85258

Applicant's initial GJR

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JAN 2021	MY MEDICAL SUPPLY	
Title	**Description of Duties**	**Name of Supervisor**
PRESIDENT		—

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JAN 2006 - OCT 2020	FOCUS LABORATORIES	READY FOR NEW ADVENTURE
Title	**Description of Duties**	**Name of Supervisor**
VP of SALES		BRAD WINFREY

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JUNE 2002 - DEC 2005	BLANSETT PHARMACAL	NEW OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
NATIONAL SALES MGR		LARRY BLANSETT

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
AUG 96 - JUNE 2002	THE HILLCROSS GROUP	NEW OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
OWNER	RECRUIT DOCTORS & SALES PEOPLE	ME

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JAN 95 - AUG 96	THE HUNT COMPANY	NEW OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
RECRUITER	PLACE PHYSICIANS IN JOBS	COLEN CHAMBERLAIN

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
S&J DISTRIBUTORS	AUG 93 - JAN 95	NEW OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
SALES REP	SALES	STEVEN LAFRANCE

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
JULY 89 - AUG 93	ARKANSAS POWER & LIGHT	NEW OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
CUSTOMER SERVICE REP	DESIGN JOBS TO GET PEOPLE POWER	JOY HENDRICKS

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial CJR

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name CHRIS WHALEY	Home	LITTLE ROCK,	AR		[redacted]	20+
Employer BAPTIST HEALTH	Business	OCCUPATIONAL THERAPIST				
Name MATT MCNEELY	Home	LITTLE ROCK,	AR		[redacted]	15+
Employer CENTENNIAL BANK	Business	UPPER MANAGEMENT - BANKING				
Name MITCH PERRY	Home	LITTLE ROCK,	AR		[redacted]	6 YRS
Employer HOOF + HAIL	Business	SALES				
Name BRIAN CAHALAN	Home	LITTLE ROCK,	AR		[redacted]	7 YRS
Employer AR HEART CTR	Business	~~CEO~~ CIO				
Name THAD WAUGH	Home	LITTLE ROCK,	AR		[redacted]	7 YRS
Employer LITTLE CREEK	Business	OWNER - RESTAURANT				

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑
If yes, state type, where and years held

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☑ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

FOCUS LABORATORIES, OWNER 7645 COUNTY MASSIE RD, NORTH LITTLE ROCK, AR 72113, PHARMACEUTICAL DISTRIBUTOR

Applicant's initial GR

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑

Date of photograph 3/22/21

Applicant's initial GR

STATE OF ARKANSAS

ss.

COUNTY OF PULASKI

I, GREGORY J. RIDEOUT, 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 case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 1st day of April, 2021

Notary Public

(seal)

MICHELLE L GREGORY-SPICER
Arkansas - Saline County
Notary Public - Comm# 12385489
My Commission Expires Jan 2, 2022

Applicant's initial GJR

Applicant's initial_____

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. LP21-000001-00

Application/License No. _____

Organic Poag LLC DBA: My Medical Supply (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1300 Westpark Drive, Suite 7, Little Rock, AR 72204 (Address of Applicant/Principal), as PRINCIPAL, and U.S. Insurance Company of America (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 3131 Greenhead Drive, Springfield, IL 62711 (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 June 1, 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 18th day of August, 2021.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Priscila Cergol, 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

U.S. INSURANCE COMPANY OF AMERICA

3131 Greenhead Drive, Springfield, IL 62711

LIMITED POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the U.S. INSURANCE COMPANY OF AMERICA, a stock insurance corporation organized and existing by virtue of the laws of the State of Illinois, and having its principal office in the City of Springfield, Illinois, does hereby constitute and appoint:

*** Priscila Cergol ***

its true and lawful Attorney(s)-in-Fact to sign, execute, attest, seal and deliver for and on its behalf, as Surety, and as its act and deed, where required, any and all bonds, undertakings, recognizances, or other written obligations, the penal sum not to exceed $1,600,000.

Such bonds and undertakings, when duly executed by the aforesaid Attorney(s)-in-Fact shall be binding upon the said Company as fully and to the same extent as if such bonds and undertakings were signed by the President and Secretary of the Company and sealed with its corporate seal.

This power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of the Company on the 15th day of January, 2008:

> **RESOLVED,** that the President of the Company or any person designated by him, is hereby authorized to execute Powers of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Company, bonds, undertakings and all contracts of suretyship, and that the Secretary of the Company is hereby authorized to attest the execution of any such Power of Attorney, and to attach thereto the Seal of the Company, and it was
>
> **FURTHER RESOLVED,** that the signature of such officers and the 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 thereafter valid and binding upon the Company with respect to any bond, undertaking or contract of suretyship to which it is attached.

Bonds executed under this Power of Attorney may be executed under facsimile signature and seal pursuant to the following Resolution adopted by the Board of Directors of the Company on the 15th day of January 2008:

> **RESOLVED,** that the signature of the President of this Company, and the seal of this Company may be affixed or printed on any and all bonds, undertakings, recognizances, or other written obligations thereof, on any revocation of any Power of Attorney, or on any certificate relating thereto, by facsimile, and any Power of Attorney, any revocation of any Power of Attorney, bonds, undertakings, recognizances, certificate or other written obligation, bearing such facsimile signature or facsimile seal shall be valid and binding upon the Corporation.

IN WITNESS WHEREOF, the U.S. INSURANCE COMPANY OF AMERICA has caused its corporate seal to be hereunto affixed, and these presents to be signed by its duly authorized officers this 1st day of March, 2021.

U.S. INSURANCE COMPANY OF AMERICA

Tyler J. Klunick

STATE OF ILLINOIS

On this 1st day of March, 2020, before me personally came Tyler J. Klunick, to me known, who, being duly sworn, did depose and say: that he is President of the Company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to the aforesaid instrument is such corporate seal and was affixed thereto by order and authority of the Board of Directors of said Company; and that he executed the said instrument by like order and authority.

Andrew Krisak
Notary Public, State of Illinois
My commission expires 12-12-2021

I, Mark E. Freiburg, Secretary of the U.S. INSURANCE COMPANY OF AMERICA, a stock insurance corporation of the State of Illinois, do hereby certify that the above and foregoing is a full, true and correct copy of the Power of Attorney issued by said Company, and that I have compared same with the original and that it is a correct transcript therefrom 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.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Company, at the City of Springfield, this 18th day of August, 2021.

Mark E. Freiburg, Secretary

4Z

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

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

Is your facility a reverse distributor? ☐ Yes ☑ No

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 _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Optum Wholesale, Inc.

Physical Address: 277 E. Rowland St.

City: Covina State: CA Zip: 91723

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 626-536-2927 Website: optumwholsaleinc.com

Name of Designated Representative (DR): Shabana Yasmin

Licensing Company Email: info@optumwholesaleinc.com DR Email: syasmin2003@yahoo.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)?		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

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 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: Health Source Distributors
Address: 7200 Rutherford Rd. #150 City: Windsor Mill State: MD Zip: 21244
Name: Keysource Medical
Address: 7820 Palace Dr., City: Cincinnati State: OH Zip: 45249
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: CA
Parent Company (if any): N/A
Corporation/Organization Name: Optum Wholesale, Inc.
Mailing Address: 277 E. Rowland St.
City: Covina State: CA Zip: 91723
Telephone: 626-536-2927 Email: info@optumwholesaleinc.com
Contact Person Name: Shabana Yasmin

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Shabana Yasmin

Print Name of Authorized Person Submitting Application

Shabana Yasmin

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

12/1/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ processed 12/17/21

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	OPTUM WHOLESALE INC.
File Number:	C4627806
Registration Date:	08/05/2020
Entity Type:	DOMESTIC STOCK CORPORATION
Jurisdiction:	CALIFORNIA
Status:	ACTIVE (GOOD STANDING)

As of October 27, 2021 (Certification Date), the entity is authorized to exercise all of 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 Certification Date and does not reflect documents that are pending review or other events that may affect 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 October 28, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: Z1EP2BR

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at *bebizfile.sos.ca.gov/certification/index*.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 7890

ISSUE DATE MARCH 08, 2021

OPTUM WHOLESALE INC

277 E ROWLAND ST
COVINA CA 91723

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
SHABANA YASMIN

EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL MARCH 01, 2022

RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

3/09/21
3/09/21

----- POST IN PUBLIC VIEW -----

OPHWS1 09/30/19 WLS

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RO0604365	12-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-03-2021

OPTUM WHOLESALE INC.
277 E. ROWLAND ST.
COVINA, CA 91723

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
RO0604365	12-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-03-2021

OPTUM WHOLESALE INC.
277 E. ROWLAND ST.
COVINA, CA 91723

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Form DEA-223 (9/2016)

Nevada Wholesaler Application

Optum Wholesale Inc.

Officers/Directors:

Shabana Yasmin, Pharm.D. – President/CFO/Secretary/Director

Shareholders:

Shabana Yasmin, Pharm.D. – 100% shareholder

Optum Wholesale Inc.		Designation	Issue Date	Expiration
277 E. Rowland St., Covina, CA 91723				
Phone #	(626) 367-5389			
EIN #	85-2596772		8/19/2020	
State EIN	4627806			
License #	WLS 7890		3/8/2021	3/1/2022
emails	info@optumwholesaleinc.com			
	shabana@optumwholesaleinc.com	President/COO		
	samia@optumwholesaleinc.com	HR/Compliance/Sales/Contracting		
	Imran@optumwholesaleinc.com	IT/ Equipment		
	Michelle@optumwholesaleinc.com	AR/AP/Sales		
	Ambareen.masood@optumwholesaleinc.com	Web Design/Marketing Associate		
	Kamil@Optumwholesaleinc.com	Operations Manager		
	Riz@optumwholesaleinc.com	Director of Purchasing		
Fax #	(626)331-0224			
Phone #	(833)687-7786			
Seller's Permit	223887424-00001			
DEA	RO0604365			

Optum Wholesale, Inc.- Employee list

Shabana Yasmin, PharmD- President/CEO, - Sole Corporate Officer. - Designated Exemptee

Samia Hasan- HR/ Compliance

Kamil Masood, M.D.- Operations Manager (Son)

Rizwan Masood, PhD.- Purchasing Manager (Husband)

Imran Masood- IT/ Security Manager (Brother-in-Law)

Ambareen Masood- Web design/ Sales Associate (Daughter)

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 Optum Wholesale, Inc.

Physical Address 277 E. Rowland St.

City Covina State CA Zip 91723

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 626-536-2927 Website _____

Licensing Company Email info@optumwholesaleinc.com

Section 2: Personal Information

First Shabana Middle _____ Last Yasmin

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

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

Mailing Address [redacted] E. Rowland St.

City Covina State CA Zip 91723

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.)		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?		

Applicant's initials SY

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)	
USC. - Pharm D School of Pharmacy			1996 - 2000	
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)	
USC - Undergrad - Biochemistry			1994 - 1996	
Address		City	State	Zip
3607 Trousdale Pkwy		Los Angeles	CA	90089
Diploma/Degree obtained, if any				
—				

School Name			From - To (MM/YY – MM/YY)	
PCC (Pasadena City College			1991 - 1994	
Address		City	State	Zip
1570 E. Colorado Blvd.		Pasadena	CA	91106
Diploma/Degree obtained, if any				
—				

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

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
11/1/20 - Present	[redacted] Coronado Pointe	Laguna Niguel	CA	92677
1/1/2002 - Present	[redacted] Sky Meadow Pl.	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

Applicant's initials QY

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: Optum wholesale Inc.			From - To (MM/YY – MM/YY): 08/2000 - Present	
Business Address: 277 E. Rowland St.	City: Covina		State: CA	Zip: 91723
Phone: (626) 536-2927	Title: President		Number of Employed Hours: 41,600	
Description of Duties: CEO. Designated Representative, Pharmacist in charge				
Business Name: Med-Plus Pharmacy Inc.			From - To (MM/YY – MM/YY): 3/2003 - Present	
Business Address: 760 Arrow Grand Circle	City: Covina		State: CA	Zip: 91722
Phone: 866-463-3757	Title: Sr. V.P of Operations		Number of Employed Hours: 41,600	
Description of Duties: Manage & Oversee pharmacy Operations, Marketing, Contracting				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description 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

Continue on next page if additional space is needed.

Applicant's initials SY

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

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

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

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

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*: 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:

Shabana Yasmin

Original Signature (electronic, copies or stamps not accepted)

11/30/2021

Date

Applicant's initials SY

I, Shabana Yasmin, **certify that as the designated representative for** Optum Wholesale 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

Shabana Yasmin

Print Name (First, Last)

Shabana Yasmin

Original Signature (electronic, copies or stamps not accepted)

11/30/2021

Date

Applicant's initials SY

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.

Shabana Yasmin

Print Name (First, Last)

Shabana Yasmin

Original Signature (electronic, copies or stamps not accepted)

11/30/2021

Date

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

State of California, ss. County of Los Angeles

I, Shabana Yasmin, 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.

Shabana Yasmin

Original Signature

11/30/2021

Date

Subscribed and Sworn to before me this 30 day of November.

Notary Public Signature

EVELYN PADILLA
COMM. # 2377171
NOTARY PUBLIC - CALIFORNIA
LOS ANGELES COUNTY
My Comm. Expires OCTOBER 1, 2025

(Seal)

Applicant's initials SY

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 Optum Wholesale, Inc.

Physical Address 277 E. Rowland St.

City Covina State CA Zip 91723

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 626-536-2927 Website _____

Licensing Company Email info@optumwholesaleinc.com

Section 2: Personal Information

First Shabana Yasmin Middle _____ Last Yasmin

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

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

Mailing Address [redacted]E. Rowland St.

City Covina State CA Zip 91723

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.)		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?		X

Applicant's initials SY

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)	
USC - Pharm D School of Pharmacy			1996 – 2000	
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)	
USC - Undergrad - Biochemistry			1994 - 1996	
Address		City	State	Zip
3607 Trousdale Pkwy		Los Angeles	CA	90089
Diploma/Degree obtained, if any				
—				

School Name			From - To (MM/YY – MM/YY)	
PCC (Pasadena City College)			1991 - 1994	
Address		City	State	Zip
1570 E. Colorado Blvd		Pasadena	CA	91106
Diploma/Degree obtained, if any				
—				

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

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
11/1/20 - Present	[redacted] Coronado Pointe	Laguna Niguel	CA	92677
01/01/02 - Present	[redacted] Sky Meadow Pl.	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

Applicant's initials SY

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: Optum Wholesale Inc.			From - To (MM/YY – MM/YY): 08/2020 - Present
Business Address: 277 E. Rowland St	City: Covina	State: CA	Zip: 91723
Phone: (626) 536-2927	Title: President		
Description of Duties: CEO, Pharmacist-in-charge			

Business Name: Med-Plus Pharmacy, Inc.			From - To (MM/YY – MM/YY): 03/03 - Present
Business Address: 760 Arrow Grand Circle	City: Covina	State: CA	Zip: 91722
Phone: 866 463 3757	Title: Sr. V.P. Operations		
Description of Duties: Manage Pharmacy; Oversee Operations, Marketing, Contracting.			

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: N/A.		
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.

Applicant's initials SY

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 _____

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

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*: 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:

Shabana Yasmin

Original Signature (electronic, copies or stamps not accepted)

11/30/2021

Date

Applicant's initials SY

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.

Shabana Yasmin
Print Name (First, Last)

Shabana Yasmin
Original Signature (electronic, copies or stamps not accepted)

11/30/2021
Date

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

State of California, ss. County of Los Angeles

I, Shabana Yasmin, 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.

Shabana Yasmin
Original Signature

11/30/2021
Date

Subscribed and Sworn to before me this 30 day of November.

Notary Public Signature

EVELYN PADILLA
COMM. # 2377171
NOTARY PUBLIC - CALIFORNIA
LOS ANGELES COUNTY
My Comm. Expires OCTOBER 1, 2025

(Seal)

Applicant's initials SY

SOMPO INTERNATIONAL

Lexon Insurance Company
PO Box 947805
Atlanta, GA 30394-7805

Phone: 615-553-9500
Fax: 615-553-9502

Mailing Address:

Optum Wholesale Inc
277 E Rowland St
Covina, CA 91723-3149

Please remit all payments to above address

or make a payment online at
www.suretygroup.com

Invoice Date: Nov 23, 2021

Bond Executed in the following Company **Customer Copy**

Lexon Insurance Company

Principal:

Optum Wholesale Inc
277 E Rowland St
Covina, CA 91723-3149

Obligee:

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

Bond Number	Term	Effective Date	Expiration Date	Statement Date
LICX3000939	1	11/23/2021	11/23/2022	NOV 2021

Bond Amount	Invoice Type	Invoice Number
$100,000.00	Summary	S00000084053

Bond Description
Wholesale Pharmaceutical

Gross Premium	Surcharge	Other Fees	Other Taxes
$1,500.00	$0.00/0%	$10.00	$0.00

Total Amount	Payment to Date	Net Balance Due
$1,510.00	$0.00	$1,510.00

Agent Name: Frontier-TSGA-TN-MtJuliet

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. LICX3000939

Application/License No. _____

Optum Wholesale Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 277 E Rowland St Covina CA 91723-3149 (Address of Applicant/Principal), as PRINCIPAL, and Lexon Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 10002 Shelbyville Rd Suite 100 Louisville KY 40223 (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 11/23/2021 (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 23 day of November, 2021.

APPLICANT/PRINCIPAL

COMPANY

Shabana Yasmin
Authorized Representative

SURETY

Penny Kowalke
Surety Company's Representative

Penny Kowalke, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Michael Tanguay

Witness Katie Laughlin

Countersigned by:

N/A
Nevada Resident Agent

SOMPO INTERNATIONAL
INSURANCE

POWER OF ATTORNEY

14885

KNOW ALL BY THESE PRESENTS, that **Endurance Assurance Corporation**, a Delaware corporation, **Endurance American Insurance Company**, a Delaware corporation, **Lexon Insurance Company**, a Texas corporation, and/or **Bond Safeguard Insurance Company**, a South Dakota corporation, each, a "Company" and collectively, "**Sompo International**," do hereby constitute and appoint: **Penny Kowalke** as true and lawful Attorney(s)-In-Fact to make, execute, seal, and deliver for, and on its behalf as surety or co-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 so made, executed and delivered shall obligate the Company for any portion of the penal sum thereof in excess of the sum of **ONE HUNDRED MILLION Dollars ($100,000,000.00)**.

Such bonds and undertakings for said purposes, when duly executed by said attorney(s)-in-fact, shall be binding upon the Company as fully and to the same extent as if signed by the President of the Company under its corporate seal attested by its Corporate Secretary.

This appointment is made under and by authority of certain resolutions adopted by the sole shareholder of each Company by unanimous written consent effective the 15th day of June, 2019, a copy of which appears below under the heading entitled "Certificate".

This Power of Attorney is signed and sealed by facsimile under and by authority of the following resolution adopted by the sole shareholder of each Company by unanimous written consent effective the 15th day of June, 2019 and said resolution has not since been revoked, amended or repealed:

RESOLVED, that the signature of an individual named above and the seal of the Company may be affixed to any such power of attorney or any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signature or 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, each Company has caused this instrument to be signed by the following officers, and its corporate seal to be affixed this 15th day of June, 2019.

Endurance Assurance Corporation	Endurance American Insurance Company	Lexon Insurance Company	Bond Safeguard Insurance Company
By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel

Endurance Assurance Corporation CORPORATE SEAL 2002 DELAWARE

Endurance American Insurance Company CORPORATE SEAL 1996 DELAWARE

LEXON INSURANCE COMPANY CORPORATE SEAL MARCH 16, 1964 STATE OF TEXAS

BOND SAFEGUARD INSURANCE COMPANY A SOUTH DAKOTA INSURANCE COMPANY

ACKNOWLEDGEMENT

On this 15th day of June, 2019, before me, personally came the above signatories known to me, who being duly sworn, did depose and say that he/they is an officer of each of the Companies; and that he executed said instrument on behalf of each Company by authority of his office under the by-laws of each Company.

By: Amy Taylor, Notary Public – My Commission Expires 5/9/23

AMY TAYLOR STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY

CERTIFICATE

I, the undersigned Officer of each Company, DO HEREBY CERTIFY that:

1. That the original power of attorney of which the foregoing is a copy was duly executed on behalf of each Company and has not since been revoked, amended or modified; that the undersigned has compared the foregoing copy thereof with the original power of attorney, and that the same is a true and correct copy of the original power of attorney and of the whole thereof;
2. The following are resolutions which were adopted by the sole shareholder of each Company by unanimous written consent effective June 15, 2019 and said resolutions have not since been revoked, amended or modified:

   "RESOLVED, that each of the individuals named below is authorized to make, execute, seal and deliver for and on behalf of the Company any and all bonds, undertakings or obligations in surety or co-surety with others: RICHARD M. APPEL, BRIAN J. BEGGS, CHRISTOPHER DONELAN, SHARON L. SIMS, CHRISTOPHER L. SPARRO, MARIANNE L. WILBERT

   ; and be it further

   RESOLVED, that each of the individuals named above is authorized to appoint attorneys-in-fact for the purpose of making, executing, sealing and delivering bonds, undertakings or obligations in surety or co-surety for and on behalf of the Company."
3. The undersigned further certifies that the above resolutions are true and correct copies of the resolutions as so recorded and of the whole thereof.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal this 23 day of November, 20 21.

By: Daniel S. Lurie, Secretary

NOTICE: U. S. TREASURY DEPARTMENT'S OFFICE OF FOREIGN ASSETS CONTROL (OFAC)

No coverage is provided by this Notice nor can it be construed to replace any provisions of any surety bond or other surety coverage provided. This Notice provides information concerning possible impact on your surety coverage due to directives issued by OFAC. **Please read this Notice carefully.**

The Office of Foreign Assets Control (OFAC) administers and enforces sanctions policy, based on Presidential declarations of "national emergency". OFAC has identified and listed numerous foreign agents, front organizations, terrorists, terrorist organizations, and narcotics traffickers as "Specially Designated Nationals and Blocked Persons". This list can be located on the United States Treasury's website – https://www.treasury.gov/resource-center/sanctions/SDN-List.

In accordance with OFAC regulations, if it is determined that you or any other person or entity claiming the benefits of any coverage has violated U.S. sanctions law or is a Specially Designated National and Blocked Person, as identified by OFAC, any coverage will be considered a blocked or frozen contract and all provisions of any coverage provided are immediately subject to OFAC. When a surety bond or other form of surety coverage is considered to be such a blocked or frozen contract, no payments nor premium refunds may be made without authorization from OFAC. Other limitations on the premiums and payments may also apply.

Any reproductions are void.

Surety Claims Submission: LexonClaimAdministration@sompo-intl.com
Telephone: 615-553-9500 Mailing Address: Sompo International; 12890 Lebanon Road; Mount Juliet, TN 37122-2870

4AA

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located? ☐ Nevada ■ Out-of-State

Is your facility a reverse distributor? ☐ Yes ■ No

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 _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: SpecialtyCare, Inc.

Physical Address: 902 Airpark Drive

City: Nashville State: TN Zip: 37217

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 615-346-8808 Website: specialtycare.net

Name of Designated Representative (DR): Jose Segura

Licensing Company Email: _____ DR Email: joe.segura@specialtycare.net

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.

[redacted]

Name: Advantage Medical Electronics LLC

Address: 11705 NW 39th St. City: Coral Springs State: FL Zip: 33065

Name: Neurovision Medical Products Inc.

Address: 353 Sanjon Rd City: Ventura State: CA Zip: 93001

Name: Cadwell Laboratories

Address: 909 Kellogg St City: Kennewick State: WA Zip: 99336

Name: PMT Corporation

Address: 1500 Park Road City: Chanhassen State: MN Zip: 55317

[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): SpecialtyCare Holdings, LLC

Corporation/Organization Name: SpecialtyCare, Inc.

Mailing Address: 902 Airpark Drive

City: Nashville State: TN Zip: 37217

Telephone: 615-346-8808 Email: joe.segura@specialtycare.net

Contact Person Name: Jose Segura

[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:		✓
1. Copy of Certification 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Jeffrey T. Gray, CFO

Print Name of Authorized Person Submitting Application

Jeffrey J Dry

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

10.11.21

Date

Board Use Only	Date Received: _____	Amount: $500 check 795975

SpecialtyCare, Inc. Officer and Directors Information

Full Name	Title	Business Address
Samuel Weinstein, M.D.	President and Chief Executive Officer	Three Maryland Farms Suite 200 Brentwood, TN 37027
Jeffrey Todd Gray	Chief Financial Officer and Treasurer	Three Maryland Farms Suite 200 Brentwood, TN 37027
John Giovanni Arena	General Counsel and Secretary	Three Maryland Farms Suite 200 Brentwood, TN 37027
Samuel Weinstein, M.D.	Director	Three Maryland Farms Suite 200 Brentwood, TN 37027
Jeffrey Todd Gray	Director	Three Maryland Farms Suite 200 Brentwood, TN 37027

List of Shareholders

Full Legal Name	Title	Percentage of Ownership Interest
SpecialtyCare Holdings, LLC	Sole Shareholder of SpecialtyCare, Inc.	100%

12597583

29706

State of Tennessee
Department of Health

TENNESSEE BOARD OF PHARMACY
WHOLESALE/DISTRIBUTOR
SPECIALTYCARE, INC.
902 AIRPARK CENTER DR.
NASHVILLE TN 37217

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004611
EXPIRATION DATE: 07/31/2022

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER

DCF171

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SPECIALTYCARE, 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 EIGHTH DAY OF OCTOBER, A.D. 2021.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SPECIALTYCARE, INC." WAS INCORPORATED ON THE FOURTH DAY OF JANUARY, A.D. 2007.

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

Jeffrey W. Bullock, Secretary of State

4278623 8300

SR# 20213463774

Authentication: 204361851

Date: 10-08-21

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

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 SpecialtyCare, Inc.

Physical Address 902 Airpark Drive

City Nashville State TN Zip 37217

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 615-346-8808 Website specialtycare.net

Licensing Company Email joe.segura@specialtycare.net

Section 2: Personal Information

First Jose Middle Angel Last Segura

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

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

Mailing Address [redacted] Airpark Drive

City Nashville State TN Zip 37217

Telephone [redacted] Email joe.segura@specialtycare.net

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 638.120)	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?		✓

Applicant's initials JS

School Name		From - To (MM/YY – MM/YY)	
Windsor High School		08/1985-05/1989	
Address	**City**	**State**	**Zip**
110 Main St.	Windsor	Co	80550
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Northern Colorado		08/1989-05/1994	
Address	**City**	**State**	**Zip**
501 20th Street	Greeley	CO	80639
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
University of Northern Colorado		08/1995-05/1996	
Address	**City**	**State**	**Zip**
501 20th Street	Greeley	CO	80639
Diploma/Degree obtained, if any			
Master of Arts			

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
05/2021-Present	[redacted]Hollands Way	Portland	TN	37148
11/2016-05/2021	[redacted] Tanglewood Lane	Hendersonville	TN	37075
05/2013-11/2016	[redacted]Brookville Circle	Goodlettsville	TN	37072
08/2012-05/2013	[redacted]Birchwood	Hendersonville	TN	37075
08/2011-08/2012	[redacted]Doe Valley Court	Hendersonville	TN	37075
08/2010-08/2011	[redacted] Grove Lane South	Hendersonville	TN	37075
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 JS

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)	
SpecialtyCare, Inc.			10/12- present	
Business Address		**City**	**State**	**Zip**
902 Airpark Drive		Nashville	TN	37217
Phone	**Title**		**Number of Employed Hours**	
615-346-8808	Warehouse Supervisor		18,720	
Description of Duties				
Lead operations by assigning and prioritizing activities and monitoring operating standards to ensure efficient operations of personnel and equipment, responsible and accountable for operational costs, inventory management, budgets, personnel				

Business Name			From - To (MM/YY – MM/YY)	
Kroger			08/10-10/12	
Business Address		**City**	**State**	**Zip**
2011 Nashville Pike		Gallatin	TN	37066
Phone	**Title**		**Number of Employed Hours**	
	Assistant Store Manager		17,472	
Description of Duties				
Lead process improvement and initiated change, enforced and promoted safe working environment, responsible for overall operations of store, responsible for risk management of facility, responsible for meeting all Health Department Requirements				

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

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

I, Jose Segura, **certify that as the designated representative for** Specialtycare 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

Jose Segura

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/11/21

Date

Applicant's initials JS

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.

Jose A Segura

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/11/2021

Date

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

State of Tennessee, ss. County of Davidson

I, Jose A Segura, 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

10/11/2021

Date

Subscribed and Sworn to before me this 11th day of October 2021.

Commission exp: 10/2/2023

Notary Public Signature

LYNNETTE LAWHON NOTARY PUBLIC STATE OF TENNESSEE DAVIDSON COUNTY (Seal)

Applicant's initials JJ

Becker,Greg	Instrumentation Management	TN003	Regular	Full-Time	40.00	3/20/2011	Mgr, Instrumentation	Manager
Ashburn,Stanley E	Instrumentation Management	TN003	Regular	Part-Time	24.00	3/20/2011	Instrumentation Representative	Representative
Lodhi,Fakhruddin	IONM Biomedical Services	TN003	Regular	Full-Time	40.00	6/1/2011	Biomedical Equipment Tech	Technician
Segura,Jose A	Supply Chain Services	TN003	Regular	Full-Time	40.00	11/27/2012	Warehouse Supervisor	Supervisor
Cook,Robert Scott	Supply Chain Services	TN003	Regular	Full-Time	40.00	12/1/2019	Supply Chain Analyst	Representative
Holder,Christopher Anthony	IONM Biomedical Services	TN003	Regular	Full-Time	40.00	7/26/2020	Biomedical Equipment Tech	Technician
Brown-Goodwin,Dakota Lee	IONM Biomedical Services	TN003	Regular	Full-Time	40.00	5/16/2021	Biomedical Equipment Tech	Technician
Darden,Louis J	Supply Chain Services	TN003	Regular	Full-Time	40.00	6/13/2021	Rep, Warehouse	Representative

Name	Group	Region	Ops Group	Descr	Pay Status	Reg/Temp	Full/Part	Descr	Job Family	Tax Loc	City	State	Postal
Yamboliev,Ilia	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Greater Lake Tahoe IONM Team	Active	Regular	Full-Time	Sr Surg Neurophysiologist I	IOMTEC	NV001	Reno	NV	89523
Correa,Maria Corazon	IONM Service Line	West IONM Region	West IONM Reg Adm	Travelers -West IONM Region	Active	Regular	Full-Time	Surg Neurophys, Traveler	IOMTEC	NV001	Las Vegas	NV	89120
Wang,Gexin	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Greater Lake Tahoe IONM Team	Active	Regular	Full-Time	Sr Surg Neurophysiologist II	IOMTEC	NV001	Reno	NV	89521
Pavlova,Oxana	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Bay Area IONM Team	Active	Per Diem	Part-Time	Surg Neurophysiologist III	IOMTEC	NV001	Reno	NV	89503
Shedd,Monica	IONM Service Line	IONM Service Line Adm	IONM Service Line Adm	IONM Physicians-N Central Reg	Active	Regular	Full-Time	Remote Neuromonitoring Prof	IOMTEC	NV001	Las Vegas	NV	89138
Bradley,Adam James	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Greater Lake Tahoe IONM Team	Active	Regular	Full-Time	Surg Neurophysiologist II	IOMTEC	NV001	Reno	NV	89502
Yu,Tinki	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Greater Lake Tahoe IONM Team	Active	Regular	Full-Time	Surg Neurophysiologist I	IOMTEC	NV001	Sparks	NV	89431
Sprenger-McLelland,Christiana R.	IONM Service Line	West IONM Region	CA-NV-OR IONM Ops Grp	Greater Lake Tahoe IONM Team	Active	Regular	Full-Time	Surgical Neurophys	IOMTEC	NV001	Reno	NV	89523

TRAVELERS

Travelers Casualty and Surety Company of America
Hartford, CT 06183

License No. _____

RIDER

To be attached to and form part of Bond No. **107471785**.

Issued on behalf of **SPECIALTYCARE , INC.** as Principal, and in favor of **Nevada State Board of Pharmacy** as Obligee.

It is agreed that:

1. The Surety hereby gives its consent to change the Name:

   from: _____

   to: _____

2. The Surety hereby gives its consent to change the Address:

   from: **THREE MARYLAND FARMS, STE. 200, BRENTWOOD, TN 37027**

   to: **902 AIRPARK DRIVE, NASHVILLE, TN 37217**

3. The Surety hereby gives its consent to change the _____

   from: _____

   to: _____

This rider shall become effective as of **November 12, 2021**

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated **November 15, 2021**.

Travelers Casualty and Surety Company of America

By: _____
Attorney-in-Fact

Accepted: **Nevada State Board of Pharmacy**
Obligee

or **SPECIALTYCARE , INC.**
Principal

By: _____

By: _____

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD, CONN.

S-4111 (05/20)

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 **A. Warren Phillips III** of **BRENTWOOD**, Tennessee, 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 **17th** day of **January, 2019.**

State of Connecticut

City of Hartford **ss.**

By: _____
Robert L. Raney, Senior Vice President

On this the **17th** day of **January, 2019**, 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 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, 2021**

_____
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 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 15th day of November, 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-in-Fact and the details of the bond to which this Power of Attorney is attached.

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. 107471785

Application/License No. _____

SpecialtyCare, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is Three Maryland Farms, Suite 200, Brentwood, TN 37027 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (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 One Tower Square, Hartford, CT 06152 (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 October 11, 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 11th day of October, 2021.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

A. Warren Phillips, III, Attorney-in-fact

print name

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD CONN.

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent Ryan P. Rothrock

Posted February 20, 2020

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 **A. Warren Phillips III** of **BRENTWOOD** Tennessee , 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 **17th** day of **January, 2019.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **17th** day of **January, 2019**, 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 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, 2021**

_____
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 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 11th day of October 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-in-Fact and the details of the bond to which this Power of Attorney is attached.

The Surety bond can also be emailed to me if you prefer, otherwise the address on my signature would be ok to send it to.

Regards,
Maria H.

From: Segura, Joe <Joe.Segura@specialtycare.net>
Sent: Thursday, November 11, 2021 6:22 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: RE: [EXTERNAL] Nevada Out-of-State Wholesaler Application-SpecialtyCare, Inc.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

This message was sent securely using Zix®

Thank you, Ms. Herrera for your email. SpecialtyCare plans to operate under the Wholesaler Permit moving forward, and will withdraw the MDEG permit once the Wholesaler Permit is issued. Therefore, I will not be serving in both capacities. Please let me know if you have any further questions or if you prefer we handle this another way, please let me know. In the meantime, we have requested that the address on the bond be corrected, and we will send that to you once issued. Should we overnight that directly to your attention at the address in your email?

Joe

SpecialtyCare

Joe Segura
Nashville Warehouse Supervisor
direct: 615.346.8808
902 Airpark Center Drive
Nashville, TN 37217
Joe.segura@specialtycare.net

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, November 9, 2021 5:11 PM
To: Segura, Joe <Joe.Segura@specialtycare.net>
Subject: [EXTERNAL] Nevada Out-of-State Wholesaler Application-SpecialtyCare, Inc.

The Nevada State Board of Pharmacy received an Out-of-State Wholesaler application from SpecialtyCare, Inc.

4BB

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?

- [x] Nevada
- [ ] Out-of-State

Type of Application (check applicable box)		Ownership Type (check applicable box)
[x] New Pharmacy	* If making a change, provide current license number:	[ ] Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
[ ] Ownership Change*		[ ] Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
[ ] Location Change *		[ ] Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
[ ] Name Change*	PH_____	[x] Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Omnia Pharmacy Inc

Physical Address: 1807 W. Charleston Blvd Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 480-577-7919 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: alymolokhia@hotmail.com

Website: _____

Nevada Business License # (if applicable) NV20212241976

Supervising/Managing Pharmacist Name (NRS 639.220): Pamela Kalyan

Supervising/Managing Pharmacist NV Pharmacist Registration #: 15083

Type of Pharmacy (check all applicable)

- [x] Retail/Community
- [ ] Hospital (# beds _____)
- [ ] Internet
- [ ] Nuclear
- [ ] Other: _____

Services the Pharmacy will Provide (check all applicable)

- [x] Retail/Community
- [ ] Non-sterile Compounding
- [ ] Sterile Compounding
- [ ] Mail-Order Service
- [ ] Off-site Cognitive Services
- [ ] Long Term Care
- [ ] Hospital
- [ ] Other:

Days of Operation

[x] Monday [x] Tuesday [x] Wednesday [x] Thursday [x] Friday [x] 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: Pamela Kalyan	NV Pharmacist Registration #: 15083
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)?		X
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?		X
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?		X
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?		X
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)?		X

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: Aly Molokhia

Business Name: Omnia Pharmacy Inc

Business Address: 1807 W Charleston Blvd Suite 110

City: Las Vegas State: NV Zip: 89102

Telephone: 480-577-7919 Email: alymolokhia@hotmail.com

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 Omnia Pharmacy 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).

Pamela S. Kalyan
Print Name of Authorized Person

Pamela S. Kalyan
Original signature of Authorized Person (copies or stamps not accepted)

1-12-22
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Pamela S. Kalyan 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 Omnia Pharmacy Inc (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.

Pamela S. Kalyan
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12TH day of January, 2022

Alejandra Lopez
Notary Public

ALEJANDRA LOPEZ
Notary Public - State of Nevada
Appointment Recorded in Clark County
No: 21-9195-01 - Expires November 27, 2025

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: Pamela S. Kalyan Pharmacist Registration #: 1-12-22

Pharmacy Name: Omnia Pharmacy Inc

Initial each statement below to indicate you have read and agree with the following:

PSK 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.

PSK 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.

PSK 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.

PSK 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)).

PSK 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?		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?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
License 1 yr Probation	NV	7/25/2007	06-069A-RPHS

Criminal Action:	State:	Date:	Case #:	County:	Court:

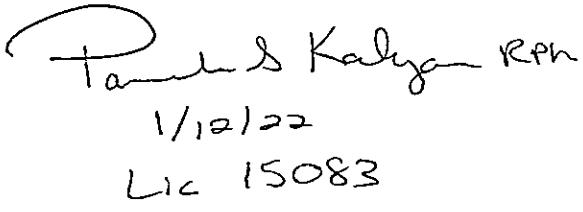
I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire 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.

Pamela S. Kalyan 1-12-22

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

In July of 2007 I appeared before the board regarding the fatal error that occurred at Summerlin Hospital with Alyssia Shinn. I had been on duty earlier in the day and we were extremely short staffed. I had been helping to enter orders into the TPN compounding machine. At one point I went back into the system to edit one of the components and when I did, I had not realized the system had converted to milligrams as opposed to micrograms and there were no warning levels set on the machine to alert you to such extreme out of range calculations. I handed the order to a pharmacist to verify and then be sent to compound. I had left for the night and had never seen the order after that. The order was compounded and administered with the error. The order was verified by 2 pharmacists and 2 nurses in the time after I had left. When I came to work the next morning and learned of what happened I was devastated, and I am the person who came directly to the board. I wanted to be sure that something like this never happened again and the parents knew what happened with their daughter. I cooperated and worked with the board to ensure that this matter was handled in the best interests of family. This is something that will live with me forever, but I am sure to work every day to ensure the health, safety and well-being of all my patients and be sure something like this never happens again.

Pamela S Kalyan RPh



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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Pamela Kalyan

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

Pamela S Kalyan — 1-12-22

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

Board Use Only	Date Received: _____ Amount: _____

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: Omnia Pharmacy Inc

Physical Address: 1807 W Charleston Blvd Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 480-577-7919 Website:

Licensing Company Email: alymolokhia@hotmail.com

Section 2: Personal Information

First: Pamela Middle: Suzanne Last: Kalyan

Alias(es, nicknames, name changes, etc.): Pamela Goff

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

Mailing Address: [redacted] W Desert Inn Rd [redacted]

City: Las Vegas State: NV Zip: 89117

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.)		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: N/A 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?		

Applicant's Initials: PSK

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)	
Northeastern University		08/94-06/99	
Address	**City**	**State**	**Zip**
360 Huntington Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
BS in Pharmacy and minor in toxicology			
School Name		**From - To (MM/YY – MM/YY)**	
Marian Catholic High School			
Address	**City**	**State**	**Zip**
166 Marian Ave	Tamaqua	PA	18252
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
05/21-current	[redacted]W Desert Inn Rd[redacted]	Las Vegas	NV	89117
05/20-05/21	6250 W Flamingo Rd	Las Vegas	NV	89103
10/02-05/20	5814 Falling Stream Ave	Las Vegas	NV	89131

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)
Evergreen Pharmacy			04/20-present
Business Address	**City**	**State**	**Zip**
4110 S Maryland Pkwy #17	Las Vegas	NV	89119
Phone	**Title**	**Number of Employed Hours**	
702-462-6262	Pharmacy Manager PIC	3,696	

Description of Duties

Type, fill, and verify prescriptions. Monitor inventory and regulate the receipt of all medications and controlled substances, ensure all records are maintained in accordance with all state and federal laws and regulations.

Business Name			From - To (MM/YY – MM/YY)
Consonus Pharmacy			11/16-11/19
Business Address	**City**	**State**	**Zip**
6351 N Fort Apache Rd #200	Las Vegas	NV	89149
Phone	**Title**	**Number of Employed Hours**	
844-545-9342	Staff Pharmacist	6240	

Description of Duties

Type, fill, and verify prescriptions. Monitor inventory and regulate the receipt of all medications and controlled substances, ensure all records are maintained in accordance with all state and federal laws and regulations

Business Name			From - To (MM/YY – MM/YY)
Omnicare Pharmacy			10/15-10/16
Business Address	**City**	**State**	**Zip**
1525 E Sunset Rd	Las Vegas	NV	89119
Phone	**Title**	**Number of Employed Hours**	
702-407-0124	Pharmacy Manager/PIC	2,080	

Description of Duties

Type, fill, and verify prescriptions. Monitor inventory and regulate the receipt of all medications and controlled substances, ensure all records are maintained in accordance with all state and federal laws and regulations

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			02/10-02/12
Business Address	**City**	**State**	**Zip**
Various locations in Las Vegas	Las Vegas	NV	89030
Phone	**Title**	**Number of Employed Hours**	
702-649-1991	Pharmacy Manager/PIC	4,160	

Description of Duties

Type, fill, and verify prescriptions. Monitor inventory and regulate the receipt of all medications and controlled substances, ensure all records are maintained in accordance with all state and federal laws and regulations

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			08/00-02/10
Business Address	**City**	**State**	**Zip**
Various locations in Las Vegas	Las Vegas	NV	89118
Phone	**Title**	**Number of Employed Hours**	
702-889-8274	Staff Pharmacist/Pharmacy Manager/PIC	20,800	

Description of Duties

Type, fill, and verify prescriptions. Monitor inventory and regulate the receipt of all medications and controlled substances, ensure all records are maintained in accordance with all state and federal laws and regulations

Continue on next page if additional space is needed.

Applicant's initials PSK 4

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

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

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

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

Page intentionally Left Blank

Applicant's initials _____ 5

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?		
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:

N/A

Pamela S Kelly

Original Signature (electronic, copies or stamps not accepted)

1-12-22

Date

Applicant's initials PSK

I, Pamela S. Kalyan, **certify that as the designated representative for**

Omnia Pharmacy 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

Pamela Kalyan

Print Name (First, Last)

Pamela S. Kalyan

Original Signature (electronic, copies or stamps not accepted)

1/12/22

Date

Applicant's initials PSK 8

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.

Pamela Kalyan
Print Name (First, Last)

Pamela S. Kalyan
Original Signature (electronic, copies or stamps not accepted)

1/12/22
Date

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

State of Nevada, ss. County of Clark

I, Pamela S. Kalyan, 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.

Pamela S Kalyan
Original Signature

1-12-22
Date

Subscribed and Sworn to before me this 12th day of January 2022

Alejandra Lopez
Notary Public Signature

ALEJANDRA LOPEZ
Notary Public - State of Nevada
Appointment Recorded in Clark County
No: 21-9195-01 - Expires November 27, 2025

(Seal)

Applicant's initials PSK

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 OMNIA PHARMACY INC

Physical Address 1807 W CHARLESTON BLVD #110

City LAS VEGAS State NV Zip 89102

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 4805777919 Website _____

Licensing Company Email _____

Section 2: Personal Information

First ALY Middle HOSSNY Last MOLOKHIA

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

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

Mailing Address [redacted] E BEACON ST [redacted]

City ALHAMBRA State CA Zip 91801

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 AM

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
5/2010-06/2019	[redacted]SCUDDER WAY	MONTEREY PARK	CA	91754
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 AM

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)
EVERGREEN PHARMACY INC			6/2019-CURRENT
Business Address	**City**	**State**	**Zip**
4110 S MARYLAND PKWY #17	LAS VEGAS	NV	89119
Phone	**Title**		
7024626262	CEO		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
FREEWAY TOWING			2001-CURRENT
Business Address	**City**	**State**	**Zip**
1350 MONTEREY PASS RD	MONTEREY PARK	CA	91754
Phone	**Title**		
3232663355	GENERAL 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			

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 A.M.

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:

Aly Malakhy
Original Signature (electronic, copies or stamps not accepted)

12-13-21
Date

AM
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.

ALY MOLOKHIA

Print Name (First, Last)

Aly Molokhia

Original Signature (electronic, copies or stamps not accepted)

12-13-2021

Date

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

State of Nevada, ss. County of Clark

I, Aly Molokhia, 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.

Aly Molokhia

Original Signature

12-13-21

Date

Subscribed and Sworn to before me this 13th day of December

Notary Public Signature

S. TABACZYNSKI
Notary Public, State of Nevada
Appointment No. 06-104195-1
My Appt. Expires Mar 31, 2022

(Seal)

Applicant's initials AM

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

Date of this notice: 11-29-2021

Employer Identification Number:
87-3741302

Form: SS-4

Number of this notice: CP 575 A

OMNIA PHARMACY INC
3450 ERVA ST 245
LAS VEGAS, NV 89117

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 87-3741302. 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 1120 04/15/2022

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.

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 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 11-29-2021 OMNI 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: 11-29-2021
EMPLOYER IDENTIFICATION NUMBER: 87-3741302
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

OMNIA PHARMACY INC
3450 ERVA ST 245
LAS VEGAS, NV 89117

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

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

Omar Koury
2062 Country Cove Ct
Las Vegas, NV 89135, USA

Work Order #: W2021100101638
October 1, 2021
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 66574

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Incorporation-For-Profit • 1,000,000@0.001 Authorized = $1,000.00 • # Of No Par Values Shares 0 • Authorized Value $1,000.00	Fees	20211794900	10/1/2021 2:54:50 PM	InternalReview	1	$75.00	$75.00
Initial List	Fees	20211794902	10/1/2021 2:54:51 PM	InternalReview	1	$150.00	$150.00
Initial List	Business License Fee	20211794902	10/1/2021 2:54:51 PM	InternalReview	1	$500.00	$500.00
Total							$725.00

Payments

Type	Description	Payment Status	Amount
Credit Card	6331252792486675103059	Success	$725.00
Total			$725.00

Credit Balance: $0.00

Omar Koury
2062 Country Cove Ct
Las Vegas, NV 89135, USA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

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

Omar Koury
2062 Country Cove Ct
Las Vegas, NV 89135, USA

Work Order #: W2021100101638
October 1, 2021
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 66574

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Incorporation-For-Profit • 1,000,000@0.001 Authorized = $1,000.00 • # Of No Par Values Shares 0 • Authorized Value $1,000.00	Fees	20211794900	10/1/2021 2:54:50 PM	InternalReview	1	$75.00	$75.00
Initial List	Fees	20211794902	10/1/2021 2:54:51 PM	InternalReview	1	$150.00	$150.00
Initial List	Business License Fee	20211794902	10/1/2021 2:54:51 PM	InternalReview	1	$500.00	$500.00
Total							$725.00

Payments

Type	Description	Payment Status	Amount
Credit Card	633125279248667510305 9	Success	$725.00
Total			$725.00

Credit Balance: $0.00

Omar Koury
2062 Country Cove Ct
Las Vegas, NV 89135, USA

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings 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

Business Entity - Filing Acknowledgement

10/01/2021

Work Order Item Number:	W2021100101638 - 1624060
Filing Number:	20211794900
Filing Type:	Articles of Incorporation-For-Profit
Filing Date/Time:	10/01/2021 14:54:50 PM
Filing Page(s):	3

Indexed Entity Information:

Entity ID: E17949012021-2

Entity Name: Omnia Pharmacy Inc

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
Shereen Hassan
3450 Erva St, #245, Las Vegas, NV 89117, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings 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

Business Entity - Filing Acknowledgement

10/01/2021

Work Order Item Number:	W2021100101638 - 1624061
Filing Number:	20211794902
Filing Type:	Initial List
Filing Date/Time:	10/01/2021 14:54:51 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E17949012021-2

Entity Name: Omnia Pharmacy Inc

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
Shereen Hassan
3450 Erva St, #245, Las Vegas, NV 89117, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
Barbara K. Cegavske	E17949012021-2
Secretary of State	Filing Number
State Of Nevada	20211794900
	Filed On
	10/01/2021 14:54:50 PM
	Number of Pages
	3

1186

Formation - Profit Corporation

☑ NRS 78 - Articles of Incorporation Profit Corporation ☐ NRS 80 - Foreign Corporation ☐ NRS 89 - Articles of Incorporation Professional Corporation

☐ 78A Formation - Close Corporation

(Name of closed corporation MUST appear in the below heading)

Articles of Formation of _____ **a close corporation (NRS 78A)**

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGH LIGHT

1. Name of Entity: (If foreign, name in home jurisdiction)

Omnia Pharmacy Inc

2. Registered Agent for Service of Process: (Check only one box)

☐ Commercial Registered Agent (name only below) ☑ Noncommercial Registered Agent (name and address below) ☐ Office or position with Entity (title and address below)

Shereen Hassan
Name of Registered Agent **OR** Title of Office or Position with Entity

3450 Erva St, #245 — Street Address
Las Vegas — City
Nevada 89117 — Zip Code

Mailing Address (If different from street address)
City
Nevada
Zip Code

2a. Certificate of Acceptance of Appointment of Registered Agent:

I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.

X Shereen Hassan — Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity
10/01/2021 — Date

3. Governing Board: (NRS 78A, close corporation only, check one box; if yes, complete article 4 below)

This corporation is a close corporation operating with a board of directors ☐ Yes OR ☑ No

4. Names and Addresses of the Board of Directors/ Trustees or Stockholders

(NRS 78: Board of Directors/ Trustees is required.

NRS 78a: Required if the Close Corporation is governed by a board of directors.

NRS 89: Required to have the Original stockholders and directors. A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing. See instructions)

1) Aly Molokhia — Name
3450 Erva St, #245 — Address
Las Vegas — City
NV — State
89117 — Zip Code

5. Jurisdiction of Incorporation: (NRS 80 only)

5a. Jurisdiction of incorporation:

5b. I declare this entity is in good standing in the jurisdiction of its incorporation. ☐

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Formation - profit Corporation

Continued, Page 2

6. Benefit Corporation: (For NRS 78, NRS 78A, and NRS 89, optional. See instructions.)	By selecting "Yes" you are indicating that the corporation is organized as a benefit corporation pursuant to NRS Chapter 78B with a purpose of creating a general or specific public benefit. The purpose for which the benefit corporation is created must be disclosed in the below purpose field. **Yes** ☐
7. Purpose/Profession to be practiced: (Required for NRS 80, NRS 89 and any entity selecting Benefit Corporation. See instructions.)	**to engage in any lawful activity for which corporations may be incorporated in Nevada.**
8. Authorized Shares: (Number of shares corporation is authorized to issue)	Number of common shares with Par value: 0 Par value: $ 0 Number of preferred shares with Par value: 0 Par value: $ 0 Number of shares with no par value: **0** If more than one class or series of stock is authorized, please attach the information on an additional sheet of paper.
9. Name and Signature of: Officer making the statement or Authorized Signer for NRS 80. **Name, Address and Signature of the Incorporator** for NRS 78, 78A, and 89. NRS 89 - Each Organizer/ Incorporator must be a licensed professional.	**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.** George Omar Koury, Esq. (Name) — United States (Country) Paradise Law LLC, PO Box 96537 (Address) — Las Vegas (City) — NV (State) — 89193 (Zip/Postal Code) X George Omar Koury, Esq. (attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

Filed in the Office of	Business Number
Barbara K. Cegavske	E17949012021-2
Secretary of State	Filing Number
State Of Nevada	20211794900
	Filed On
	10/01/2021 14:54:50 PM
	Number of Pages
	3

1188

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Registered Agent Acceptance/Statement of Change

(PURSUANT TO NRS 77.310, 77.340, 77.350, 77.380)

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGHLIGHT

1. Entity information:	Name of represented entity. OMNIA PHARMACY INC Entity or Nevada Business Identification Number (NVID): (for entities currently on file)
2. Registered Agent Acceptance:	× Registered Agent Acceptance
3. Information Being Changed:	Statement of Change takes the following effect: (select only one) Appoints New Agent (complete section 5) Update Represented Entity Acting as Registered Agent (complete sections 5) Update Registered Agent Name (complete sections 4 & 5) Update Registered Agent Address (complete sections 4 & 5)
4. Registered Agent Information Before the Change: (Non-commercial registered agents ONLY)	Name of Registered Agent **OR** Title of Office or Position with Entity Street Address / City / Nevada / Zip Code Mailing Address (if different from street address) / City / Nevada / Zip Code
5. Newly Appointed Registered Agent or Registered Agent Information After the Change:	☐ Commercial Registered Agent (name only below) ☒ Noncommercial Registered Agent (name and address below) ☐ Office or Position with Entity (title or position and address below) Shereen Hassan Name of Registered Agent **OR** Title of Office or Position within Entity 3450 Erva St, #245 / Las Vegas / Nevada 89117 Street Address / City / Zip Code Mailing Address (if different from street address) / City / Nevada / Zip Code
6. Electronic Notification: (Optional)	Email address for electronic notifications for "Non-Commercial" or "Office or Positions with Entity" registered agents only
7. Certificate of Acceptance of Appointment of Registered Agent: (Required)	*I hereby accept appointment as Registered Agent for the above named Entity* X _____ 09.30/2021 Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity / Date
8. Signature of Represented Entity: (Required)	X _____ 10/01/2021 Authorized Signature On Behalf of the Entity / Date

FEE: $60.00
This form must be accompanied by appropriate fees

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Secretary of State
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Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
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Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Omnia Pharmacy Inc

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☑ Corporation

☐ This corporation is publicly traded, the Central Index Key number is:

Filed in the Office of Barbara K. Cegavske Secretary of State State Of Nevada	Business Number E17949012021-2
	Filing Number 20211794902
	Filed On 10/01/2021 14:54:51 PM
	Number of Pages 2

☐ Nonprofit Corporation (see nonprofit sections below)

☐ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)

☐ Business Trust

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

☐ 001 - Governmental Entity

☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee.
Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C S 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. §501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required

☐ Yes - the "Charitable Solicitation Registration Statement" is required.

☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
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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 PRESIDENT:

Name	Country	Address	City	State	Zip/Postal Code
Aly Molokhia	USA	3450 Erva St, #245	Las Vegas	NV	89117

CORPORATION, INDICATE THE SECRETARY:

Name	Country	Address	City	State	Zip/Postal Code
Aly Molokhia	USA	3450 Erva St, #245	Las Vegas	NV	89117

CORPORATION, INDICATE THE DIRECTOR:

Name	Country	Address	City	State	Zip/Postal Code
Aly Molokhia	USA	3450 Erva St, #245	Las Vegas	NV	89117

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 George Omar Koury, Esq.
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*

Incorporator
Title

10/01/2021
Date

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC CORPORATION (78) CHARTER

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Omnia Pharmacy Inc** did, on 10/01/2021, file in this office the original Articles of Incorporation-For-Profit 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 10/01/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate
Number: B202110012039852
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Omnia Pharmacy Inc

Nevada Business Identification # NV20212241976
Expiration Date: 10/31/2022

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 10/01/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202110012039853
You may verify this certificate online at http://www.nvsos.gov

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1807 W CHARLESTON COMMERCIAL LEASE

This Lease, dated for reference purposes only, DECEMBER 10, 2021, is made by and between 1807 WC LLC, a Nevada Limited Liability Company (hereinafter called "LANDLORD"), and ALY MOLOKHIA, President d/b/a OMNIA PHARMACY LLC d/b/a OMNIA PHARMACY INC, A Nevada Corporation, (hereinafter called "TENANT").

1. PREMISES.

1.1 DESCRIPTION. LANDLORD hereby leases to TENANT, for the term, at the rental and upon all the conditions set forth herein, that certain real property, located in the City of Las Vegas, County of Clark and State of Nevada, described as follows:

1807 W Charleston Blvd Suite 110, Las Vegas, NV 89102, APN # 162-04-112-021

consisting of an **approximately 1,215 SF suite** which is a portion of a 4,860 SF Free-Standing Building, located on approximately 0.42 AC paved lot. Said real property, including the land and all improvements thereon, is herein called the "PREMISES".

1.2 CONDITION OF PREMISES. TENANT hereby accepts the PREMISES "as is" and in the condition existing as of the date of the execution hereof, subject to applicable zoning, municipal, county and state laws, ordinances, rules and regulations governing and regulating the use of the PREMISES and accepts this Lease subject thereto and to all matters disclosed thereby. TENANT hereby acknowledges that neither LANDLORD, nor LANDLORD'S agent, has made any representation or warranty as to the suitability of the PREMISES, for the conduct of TENANT'S business.

2. TERM.

2.1 DURATION. The term of this Lease shall be for a period of Five (5) years commencing on May 1, 2022 and terminating on April 30, 2027.

2.2 POSSESSION. If LANDLORD, for any reason, cannot deliver possession of the PREMISES to TENANT on the commencement of the term, this Lease shall not be void or voidable, nor shall LANDLORD be liable to TENANT for any loss or damage resulting from such delay. In the event LANDLORD cannot deliver the PREMISES, within one hundred eighty (180) days of the commencement date, TENANT'S sole and exclusive remedy shall be to declare the Lease null and void. Early termination of this Lease by the TENANT, prior to the expiration of its term, will not be granted, unless otherwise noted or permitted by LANDLORD.

2.3 HOLDOVER. Should TENANT hold possession of the PREMISES, with consent of the LANDLORD, after the expiration of the stated Term of this Lease, such holding over shall create a month-to-month tenancy only, upon the same terms and conditions, as set forth herein, except that minimum rent shall be one hundred twenty five (125%) percent of the adjusted minimum rent, as determined in Article 4 hereof. Nothing contained in this Lease shall be construed as consent to such holding over.

3. EXTENSION OF TERM OF LEASE.

LANDLORD hereby grants to TENANT, an Option and Right to Extend the Term of this Lease ("Option") for one additional Five (5) Year Term, upon the same terms and conditions. This Lease shall be automatically extended, unless Tenant is in default or gives written notice of intent to terminate the Lease, two (2) months prior to expiration of the Initial Lease Term or any Extension thereof. If Option is exercised, this Lease continues in full force and effect, and the monthly Base Rent increases, per Paragraph 4.4. All Options are contingent upon these provisions:

A. If TENANT wishes to terminate upon expiration of any Term, notice must be given in writing, at least sixty (60) days, prior to the expiration of this Lease. **If TENANT fails to give written notice, during the prescribed notice period, the Term of this Lease shall be automatically extended, upon all terms and conditions contained herein.**

B. TENANT shall not be in default under any of the material obligations of this Lease to be performed by TENANT both at the time of exercise of the Option and the commencement of the Option term (unless cured by TENANT).

C. All new terms and conditions of the Option are to be mutually agreed upon by the parties in writing, at least fifteen (15) days prior to the expiration of this Lease, if applicable.

D. This right of extension is not assignable or transferable by TENANT separate from the Lease.

4. RENT.

4.1 BASE RENT. TENANT shall pay to LANDLORD, as "Base Rent" for the PREMISES, the sum of TWO THOUSAND FOUR HUNDRED THIRTY DOLLARS ($2,430.00) monthly, on or before the first day of each month for the first year, commencing May 1, 2022 and concluding April 30, 2023. All rent shall be paid without prior demand or notice and without any deduction or offset whatsoever. Rent due for any partial month shall be prorated, at the rate of 1/30th of the total monthly rent per day. Rent shall be payable in lawful money of the United States, to LANDLORD at the address stated herein or to other persons or places as LANDLORD may designate in writing.

1807 WC LLC
5395 Polaris Ave. Suite 100
Las Vegas, NV 89118-2456

4.2 DEFERRED RENT. **TENANT shall receive 8 months of 50% deferred rent. 50% rate of $1,215 shall be due for June 2022 - December 2022 and January 2023;** If the business is sold or the Lease is assigned or terminated earlier than provided herein, the Deferred Rent ($9,720) shall become due and payable.

4.3 TRIPLE NET LEASE. It is the express understanding and agreement of LANDLORD and TENANT that this Lease is a "Triple Net" Lease and that, except as otherwise set forth herein, all costs, expenses and/or obligations of any kind or nature whatsoever relating to the PREMISES, and TENANT'S use of the PREMISES, shall be paid by TENANT, without cost or obligation of any type whatsoever to LANDLORD.

4.4 ADDITIONAL RENT. LANDLORD shall receive the rent, set forth in Paragraph 4.1, free and clear of any and all other impositions, taxes, liens, charges, utilities or expenses of any nature whatsoever in connection with the operation of the PREMISES. TENANT shall pay to the parties respectively entitled thereto, or shall reimburse LANDLORD therefore: insurance premiums, property taxes, operating costs, utilities, maintenance charges, construction costs and any other expenses which arise or may be contemplated under provisions of this Lease, during the term hereof. All expenses, under the terms of this Lease, shall be deemed as "Additional Rent" and upon the failure of TENANT to pay any such expenses; LANDLORD shall have the same rights and remedies as otherwise provided in the Lease for the failure of TENANT to pay rent. LANDLORD may request payment of any Additional Rent owed, at any time during the term of this Lease. It is the intent of the parties hereto, that this Lease shall not be terminable for any reason by the TENANT and that TENANT shall in no event be entitled to abatement of, or reduction in, rent payable hereunder, except as expressly provided herein.

4.5 ADJUSTMENT IN RENT. There shall be an annual rent adjustment, for increases in the cost of living, during the Term of this Lease and any Option period thereof, on the Commencement Anniversary date May 1. No adjustment shall be made for decreases in the cost of living, if any.

Year 1	5/1/22-4/30/23	**$2,430 per month**
Year 2	5/1/23-4/30/24	**$2,503 per month**
Year 3	5/1/24-4/30/25	**$2,578 per month**
Year 4	5/1/25-4/30/26	**$2,655 per month**
Year 5	5/1/26-4/30/27	**$2,735 per month**

If Option to extend is exercised:

Year 6	5/1/27-4/30/28	**$2,817 per month**
Year 7	5/1/28-4/30/29	**$2,902 per month**
Year 8	5/1/29-4/30/30	**$2,989 per month**
Year 9	5/1/30-4/30/31	**$3,078 per month**
Year 10	5/1/31-4/30/32	**$3,171 per month**

4.6 UNAUTHORIZED OCCUPANCY. Should TENANT be found occupying any portions of the parking areas or PREMISES not contracted for herein, additional rents may be charged.

4.7 LATE CHARGES. TENANT acknowledges that late payment, by TENANT to LANDLORD, of any Base Rent, Additional Rent or other charges due under this Lease, will cause LANDLORD to incur costs not contemplated by this Lease, the exact amount difficult to ascertain. Such costs include without limitation; processing, accounting and late charges that may be imposed on LANDLORD by the terms of any encumbrance or note secured by PREMISES or any bank. Therefore, if any rent or other sum due from TENANT is not received within five business (5) days, after the date due of any month of this Lease, TENANT shall pay to LANDLORD an additional sum equal to five percent (5%) of each overdue payment, payable on demand, which shall be deemed Additional Rent. LANDLORD and TENANT hereby agree that such late charge represents a fair and reasonable estimate of the costs that LANDLORD will incur by reason of any such late payment and that the late charge shall not be deemed a waiver of any other default. Additionally, all such delinquent rent, additional rent or any other charges due, plus this late charge, shall bear interest from thirty (30) days after due date thereof to the date of payment, at a rate equal to twelve percent (12%) per annum, compounded monthly. Any payments of any kind returned for insufficient funds will be subject to an additional handling charge of $35.00 and thereafter LANDLORD may require TENANT to pay all future payments of rent or other sums due by money order or cashiers check.

4.8 PRORATION. If any payments, rights or obligations hereunder relate to a period in part before the commencement of this Lease, or in part after the termination of this Lease, appropriate adjustments and proration shall be made between LANDLORD and TENANT for such property-related expenses.

5. SECURITY AND CLEANING DEPOSIT.

TENANT shall deposit with LANDLORD, upon execution hereof, **Two Thousand Seven Hundred Thirty Five Dollars ($2,735.00)**, as security for TENANT'S faithful performance of the provisions of this Lease, **which may not be applied to the last month's rent.** This security deposit shall always equal, or exceed, the last month's rent in the Term and any Extension thereof and shall be increased every time the Lease is extended. LANDLORD may use, apply or retain all or any portion of said deposit for the payment of rent or any other charge in default or to compensate LANDLORD for any loss or damage, including cleaning of PREMISES, which LANDLORD may suffer thereby. If LANDLORD applies any portion of said deposit, TENANT shall restore it to the full amount stated herein, within ten (10) days after written demand. TENANT'S failure to do so shall be a material breach of this Lease. LANDLORD shall not be required to keep said deposit separate from its general accounts. If TENANT performs all of TENANT'S obligations hereunder and leaves the entire PREMISES clean, including all the furnishings and fixtures therein and the PREMISES free from all debris or hazardous waste; upon vacating, said deposit or balance thereof, which has not been applied by LANDLORD, shall be returned without payment of interest to TENANT at the expiration of the term or at LANDLORD'S option, to the last assignee, if any, of TENANT'S interest hereunder.

6. BUSINESS RIGHTS AND RESTRICTIONS.

6.1 USE. The PREMISES shall be used solely for the following purpose(s):

The operation of a **Retail Pharmacy** and may be used, for other legal purposes that are compatible therewith and which do not conflict or compete with any existing Tenants' business. LANDLORD'S prior written consent shall be required for any such additional use, which shall not be unreasonably withheld or delayed, provided however, that proper licensing is obtained and any additional improvements on said PREMISES, necessitated thereby, shall be at the sole expense of TENANT.

6.2 RESTRICTIONS. TENANT shall not occupy a greater percentage of available paved PARKING than what is designated. TENANT shall not restrict ingress and egress to any buildings on the PREMISES

at any time. TENANT shall comply with all applicable fire ordinances requiring fire lanes to all buildings be free of any obstruction at all times.

6.3 OPERATION OF BUSINESS.

(a) During the entire Lease term, TENANT shall not use, or permit to be used, the PREMISES, in any manner that will create waste, constitute a nuisance or unreasonable annoyance to the public, the LANDLORD or otherwise interfere with the quiet use and enjoyment of other TENANTS and neighbors, or that will injure the reputation of the PREMISES, or for any extra hazardous purpose, or in any manner that will impair the structural strength of the building of which the PREMISES are a part.

(b) TENANT hereby covenants and agrees that it's agents, employees, SUBTENANTS and licensees shall abide by the rules and regulations as set forth in this Lease and incorporated herein and amendments and modifications of any of the foregoing, as LANDLORD may, from time to time, adopt for the safety, care and cleanliness of the PREMISES and Common Areas or for the preservation of good order thereon.

(c) **TENANT must notify LANDLORD of their intention to become delivery only or close doors to the public as long as all rent, additional rent, utilities, taxes and insurances are paid and PREMISES is maintained.**

6.4 COMPLIANCE WITH LAW. TENANT shall conduct its business on the PREMISES in a commercially reasonable and first class manner, to insure the maximum in cleanliness and health standards as required by law. TENANT shall, at TENANT'S expense, observe and comply promptly with all applicable statutes, ordinances, rules, regulations, orders and insurance requirements in effect during the term, or any part of the term, regulating the use by TENANT of the PREMISES, or any part of the Common Area which is under TENANT'S exclusive control, and promulgated during the term of this Lease.

(a) "Licenses and Permits". TENANT is required at its sole expense, to obtain all licenses and permits, both governmental and private, which may be required to use and operate the PREMISES for the conduct of this business within the terms of this Lease, as more fully described in Paragraph 6.1. LANDLORD shall join TENANT in providing reasonable assistance, as required.

6.5 CRIME-FREE/DRUG-FREE ENVIRONMENT. TENANT, TENANT'S employees, customers or invitees shall not engage in any of the following on or about the PREMISES:

(a) Any act intended to facilitate illegal activity or to permit the PREMISES to be used to facilitate illegal activity, including drug-related illegal activity, regardless of whether the individual engaging in such activity is a TENANT of the PREMISES.

(b) Smoking or Vaporizing Medical or Recreational Cannabis Products on PREMISES.

(c) Engage in acts of violence or threats of violence, including but not limited to the unlawful discharge of firearms, prostitution, criminal street gang activity, intimidation or any other breach of the Lease that otherwise jeopardizes the health, safety or welfare of LANDLORD, LANDLORD'S or TENANT'S agents, the property in which the PREMISES are located and the public.

Violation of the above provisions shall be a material breach of the Lease and cause for immediate termination of tenancy. Unless otherwise provided by law, proof of violation shall not require criminal conviction, but shall be by the preponderance of evidence.

6.6 DISABILITIES ACT. TENANT agrees that it shall be responsible for complying in all respects with the Americans with Disabilities Act of 1990 and all regulations promulgated there under (collectively, the "ADA"), as it affects the PREMISES. TENANT further agrees that any and all alterations made to the PREMISES during the Lease Term will comply with the requirements of the ADA. All plans for alterations, which must be submitted to LANDLORD, must include a statement from a licensed Architect or Engineer certifying that they have reviewed the plans, and that the plans comply with all applicable provisions of the ADA. TENANT agrees that it will defend, indemnify and hold harmless LANDLORD and LANDLORD'S managers, partners, trustees, officers and agents from all claims, demands, causes of action, suits, liabilities, damages and expenses, including reasonable attorneys' fees, caused by, incurred or resulting from TENANT'S failure to comply with it's obligations under this Paragraph 6.6.

6.7 WARRANTIES OF TENANT.

(a) "Indemnification". TENANT shall indemnify LANDLORD and the managers, directors, officers, partners, trustees, agents, employees, representatives, contractors, affiliates, lenders, successors and assigns of LANDLORD, against all expenses, liabilities and claims of every kind including reasonable attorneys' fees, by or on behalf of any person or entity arising out of: (i) A failure by TENANT to perform any of the terms or conditions of this Lease; (ii) Any injury or damage happening on or about the demised PREMISES; (iii) Failure to comply with any law of any governmental authority; or (iv) Any mechanic's lien or security interest filed against the demised PREMISES or equipment, materials or alterations of building or improvements thereon, which are not permitted under the terms of this Lease or which have not been consented to by LANDLORD in writing.

(b) "Litigation". There are no suits, actions or investigations pending or, to the best of its knowledge, threatened against or involving TENANT before any court, arbitrator or governmental authority which will, in LANDLORD'S reasonable judgment, result in any material adverse change in the contemplated business, worth or operations of TENANT or the PREMISES. TENANT shall notify LANDLORD in writing within five (5) days of the commencement of any action, suit or proceeding and/or of the issuance of any order, writ, injunction, award or decree of any court, arbitration panel, administrative body or other governmental entity, which may adversely affect the operation or financial condition of the TENANT; acknowledging that such an event shall not affect TENANT'S obligations pursuant to this Lease.

6.8 PETS. No pets or animals of any kind shall be brought on the PREMISES without the prior written consent of the LANDLORD. In the event that such written consent is given, the TENANT agrees to keep such pet vaccinated and restrained at all times, to not allow pet to disturb neighbors and to keep the PREMISES clean and odorless.

7. SIGNAGE.

All signage shall comply with rules and regulations set forth by LANDLORD and government authority, which may be modified from time to time. TENANT shall not fix or maintain signs, trademarks, descriptive material or any other such items on the exterior of the PREMISES, without the prior written approval of LANDLORD (which shall not be unreasonably withheld) as to size, type, color, location, copy, nature and display qualities. TENANT will be responsible for the cost of installing, lettering and maintaining any illuminated sign. The LANDLORD must authorize removal of signs and any damage to the building, due to sign removal, will be repaired at TENANT'S expense.

7.1 GENERAL REQUIREMENTS. TENANT shall not maintain any signs, wall or window display or advertising which is not professionally made and in good taste. Current rules and regulations relating to signage are described as follows:

(a) TENANT shall submit a sketch of proposed sign to the LANDLORD for approval, and be responsible for the fulfillment of all permit requirements and general specifications.

(b) No electrical or audible signs will be permitted except for electrical back lighting on the retail space.

(c) Placement of the sign and method of attachment to the building will be directed by the LANDLORD.

(d) TENANT shall not affix any sign or other equipment to the roof of the PREMISES.

(e) TENANT shall place no window covering (i.e. blinds, drapes, screens, tinting material, plywood, plastic or cardboard), stickers, signs, lettering, banners or advertising or display material on or near exterior windows or doors if such materials are visible from the exterior of the PREMISES, without LANDLORD'S prior written consent.

(f) TENANT may not install any alarm boxes, foil protection tape or other security equipment on the PREMISES without LANDLORD'S prior written consent. Any material violating this provision may be removed and destroyed by LANDLORD without compensation to TENANT.

(g) The LANDLORD must authorize removal of signs. TENANT is responsible for removal of lettering on all signs or removal expense will be deducted from security deposit. **Sign Cabinet, if installed, is the property of the LANDLORD and must be returned to LANDLORD, if removed from building.** Any damage to the building or cabinet due to removal of signage will be at TENANT'S expense.

8. HAZARDOUS SUBSTANCES.

8.1 REPORTABLE USES REQUIRE CONSENT. The term "Hazardous Substance", as used in this Lease, shall mean any substance whose presence, use, disposal or release on the PREMISES is either: (a) potentially injurious to the public health, safety or welfare, the environment or the PREMISES, (b) regulated or monitored by any governmental authority or (c) a basis for potential liability of LANDLORD to any governmental agency or third party, under any applicable statute. Hazardous Substances shall include: explosives, hydrocarbons, petroleum, gasoline or any by-products or other flammable substances. TENANT shall not engage in any activity, in or on the PREMISES, which constitutes a Reportable Use of Hazardous Substances.

"Reportable Use" shall mean: (a) the storage, use or disposal of a Hazardous Substance that requires a permit from any governmental authority and/or (b) the presence at the PREMISES of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given, to persons entering or occupying the PREMISES or neighboring properties. TENANT may use any ordinary and customary materials reasonably required for use, in the normal course of the agreed "Use of PREMISES", so long as such use is in compliance with all Applicable Requirements.

8.2 DUTY TO INFORM LANDLORD. If TENANT knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the PREMISES, other than as previously consented to by LANDLORD, TENANT shall immediately give written notice of such fact to LANDLORD and provide LANDLORD with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

8.3 TENANT REMEDIATION. TENANT shall not cause or permit any Hazardous Substance, including painting supplies, to be spilled or released in, on, under or about the PREMISES (including through the plumbing or sanitary sewer system) and shall promptly, at TENANT'S expense, take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination.

8.4 TENANT INDEMNIFICATION. TENANT shall indemnify LANDLORD, its partners, managers, trustees, agents, representatives, employees and mortgagees; harmless from and against any and all loss of rents and/or damages, liabilities, judgments and expenses of any kind arising out of or involving any Hazardous Substance brought onto the PREMISES, by or for TENANT. TENANT'S obligations shall include, but not be limited to, injury to person, property or the environment created or suffered by TENANT; and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.

9. COMMON AREAS.

9.1 DEFINITION. The "Common Area" is that area which is not occupied by buildings and includes access driveways, gates, fire lanes, sidewalks, parking areas, roof, exterior walls and perimeter fencing walls. "CAM" (Common Area Maintenance) expenses are the responsibility of the TENANT with the exception of parking lot striping, which the LANDLORD shall provide.

9.2 OPERATION AND CONTROL. LANDLORD shall have general possession and control of the entire Common Area and may from time to time adopt rules and regulations pertaining to the use thereof. The manner in which the Common Area shall be operated and maintained and the expenditures therefore shall be in LANDLORD'S sole discretion. LANDLORD reserves the right to use the roof, exterior walls (other than store fronts) and the area above and below the leased PREMISES, together with the right to install, maintain, use, repair and replace pipes, ducts, conduits, wires and structural elements now, or in the future, leading through the PREMISES.

9.3 PARKING. LANDLORD grants to TENANT and TENANT'S customers, suppliers, employees and invitees, a non-exclusive license to use the designated parking areas in the PREMISES, for the use of

motor vehicles only, during the term of this Lease. Parking of recreational vehicles, boats, trailers and inoperative vehicles is prohibited. LANDLORD reserves the right at any time to promulgate rules and regulations relating to the use of such parking areas including: reasonable restrictions on parking and designation of specific spaces for the use of TENANTS and employees, changes in the parking layout from time to time, and establishment of reasonable time limits on parking. Some specific rules relating to parking are as follows:

(a) Overnight parking is prohibited.

(b) The number of automobiles allowed is restricted to the TENANT'S pro-rata share of available parking spaces.

(c) TENANTS shall keep parking area clean of oil drippings and shall not do repairs to vehicles outside of business unit.

(d) Parking areas shall not be used for additional storage units.

Any violation of these rules and regulations are subject to the remedies included in Article 21 of this Lease.

10. REPAIRS AND MAINTENANCE.

10.1 LANDLORD'S REPAIRS. LANDLORD shall, at its own expense, keep in good condition and repair: the roof (if replacement is required), exterior plumbing, exterior electrical and foundation of the PREMISES (excluding the exterior and interior of all building and fence walls, windows, doors and plate glass) except for any damage caused thereto by any act, willful misconduct or negligence of TENANT, or its managers, partners, agents, employees, contractors, SUB-TENANTS, customers or business invitees. TENANT agrees that it will not, nor will it authorize any person to go onto the roof of the PREMISES without the prior written consent of LANDLORD, excepting for HVAC maintenance. Said consent will be given only upon LANDLORD'S satisfaction that any repairs necessitated as a result of TENANT'S action will be made by TENANT at TENANT'S expense and will be made in such manner as not to invalidate any roof guarantee. TENANT shall give the LANDLORD prompt written notice of any defects or breakage in the structure or of any unsafe condition upon or within PREMISES. It is an express condition precedent to all obligations of LANDLORD to repair and maintain that TENANT shall notify LANDLORD in writing, by fax or email, the need for such repairs or maintenance. LANDLORD shall be responsible for HVAC replacement and repairs over $500 per unit per year, provided that TENANT maintains HVAC systems as provided herein, unless repair is due to TENANT negligence or willful misconduct.

10.2 TENANT'S REPAIRS. TENANT shall pay pro-rata portion of all Triple-Net expenses and common area maintenance, except as provided herein and more particularly in Paragraph 10.1. TENANT shall be obligated to keep, maintain and repair the building and other improvements upon the PREMISES in good and sanitary order and condition including, without limitation, the maintenance and repair of the store front, awnings, sidewalks (maintenance only), walls, gates, parking areas, doors, window casements, glazing, heating and air conditioning system, plumbing, pipes and electrical wiring conduits; except for any damage thereto caused by any act of gross negligence of LANDLORD or its officers, partners, trustees, managers, agents, employees or contractors. TENANT shall also, at its own cost and expense, be responsible for any alterations or improvements to the PREMISES, necessitated as a result of the requirements of any municipal, state or federal authority. By entering the PREMISES, TENANT shall be deemed to have accepted the PREMISES as being in good and sanitary order, condition and repair. TENANT agrees on the last day of said term, or sooner termination of this Lease, to surrender the PREMISES with appurtenances, in the same condition as when received, broom cleaned, reasonable wear and tear excepted. TENANT shall repair any damage to the PREMISES (including roof and exterior) occasioned by the removal of TENANT'S trade fixtures, furnishings, equipment and signs, which repair shall include the patching and filling of holes, painting and repair of structural damage.

10.3 MAINTENANCE. From and after commencement of the Term of this Lease, TENANT shall at its expense, maintain the PREMISES, Common Areas and the improvements thereon; reasonable wear and tear, depreciation, damage and loss from the elements, loss covered by insurance and other occurrences beyond the reasonable control of TENANT excepted. LANDLORD shall not be called upon to make any improvements or repairs in or upon the PREMISES during the term of Lease except as expressly required or permitted herein. LANDLORD shall maintain Common Areas and TENANT shall be responsible for pro-rata share of Common Area Maintenance, annual washing of the building exterior, in addition to sidewalk and parking maintenance. LANDLORD, at its election, may employ an air conditioning service company to provide repair and preventive maintenance of the air conditioning units, at TENANT'S expense. LANDLORD does not provide trash disposal or janitorial services; plumbing, sewer lines, cleaning and all up-keep of restrooms shall be the responsibility of the TENANT. TENANT covenants and agrees to pay promptly when due, all claims for work and materials furnished in connection with its maintenance of said improvements and shall not permit or suffer any liens or encumbrances to attach to the PREMISES and shall indemnify LANDLORD against loss there from.

10.4 NO REPAIRS AND REPLACEMENT BY LANDLORD. LANDLORD shall not be obligated to make any repairs or replacements of any kind with respect to the PREMISES, unless provided herein, except for any damage caused by any sole act, gross negligence or willful misconduct of LANDLORD or its partners, trustees, managers, agents, employees or contractors.

10.5 LANDLORD'S RIGHTS. If TENANT fails to perform TENANT'S obligations under this Article 10, LANDLORD may at its option (but shall not be required to), enter upon the PREMISES after ten (10) days prior written notice to TENANT and put the same in good order, condition and repair and the cost thereof, together with interest thereon at the rate of twelve percent (12%) per annum, shall become due and payable, as additional rent to LANDLORD, together with TENANT'S next rental installment.

10.6 GARBAGE/PEST CONTROL. TENANT shall be responsible for a portion of dumpster fees. All garbage, refuse, cardboard and grease/oil shall be prepared for collection and kept in a locked dumpster (and/or appropriate receptacles). TENANT shall not burn any trash or garbage of any kind, in or about the PREMISES. TENANT shall use licensed exterminators to keep the PREMISES free from insects and common pests. All TENANTS with unpackaged foods are required to provide for extermination on a monthly basis.

10.7 SAFETY. Per current Fire Regulations, during the entire Term hereof, TENANT shall maintain an adequate number and type of functional fire extinguishers on the PREMISES, as are appropriate to TENANT'S business, and shall provide annual inspections, therefore. TENANT will at all times adhere to good fire and other safety practices, as such governmental authorities may require. Neither TENANT nor its employees, agents,

contractors, visitors or licensees shall at any time bring or keep upon the PREMISES, any flammable, combustible or explosive fluid, chemical or substance, except that which is normally employed in their business and which is kept safely in proper containers.

10.8 NO REPAIRS AND REPLACEMENT BY LANDLORD. LANDLORD shall not be obligated to make any repairs or replacements of any kind with respect to the PREMISES, unless provided herein, except for any damage caused by any sole act, gross negligence or willful misconduct of LANDLORD or it's partners, trustees, managers, agents, employees or contractors.

11. ALTERATIONS AND ADDITIONS.

A. TENANT shall not, without LANDLORD'S prior written consent, make any alterations, improvements, additions or utility installations (including bus ducting, power panels, fluorescent fixtures, space heaters, conduits and wiring) to the PREMISES, except for non-structural alterations. All work must be paid by TENANT and performed by a Licensed Contractor, approved by LANDLORD prior to commencing work. TENANT shall be required to obtain all applicable permits from the appropriate governmental agencies. **Walls must remain white.**

B. As a further condition to giving such consent, LANDLORD may require TENANT, at their sole cost and expense, to provide a lien and completion bond, equal to one and one-half (1-1/2) times the estimated cost of such improvements. TENANT shall pay when due, all claims for labor or materials furnished, or alleged to have been furnished, for TENANT at or for use in the PREMISES, which claims may be secured by any mechanics or material man's lien against the PREMISES, or any interest therein.

C. Unless LANDLORD requires the removal, as set forth in Articles 21 and 35, all alterations, improvements, additions and utility installations (whether or not such utility installations constitute trade fixture of TENANT) which may be made to the PREMISES, shall become the property of LANDLORD and be surrendered with the PREMISES, at the expiration of the term. TENANT'S furnishings, machinery and equipment, which can be removed without material damage to the PREMISES, shall remain the property of TENANT and may be removed subject to the provisions of Articles 21 and 35.

12. TAXES.

12.1 PERSONAL PROPERTY TAXES. TENANT shall pay before delinquency all license fees, public charges, property taxes and assessments on the furniture, fixtures, equipment and other property of or being used by TENANT, at any time situated on or installed in the PREMISES.

12.2 REAL ESTATE TAXES.

(a) TENANT shall pay as Additional Rent, before delinquency, pro rata portion of all Real Estate Taxes in general levied against the PREMISES, including special assessments, and installments thereof ("Real Estate Taxes"), any tax on rent, any license fee imposed by a local government body on the collection of rent, excluding federal and state income taxes. Said Real Estate Taxes and assessments, for the first and last Lease years hereunder shall, be pro-rated and apportioned between LANDLORD and TENANT to coincide with the Commencement and Expiration of the Lease term. As used herein, the term Real Estate Taxes shall include: (i) any form of tax or assessment, license fee or tax or any other levy charge or similar imposition, imposed by any federal, state, county or city authority having jurisdiction, or any political subdivision thereof, or other improvement or special assessment district thereof, on any interest of LANDLORD and/or TENANT in the PREMISES and/or the underlying realty; (ii) any impositions allocable to or measured by the area of the PREMISES or any rental payable hereunder, including without limitation, any gross income tax or excise tax levied by the federal, state, county or city government, with respect to the recipient of such rent, or upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by TENANT of the PREMISES, or any portion thereof and (iii) any impositions upon this Lease transaction of any document to which TENANT is a party, creating or transferring an interest or an estate in the PREMISES.

(b) TENANT shall pay such Real Estate Taxes to LANDLORD, upon demand, **(current portion $568.38 annually and subject to change) or in monthly payments with rent of $47.37 per month.**

(c) This Paragraph 12.2 shall not be construed to require TENANT to pay any tax which may be levied by any governmental authority upon the income, profits or business of LANDLORD, or any personal property taxes, franchise, inheritance or estate taxes, or taxes upon inheritance or right of succession which may be levied against any estate or interest or LANDLORD, even though such taxes shall become a lien against the PREMISES.

(d) TENANT shall have the right, at its sole cost and expense, to contest the amount or validity, in whole or in part, of any tax that TENANT is required to pay, by appropriate proceedings diligently conducted in good faith and shall, upon the final determination thereof, pay the amount of said Real Estate Taxes, together with any interest, penalties, costs and charges which may be payable in connection therewith. As a condition of such contest, TENANT shall pay such amounts and/or post such security, as LANDLORD reasonably requires to protect the PREMISES against loss or forfeiture. LANDLORD shall not be required to join in any contest or proceedings unless the provisions of any applicable law or regulations require that the proceedings be brought by or in the name of LANDLORD. However, LANDLORD agrees to join in the proceedings, or permit them to be brought in its name, provided that (i) LANDLORD shall not be subjected to any liability for the payment of any costs or expenses in connection with any contest or proceedings and (ii) TENANT shall indemnify LANDLORD against and save LANDLORD harmless from any costs and expenses and the amount of real estate taxes, including interest and penalties, due and owing in this regard. In the event of such contest, TENANT shall post such bond or take other such measures as LANDLORD may reasonably require.

12.3 BUSINESS TAXES. TENANT shall pay all special taxes and assessments or license fees levied, assessed or imposed by law or ordinance, by reason of the use of the PREMISES.

13. UTILITIES / SERVICES.

TENANT shall pay as Additional Rent, before delinquency, all charges for water, gas, power, telephone, cable, garbage, pro rata sewer service fees, security/crime control (guard and/or alarm company), pest control and other services metered, chargeable or provided to the PREMISES, including utility connection charges and deposits. TENANT shall be responsible for additional utility installations, per the specific requirements of their occupancy of

the PREMISES. Under no circumstances shall LANDLORD be responsible for any interruption of any utility service. Nothing in this Lease shall limit LANDLORD in any way from granting or using easements on, across, over and under the PREMISES for the purpose of providing utility services.

14. INSURANCE.

Throughout the Lease Term TENANT shall maintain, at its sole cost and expense, the following types and amounts of insurance (which may be included under a blanket insurance policy if all the other terms hereof are satisfied), in addition to such other insurance as LANDLORD may reasonably require. TENANT shall be responsible for reimbursement of LANDLORD'S Property/Fire Insurance (included in Paragraph 14.2), which shall be paid upon demand, **(TENANTS current portion $475.00 annually. Subject to change), or monthly payments with rent of $39.58 per month.**

14.1 PUBLIC LIABILITY INSURANCE. TENANT shall maintain Comprehensive Commercial General Liability and Property Damage insurance, including a Products Liability clause, covering LANDLORD, indemnified Parties, TENANT and its authorized representatives; against bodily injury or death of persons liability, property damage liability and automobile bodily injury and property damage liability, including without limitation any liability arising out of the ownership, maintenance, repair, condition or operation of the PREMISES, or adjoining ways, streets or sidewalks, occurring from any cause whatsoever arising out of or in connection with TENANT and its authorized representatives liability, use or occupancy of the PREMISES. Such insurance policy or policies shall be in an amount not less than ONE MILLION DOLLARS ($1,000,000) combined single limit, with an aggregate limit of not less than TWO MILLION DOLLARS ($2,000,000) including FIVE HUNDRED THOUSAND ($500,000) Fire Legal Liability Insurance and ONE MILLION DOLLARS ($1,000,000) Professional Liability, if applicable, and shall contain a broad form contractual liability endorsement under which the insurer agrees to insure TENANT'S obligations to the full extent insurable, and a "severability of interest" clause or endorsement which precludes the insurer from denying the claim of either TENANT or LANDLORD because of the negligence or other acts of the other party. Public liability insurance, product liability insurance and property damage insurance shall be in amounts of not less than $1,000,000 per injury and occurrence with respect to any insured liability, whether for personal injury or property damage, which shall insure performance by TENANT of the Indemnity provisions of Article 16. LANDLORD shall be named, as "Additional Insured" and the policy shall contain cross-liability endorsements.

14.2 "ALL RISKS" INSURANCE.

(a) TENANT shall maintain "All Risks" and/or Special Form coverage insurance against loss, damage or destruction by fire and other casualty, including theft, vandalism and malicious mischief, flood (if the PREMISES is in a location designated by the Federal Secretary of Housing and Urban Development as a flood hazard area); plate glass breakage (TENANT may self-insure); pipe breakage or sprinkler damage; all matters covered by a standard extended coverage endorsement; and such other risks as LANDLORD may reasonably require, insuring the TENANT'S personal property, improvements in or about PREMISES and the restoration of TENANT'S and LANDLORD'S improvements, the PREMISES which the TENANT occupies and all improvements thereon for not less than 100% of their full insurable replacement cost. TENANT and LANDLORD, as their interests may appear, shall be the named insured.

(b) TENANT acknowledges that LANDLORD is not required to maintain any personal property insurance for TENANT'S property and merchandise. All insurance required to be provided by TENANT under this Lease shall release LANDLORD from any claims for damages to any person, any property or the PREMISES and to TENANT'S fixtures, personal property, improvements and alterations in or on the PREMISES, caused by or resulting from risks insured against under any insurance policy carried by TENANT, in force at the time of such damage.

(c) TENANT shall not carry any stock of goods, combustible materials or do anything on or about the PREMISES which will in any way tend to increase the insurance rate on the building in which the PREMISES are located. In no event shall TENANT carry on any activities, which would invalidate any insurance coverage thereon.

(d) TENANT hereby waives any and all rights of recovery from LANDLORD, its partners, managers, trustees, officers, agents, representatives and employees for any loss or damage (including gross negligent acts) enumerated in each form of insurance policy required to be maintained by TENANT hereunder.

(e) LANDLORD does NOT insure TENANT for any personal injury or property damage, including that caused by the act or omission of any other TENANT or third party or by any criminal act or activity, war, riot, insurrection, fire, water or act of God.

14.3 WORKERS COMPENSATION. TENANT shall at all times maintain Workers Compensation insurance in compliance with Nevada state law (Employers Insurance Company of Nevada).

14.4 BUSINESS INTERRUPTION. TENANT shall at all times maintain Business Interruption insurance equal to 100% of the Base Monthly Rent and Additional Rents for a period of not less than 6 months.

14.5 GENERAL INSURANCE REQUIREMENTS.

(a) All insurance required to be provided by TENANT under this Lease shall be written by a company that is A rated and licensed to do business in Nevada, and shall expressly include, as named or additionally insured, the LANDLORD and any person or entity designated as having an insurable interest therein, as their respective interest may appear.

Additional insured to read as follows:

1807 WC LLC,
Eljoy Corp. & Josephs Properties
5395 Polaris Ave. Ste. 100
Las Vegas, NV 89118

(b) Each policy shall be primary and not contributing with the coverage, if any, which LANDLORD may carry. The coverage amounts of all insurance policies required hereunder by TENANT, shall be an amount sufficient to prevent LANDLORD from becoming a co-insurer. LANDLORD shall receive a copy of each policy or endorsement reflecting the amounts of insurance and providing that LANDLORD is an additional insured or beneficiary.

(c) All insurance shall contain an express waiver of any and all rights of subrogation whatsoever against LANDLORD, its officers, partners, managers, trustees, agents, contractors and employees. Each party ("insured") hereby waives its entire right of recovery against the other party and the other party's officers, partners, representatives, employees, trustees, managers, successors and assigns with respect to any loss or damage, including consequential loss or damage, to the insured's property caused or occasioned by any peril or perils (including acts, covered by any policy or policies carried by the "insured").

(d) TENANT shall deliver a certificate or copy of each insurance policy required by this Lease and Accord certificate, together with evidence of payment of all current premiums, to LANDLORD and all other named insured's, prior to occupancy; and policy renewals thereafter, prior to their expiration. Each of said policies of insurance, required to be maintained by TENANT, shall contain an endorsement or provision requiring not less than thirty (30) days prior written notice to LANDLORD, and all other named insured's, prior to the cancellation, diminution in the perils insured against, or change or reduction of the scope or amount of coverage of the particular policy in question.

(e) TENANT'S failure to provide evidence of such coverage to LANDLORD within ten (10) days of written request may, in LANDLORD'S sole discretion, constitute a default under this Lease.

14.6 LANDLORD'S RIGHT TO OBTAIN INSURANCE. In the event that TENANT fails to procure or maintain the insurance required hereunder, within fifteen (15) days following written notice from LANDLORD indicating TENANT'S failure to procure or maintain the required insurance, then TENANT shall be in default under this Lease. In addition to any other remedies available at law or in equity, LANDLORD may, at LANDLORD'S election, procure the required insurance and TENANT shall pay LANDLORD'S costs and expenses in obtaining such insurance with the next due monthly installment of Rent. Notwithstanding the foregoing, it is expressly covenanted and agreed that payment by LANDLORD of any such insurance premium shall not be deemed to waive or release any of TENANT'S obligations with respect to insurance.

15. DESTRUCTION OF PREMISES.

15.1 TENANT'S DUTY TO RESTORE. In the event of a total or partial destruction of the improvements, from any cause covered by the insurance which is to be maintained by TENANT, TENANT shall forthwith repair the same immediately upon receipt of the insurance proceeds or clear the PREMISES of all debris and damaged structures and remit to LANDLORD all insurance proceeds allocated to real property and LANDLORD'S interest (but not to TENANT'S property) therein received, less any sums used to clear the PREMISES and remove TENANT'S property; but such destruction shall not annul or void this Lease. Subject to Paragraph 15.3, the rents, reserved to be paid hereunder, shall be equitably adjusted according to the amount and value of the undamaged space.

15.2 ELECTION TO TERMINATE. If the improvements on the PREMISES are damaged by any insured casualty to the extent of at least thirty percent (30%) of the replacement cost (to repair or replace at the time of loss without deduction for physical depreciation) during the term of this Lease, or to any extent by an insured cause at any time during the Lease term, or by an insured or uninsured cause during the extension or renewal of the Lease term, or to any extent by an uninsured cause at any time during the Lease term; LANDLORD shall, within not more than thirty (30) days after such damage, notify TENANT of LANDLORD'S election to terminate this Lease, or to restore the improvements on the PREMISES as in LANDLORD'S sole discretion is necessary to create an economically feasible unit. If LANDLORD elects to repair or restore the damaged improvements, then with respect to the PREMISES, LANDLORD and TENANT shall each restore them in the same manner and to the same extent as work was done by each of them in the original construction and fixturization of the improvements, and the damaged improvements of the balance of the PREMISES shall be restored likewise. If LANDLORD elects not to restore as stated, this Lease shall terminate effective as of the date of such damage, upon the notice of election by LANDLORD as stated. If LANDLORD elects to restore, or fails to give notice of its election as stated, then this Lease shall remain in full force and effect. Any restoration required hereunder by LANDLORD shall be commenced within 45 days of such loss and LANDLORD will use the best effort possible to insure completion of restoration without unreasonable delays. If LANDLORD fails to undertake such restoration then TENANT shall have the right to elect to terminate this Lease. Such elections shall be on notice of ninety (90) days.

15.3 RENTAL ADJUSTMENT. If this Lease is not terminated, as provided for herein Paragraph 15.2; then during the period of repair and restoration, the rents due hereunder shall be equitably adjusted, according to the amount and value of the undamaged space.

15.4 TENANT'S OBLIGATION TO RESTORE. Notwithstanding the foregoing provisions, in the event the PREMISES, or a portion thereof, shall be damaged by fire or other casualty due to the fault or negligence of TENANT, its agents, employees, service providers, contractors, SUBTENANTS, licensees, customers or business invitees; then, without prejudice to any of the rights and remedies of LANDLORD, this Lease shall not terminate, the damage shall be repaired by TENANT at their sole expense and there shall be no apportionment or abatement of any rent.

15.5 INSURANCE PROCEEDS. All insurance proceeds payable under any fire and extended coverage risk insurance shall be payable solely to LANDLORD and TENANT shall have no interest therein, except to the extent that the proceeds are reimbursement for trade fixtures. TENANT shall in no event be entitled to compensation for damages on account of any annoyance or inconvenience in making repairs under any provision of this Lease. Except to the extent provided for in this Paragraph 15.5, neither the Rent payable by TENANT nor any of TENANT'S other obligations under any provision of this Lease shall be affected by any damage or destruction of the PREMISES or any portion thereof by any cause whatsoever.

16. INDEMNIFICATION AND WAIVER.

16.1 INDEMNIFICATION. TENANT, as a material part of the consideration to be rendered to LANDLORD, hereby waives all claims against LANDLORD and its managers, partners, officers, trustees,

representatives, employees, contractors and agents (Indemnified Parties). TENANT'S indemnification of LANDLORD under Paragraph 16.1 of the Lease, does not include claims arising from the sole act, gross negligence or willful misconduct of LANDLORD or its managers, agents, contractors or employees. TENANT, to the maximum extent permitted by law, shall defend, protect, indemnify and hold harmless the LANDLORD and the Indemnified Parties, against all claims, demands or causes of action, suits, damages, liabilities, judgments, losses and expenses (including without limitation, reasonable attorneys' fees and costs of litigation, whether incurred for LANDLORD or Indemnified Party's primary defense or for enforcement of its indemnified rights) which may be incurred by an Indemnified Party or asserted by TENANT (including without limitation, TENANT'S employees, contractors and agents) or by any third party on account of:

(a) Any personal injury, disease or death of any person(s), damage to or loss of any property or money damages or specific performance owed to any third party (by contract or operation of law) and any fines, penalties, assessments or injunctive obligations caused by, arising out of, or in any way incidental to, or in connection with actions or omissions of TENANT (including, without limitation, its employees and agents);

(b) The sole negligence, fault or strict liability of TENANT;

(c) The concurrent negligence, fault or strict liability in any combination of the Indemnified Parties and/or TENANT and/or any third party. LANDLORD shall be held harmless for the events arising from or connected with TENANT'S occupancy, use or management of the business conducted on the PREMISES; and for damages to goods, wares and merchandise upon, or about, said PREMISES from any cause arising at any time and from any breach or default on the part of TENANT in the performance of any covenant or agreement on the part of TENANT, to be performed pursuant to the terms of this Lease; or from violations of, or noncompliance with, any governmental requirements or insurance requirements; or from any acts or omissions of TENANT or any person upon PREMISES, by license or invitation of TENANT, or occupying any part of PREMISES under TENANT'S control; or from the failure of TENANT to maintain the PREMISES in the manner herein required.

16.2 LANDLORD'S INDEMNIFICATION. LANDLORD agrees to indemnify the TENANT for claims arising in the Common Area of the Shopping Center, except LANDLORD'S indemnity does not include claims arising from the sole act, gross negligence or willful misconduct of TENANT or its managers, partners, agents, contractors, employees, business invitees or customers.

16.3 WAIVER. All property stored or maintained on PREMISES shall be done so at the sole risk of TENANT and, except in the case of its gross negligence or willful misconduct, LANDLORD shall not be liable. TENANT waives all claims against LANDLORD, for damages to persons or property sustained by TENANT, or by any other person or firm, resulting from the building in which the PREMISES are located, or by reason of TENANT'S occupancy of PREMISES, or any equipment located therein, or through the acts or omissions of any persons present in the PREMISES, or renting or occupying any part of the PREMISES, or for loss or damage resulting to TENANT or his property from burst, stopped or leaking pipes, sewers, conduits, plumbing fixtures, or for interruption of any utility services, or from any failure of or defect in an electric line, circuit or facility, or any other type of improvement or service, on or furnished to the PREMISES, resulting from any accident in, out or about the PREMISES or the building in which the PREMISES are located.

17. EMINENT DOMAIN / CONDEMNATION.

If the entire leased PREMISES are taken by right of Eminent Domain ("Condemnation"), or other authority of law, during the term of this Lease or any extension thereof, this Lease shall terminate on the date of taking. If any portion of the PREMISES is taken, by right of Eminent Domain/Condemnation, this Lease shall remain in effect, except that TENANT can elect to terminate this Lease, if the remaining portion of the PREMISES is rendered unsuitable for TENANT'S continued use of the PREMISES. If TENANT elects to terminate this Lease, TENANT must exercise its right to terminate, by giving notice to LANDLORD within ten (10) days, after TENANT receives written notice from LANDLORD, of the nature and extent of the taking. If any portion of the PREMISES is taken by Condemnation and this Lease remains in full force and effect; on the Date of Taking, the rent shall be reduced, by an amount in the same ratio, as the total number of square feet in the PREMISES taken, bears to the total number of square feet in the PREMISES, immediately before the Date of Taking. All awards shall be sole property of LANDLORD, whether such awards shall be made as compensation for diminishing in value of the Leasehold or for the taking of personal property. Notwithstanding the foregoing and so long as such claims are payable separately to TENANT, TENANT shall be entitled to receive any just compensation awarded only for the following items: (a) TENANT'S Personal Property, (b) TENANT'S moving expenses, (c) TENANT'S business goodwill, including as provided in NRS 37.111, and (d) if this Lease is not terminated, severance damages, if any, suffered by TENANT, based upon interference with TENANT'S business operations, at the PREMISES (but not severance damages caused to the leasehold estate owned by LANDLORD, which damages award is the exclusive property of LANDLORD).

In the event that this Lease is not terminated by reason of such condemnation, LANDLORD shall, to the extent of severance damage received by LANDLORD in connection with condemnation, repair any damage to the PREMISES caused by such condemnation, except to the extent that TENANT has been reimbursed therefore by the condemning authority. TENANT shall pay any amount in excess of severance damages, prior to completing such repair.

18. LIENS.

TENANT shall keep the PREMISES free of any liens, or claims of lien, arising from any work performed, materials furnished or obligations incurred by TENANT, in connection with the PREMISES. If TENANT disputes the correctness or validity of any claim of lien, TENANT shall, within ten (10) days after LANDLORD'S written request, record such bond as would release said property from the lien claimed. TENANT shall give LANDLORD written notice at least ten (10) business days prior to the act or commencement of any such work on the PREMISES, to afford LANDLORD the opportunity of filing or posting appropriate notices of non-responsibility as provided by law. TENANT shall, at its expense, within fifteen (15) days after filing of any lien or record, obtain discharge and release thereof. LANDLORD may obtain said discharge and release, in the event TENANT fails or refuses to do so within said fifteen (15) day period, and TENANT shall reimburse LANDLORD upon demand for any costs, including attorneys' fees, incurred by LANDLORD in discharging or releasing such lien.

19. INSOLVENCY.

19.1 BREACH OF LEASE. The filing of any petition, by or against TENANT, under any chapter of the Bankruptcy Act, or any successor statute thereto, or the adjudication of TENANT as a bankrupt or insolvent, or the appointment of a receiver or trustee to take possession of all, or substantially all, of the assets of TENANT, or a general assignment by TENANT for the benefit of creditors, or any other action taken or suffered by TENANT under any state or federal insolvency or bankruptcy act; shall constitute a default under and a breach of this Lease by TENANT, regardless of TENANT'S compliance with other provisions of this Lease. LANDLORD may, at its option by written notice to TENANT, exercise all rights and remedies provided for in Article 21, including termination of this Lease, effective on service of such notice, without the necessity of further notice under Paragraph 21.4.

19.2 OPERATION OF LAW. Neither this Lease, nor any interest or estate created hereby, shall pass by operation of law under any state or federal insolvency or bankruptcy act, to any trustee, receiver, assignee for the benefit of creditors or any other person whatsoever. **This Lease shall not be considered an asset of TENANT in regard to any bankruptcy proceedings.** Any purported transfer, in violation of the provisions of this Article 19, shall constitute a default under and a breach of this Lease, regardless of TENANT'S compliance with the other provisions of this Lease and LANDLORD, at its option by written notice to TENANT, may exercise all rights and remedies provided for in Paragraph 21.1, including the termination of this Lease, effective upon service of such notice, without the necessity of further notice under Paragraph 21.4.

19.3 NO WAIVER. The acceptance of rent at any time by LANDLORD, from TENANT, as debtor in possession or from a transferee of the type mentioned in Paragraphs 19.1 and 19.2, shall not preclude LANDLORD from exercising its rights under Article 21, at any time thereafter.

19.4 OPTION TO TERMINATE. LANDLORD may, as its option, if the above occurs, immediately take possession of the PREMISES and terminate this Lease. Upon such termination, all installments of rent, earned to the date of termination and unpaid, shall at once become due and payable. In addition, LANDLORD shall have all rights provided by the bankruptcy laws, relative to the proof of claims, on an anticipatory breach of an executory contract.

20. FINANCIAL STATEMENTS.

TENANT shall, within ten (10) business days after written notice from LANDLORD, deliver to LANDLORD such financial statements or other documents, as LANDLORD may reasonably require, to verify the financial condition of TENANT, or any assignee, SUB-TENANT or guarantor of TENANT. In addition, TENANT shall deliver to any mortgagee or prospective mortgagee of LANDLORD, any financial statements required by the mortgagee, to facilitate the financing or refinancing of the property of which the PREMISES are a part. LANDLORD shall keep all financial information regarding TENANT, strictly confidential.

20.1 CREDIT AGENCY REPORTING. If TENANT should fail to fully perform the covenants of this Lease, as required by law, and a judicial determination is made thereof, TENANT is hereby notified that a negative credit reference reflecting on TENANT'S credit report may be submitted to any and all credit reporting agencies. TENANT herein authorizes LANDLORD to periodically check TENANT'S credit, in the event of delinquency in payment of Rent and Additional Rent.

21. TENANT'S DEFAULT.

The occurrence of any of the following shall constitute a Default by TENANT:

A. If TENANT makes, or has made, any materially false statements, representations, accounts or reports to LANDLORD, in connection with this Lease.

B. If TENANT fails to pay, when due, any installment of Rent or Additional Rent and such failure continues for a period of seven (7) business days, following receipt, by TENANT, of written notice from LANDLORD to TENANT, of such failure.

C. If there is a breach, default or expiration of any license and/or permit, permitting TENANT to operate the PREMISES, in the manner authorized; or if such license and/or permit otherwise terminates or expires and such breach, default, expiration or termination continues for a period of thirty (30) days, following receipt, by TENANT, of written notice from LANDLORD of such breach, default, expiration or termination.

D. If TENANT abandons or vacates the PREMISES: Failure to occupy the PREMISES for Fourteen (14) consecutive days without removal of property or vacation of PREMISES with removal of property, for Three (3) consecutive days, with rent due, shall be deemed an abandonment.

E. **If TENANT exercises the option to become delivery only or close doors to the public but has not paid rent, additional rent, utilities, taxes and insurances and the premises are not maintained.**

F. If TENANT fails to perform any non-monetary obligation under this Lease and such failure continues for a period of thirty (30) days, following receipt by TENANT of written notice from LANDLORD to TENANT of such failure. Provided, however, that if such failure is of a type that cannot reasonably be cured within such thirty (30) day period and TENANT commences the cure within the thirty (30) day period and diligently prosecutes the cure to completion, TENANT shall have an additional reasonable period of time to complete the cure.

G. If TENANT receives two (2) separate notices from LANDLORD, to cure the same or related defaults or violations of this Lease, during any twelve (12) month period.

H. If a threat or danger to public health or safety (under environmental laws or otherwise) results, from the maintenance or operation of the PREMISES, unless compliant with state regulations and statutes governing the TENANT'S intended use.

21.1 NOTICE AND REMEDIES. As a material inducement to LANDLORD, executing this Lease, in the event of any Default and with or without any notice or demand except the notice prior to default required pursuant to this Lease, or such other notice as may be required by statute and cannot be waived by TENANT (all other notices being hereby waived), LANDLORD shall be entitled to exercise, at its option and after the expiration of all applicable notice and cure periods, concurrently, successively or in any combination, all remedies available at law or in equity, including without limitation any one or more of the following:

(a) "Termination". To terminate this Lease, whereupon TENANT'S right to possession of the PREMISES shall cease and this Lease, except as to TENANT'S liability arising prior to the date of termination, shall be terminated.

(b) "Non-termination". To not terminate TENANT'S right to possession, because of such breach, but continue this Lease in full force and effect and in that event LANDLORD may enforce all rights and remedies under this Lease, including the right to recover the rent and all other charges which became due hereunder.

(c) "Re-entry". To re-enter and take possession of the PREMISES (but not any of TENANT'S property located upon the PREMISES, unless abandoned per Article 21 Paragraph D) without being deemed guilty in any manner of trespass or becoming liable for any loss or damage resulting therefrom (other than for damage or loss to the TENANT'S property), which TENANT shall be entitled to remove, within thirty (30) days of such taking of possession, without resort to legal or judicial process, procedure or action. No notice for LANDLORD hereunder, or under a forcible entry and detained statute or similar law, shall constitute an election by LANDLORD to terminate this Lease, unless such notice specifically so states. If TENANT shall, after default, voluntarily give up possession of the PREMISES to LANDLORD, deliver to LANDLORD or its agents the keys to the PREMISES or both, such actions shall be deemed to be in compliance with LANDLORD'S rights and the acceptance thereof, by LANDLORD or its agents, shall not be deemed to constitute a termination of the Lease. LANDLORD reserves the right, following any re-entry and/or re-letting, to exercise its right to terminate this Lease, by giving TENANT thirty (30) days written notice thereof, in which event this Lease will terminate, as specified in said notice.

(d) "Re-letting". To re-let the PREMISES or any part thereof for such term or terms (including a term which extends beyond the original term of this Lease), at such rentals and upon such other terms as LANDLORD, in its sole discretion, may determine, with all proceeds received from such re-letting being applied to the rental and other sums due from the TENANT in such order as LANDLORD may, in its sole discretion, determine which other sums include, without limitation, all repossession costs, brokerage commissions, reasonable attorneys' fees and expenses, and repair costs, normal wear and tear accepted. Except to the extent required by applicable law, LANDLORD shall have no obligation to re-let the PREMISES or such part thereof and shall in no event be liable to collect any rent due upon such re-letting and no such refusal or failure shall operate to relieve TENANT of any liability under this Lease or otherwise to affect any such liability. LANDLORD reserves the right following any re-entry and/or re-letting to exercise its right to terminate this Lease, by giving TENANT written notice thereof, in which event this Lease will terminate as specified in said notice.

(e) "Acceleration". To accelerate and recover from TENANT, all rent and other monetary sums due and owing and scheduled to become due and owing under the Lease, both before and after the date of such breach, for the entire original scheduled term of this Lease and all damages allowable by applicable statute.

21.2 TENANT PROPERTY. TENANT Property shall remain on the PREMISES, in the event of and continuing during the length of default, except in the case of abandonment or vacation per Article 21, Paragraph D. LANDLORD shall have the benefit of any applicable lien on TENANT Property located in or on the PREMISES, as may be permitted under the laws of the State of Nevada, and if such lien is asserted by LANDLORD in accordance with applicable law, TENANT shall not remove or permit the removal of such TENANT'S Property until the lien has been removed and all defaults have been cured. LANDLORD also has the option to require that TENANT remove all property forthwith and if TENANT fails to do so, LANDLORD may remove such property and place it in storage in a public warehouse, at the cost and risk of TENANT.

21.3 NOTICE OF TERMINATION. No act by LANDLORD, other than giving written notice to TENANT, shall terminate this Lease. The re-entry or re-letting of the PREMISES, acts of maintenance or the appointment of a receiver on LANDLORD'S initiative, to protect LANDLORD'S interest under this Lease, shall not constitute a termination of TENANT'S right to possession. LANDLORD may, at any time thereafter, elect to terminate TENANT'S right to possession and this Lease, in the event TENANT remains in default hereunder.

21.4 WAIVER OF NOTICE. Notwithstanding any provision of Article 21, if TENANT is required to comply with any governmental requirement, TENANT shall not be entitled to notice of default from LANDLORD and right to cure beyond the period within which such compliance may be required. If this Lease expressly provides for termination, effective upon service of notice, TENANT shall be entitled to cure its default only if such right is provided by law. If in LANDLORD'S judgment, the continuance of any default by TENANT, for the full period of notice provided for herein, would jeopardize the PREMISES or the LANDLORD'S rights; LANDLORD may, with or without notice, elect to perform those acts to which TENANT is in default, for the account and at the expense of TENANT.

21.5 EXPENSES. LANDLORD may bring an action against TENANT for any damages sustained by LANDLORD, or any equitable relief available to LANDLORD, and to recover from TENANT all costs and expenses, including reasonable attorneys' fees, court costs, expert witness fees, costs of tests and analyses, deposition and trial transcripts, copies and other similar costs and fees, paid or incurred by LANDLORD, as a result of an event of Default by TENANT; after the expiration of all applicable notice and cure periods, regardless of whether or not legal proceedings are actually commenced.

21.6 INTEREST. If, by reason of TENANT default, LANDLORD is compelled or elects to pay any sum, including without limitation reasonable attorneys' fees, such sums so paid by LANDLORD shall be due from TENANT as additional rent, on the first day of the month next following such payment by LANDLORD. Any sum accruing to LANDLORD not paid when due, under the terms and provisions of this Lease, shall bear interest at twelve percent (12%) per annum, compounded monthly until paid, unless otherwise specifically provided in this Lease.

21.7 OTHER REMEDIES. Nothing contained in this Lease shall limit LANDLORD to the remedies set forth in this Article 21 and particularly those which are set forth in Paragraph 21.1. Upon TENANT'S default, LANDLORD shall be entitled to exercise any right or remedy then provided by law including, without limitation, the right to obtain injunctive relief and the right to recover all damages caused by TENANT'S default, in the performance of any obligations under this Lease.

22. LANDLORD'S DEFAULT.

LANDLORD shall not be in default, unless LANDLORD fails to perform obligations required of LANDLORD within a reasonable time, but in no event later than thirty (30) days after written notice by TENANT to LANDLORD; provided however, that if the nature of LANDLORD'S obligation is such that more than thirty (30)

days are required for performance, LANDLORD shall not be in default if LANDLORD commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion. In no event shall TENANT have the right to terminate this LEASE as a result of LANDLORD'S default; TENANT'S remedies shall be limited to damages and/or an injunction.

23. RIGHT OF ACCESS AND ENTRY BY LANDLORD.

LANDLORD, and its authorized representatives, shall have the right to enter the PREMISES, at all reasonable times, for any business purpose including:

(a) to inspect the PREMISES and determine whether TENANT is in compliance with Lease obligations;

(b) to serve legal notice relieving LANDLORD from responsibility for the acts of the TENANT. For notices served personally or by courier, service shall be conclusively deemed made at the time of such personal service or refusal to accept service;

(c) to post "For Sale, Rent, or Lease" signs during any period;

(d) to show the PREMISES to prospective agents, buyers or tenants, at any time during the term;

(e) to maintain, improve or perform repairs, which are LANDLORD'S obligation under this Lease and to do any other act necessary for the safety or preservation of the PREMISES;

(f) to erect scaffolding and protective barricade about the PREMISES, but not obstruct entry to the PREMISES.

LANDLORD shall conduct his activities on the PREMISES in a manner that will cause the least inconvenience to TENANT. LANDLORD shall not be liable in any manner for any disturbance, inconvenience, loss of business, nuisance or other damage arising out of LANDLORD'S entry onto the PREMISES, as provided herein. TENANT shall not be entitled to an abatement or reduction of rent if LANDLORD exercises any rights reserved in this Article 23. For the aforesaid purposes, LANDLORD shall, without liability to TENANT, have the right to use any means that LANDLORD may deem proper, to obtain entry to the PREMISES. Entry to the PREMISES obtained by LANDLORD, by any reasonable means, shall not be construed to be an unlawful entry into the PREMISES or an eviction of TENANT.

24. ASSIGNMENT AND SUBLETTING.

24.1 RESTRICTIONS. TENANT shall not assign, mortgage, hypothecate or encumber TENANT'S interest in this Lease or the PREMISES, or sublease all or any portion thereof, or allow any other person or entity (except TENANT'S authorized representatives, employees or invitees) to occupy any part of the PREMISES, without prior written consent of the LANDLORD, which shall not be unreasonably withheld nor automatically granted. TENANT agrees and acknowledges that LANDLORD shall have no express or implied duty, whatsoever, to consent to any such assignment, encumbrance or sublease and that LANDLORD may reasonably withhold such consent. The consent by LANDLORD, to any matter or event requiring LANDLORD'S consent, shall not constitute a waiver of the necessity for consent to any subsequent matter or event. Any attempt at voluntary or involuntary assignment, encumbrance or subletting, without consent of LANDLORD, shall be void and shall constitute a material breach of this Lease. TENANT shall pay all expenses, including administration charges and reasonable attorneys' fees that may be incurred by LANDLORD, in administering any request of TENANT, for LANDLORD'S consent. If this Lease be assigned, or if the PREMISES or any part thereof be sublet or occupied by any one other than TENANT, LANDLORD may collect rent from the assignee, SUBTENANT or occupant and apply the net amount collected to the rent herein reserved. However, no such assignment, subletting, occupancy or collection shall be deemed a waiver of this Paragraph 24.1; nor shall the acceptance of the assignee, SUBTENANT or occupant as TENANT, be deemed a release of TENANT from the further performance by TENANT, of covenants on the part of TENANT herein contained, unless expressly released by LANDLORD in writing. No interest of TENANT, in this Lease, shall be assignable by involuntary assignment through operation of law (including without limitation the transfer of this Lease by testacy or intestacy).

Sub-leasing of 30% or more of the PREMISES shall be deemed an assignment within the meaning of this Paragraph 24.1. In addition, TENANT agrees that if TENANT assigns this Lease or sub-leases PREMISES for a greater rent than TENANT is obligated to pay hereunder, all rent payable to TENANT, pursuant to such assignment or sub-lease, including any increased rent or other cash consideration paid to TENANT by any assignee or SUB-TENANT, as consideration for such assignment or sublease, shall be the property of LANDLORD and shall be paid to LANDLORD by TENANT or, at LANDLORD'S option, shall be paid directly to LANDLORD by such assignee or sub-tenant. **LANDLORD may require a Five (5)% rent acceleration, upon sale of the business, a percentage of the business or assignment of this Lease (voluntary, involuntary or by operation of law) under this Article 24.** In the event of an assignment, any and all Base or Additional Rent, deferred throughout the entire term and any extensions hereof, shall become due and payable to the LANDLORD.

24.2 CHANGE IN CORPORATE ENTITY. If TENANT exists as a partnership, the withdrawal or change (voluntary, involuntary or by operation of law) of any partner, or the dissolution of the partnership, or the sale of at least forty percent (40%) of the business or value of the assets of TENANT, shall be deemed a voluntary assignment. If TENANT consists of more than one person, a purported assignment (voluntary, involuntary or by operation of law), from one person to the other, shall be deemed a voluntary assignment. If TENANT is a corporation, the issuance of any additional stock and/or the transfer, assignment or hypothecation of any stock or interest in such corporation, in the aggregate in excess of twenty-five percent (25%), or any dissolution, merger, consolidation or other reorganization of TENANT, or sale or other transfer of a controlling percentage of the capital stock of TENANT, or the sale of at least forty percent (40%) of the value of the assets of TENANT, shall be deemed a voluntary assignment. The phrase "controlling percentage" means ownership of and right to vote stock, possessing at least fifty percent (50%) of the total combined voting power of all classes of TENANT'S capital stock issued, outstanding and entitled to vote for election of directors. This Paragraph 24.2 shall not apply to corporations, the stock of which is traded through an exchange or over the counter.

24.3 SUB-TENANCIES. The voluntary or other surrender of this Lease, by TENANT, or mutual cancellation thereof, or the termination of this Lease by LANDLORD, pursuant to any provision contained

herein, shall not work a merger and, at the option of LANDLORD, shall either terminate any or all existing sub-leases or sub-tenancies or operate as an assignment to the LANDLORD, of any and all such sub-leases or sub-tenancies.

24.4 SUB-TENANT RENT. Rents received by TENANT, from it's sub-tenants or assignee, for monthly rent or in excess of the rent payable by TENANT to LANDLORD, under this Lease, or any cash consideration paid to TENANT in consideration of the assignment of the Lease, shall be the property of LANDLORD and shall be paid to LANDLORD by TENANT or, at LANDLORD'S option, shall be paid directly to LANDLORD by such assignee or sub-tenant.

24.5 RELEASE OF TENANT. In the absence of an express written agreement, executed by LANDLORD to the contrary, no assignment, mortgage, pledge, hypothecation, encumbrance or sub-letting hereunder, shall release TENANT from any of the terms, covenants and conditions of the Lease.

24.6 INCREASE IN RENT. In the event TENANT shall assign its interest in this Lease, through sale of business, an interest in business, change in corporate entity or sublet of 30% or more of the PREMISES, the Base Rent, specified in Paragraphs 4.1 and 4.4, may be increased, effective as of the date of such assignment or subletting, to the highest of:

(a) an amount equal to the total of the Base Rent, plus 50% of any increase amount of the rentals payable by any such assignee or sub-tenant, pursuant to such assignment or sub-lease; or;

(b) an amount equal to the total of the base annual rent, plus five percent (5%) of Base Rent, required to be paid by the TENANT pursuant to this Lease. In no event shall the Base Rent, after such assignment or subletting, be less than the Base Rent payable immediately prior thereto. Subsequent annual rent increases shall be calculated upon new Base Rent.

25. PEACEFUL POSSESSION.

Subject to provisions of this Lease and conditioned upon performance of all provisions to be performed by TENANT hereunder, LANDLORD covenants quiet enjoyment in the PREMISES unto and shall secure to TENANT, during the Lease term, the peaceful possession of the PREMISES.

26. SUBORDINATION.

LANDLORD shall have the right to subject and subordinate this Lease, to the lien of any loans or mortgages hereafter upon LANDLORD'S interest in the PREMISES, and upon the lands and buildings of which the PREMISES are a part. Upon LANDLORD'S request, TENANT will execute and deliver an instrument subjecting this Lease to the lien of any such loan or mortgage. If LANDLORD defaults in making payment under any mortgage or mortgages, or if LANDLORD is in breach or in default of any such mortgage or mortgages in any respect, TENANT shall have the right to make all rental payments, thereafter becoming due under the Lease, to the mortgage in lieu of LANDLORD and payments so made shall discharge the obligation of TENANT hereunder, respecting the payment of rent. Should LANDLORD, in connection with the mortgaging of the property of which the PREMISES are a part, execute a conditional assignment of rents, TENANT will execute an acceptance of such assignment, provided the assignment recognizes TENANT'S rights hereunder. In the event TENANT does not execute necessary documents pursuant to this Article 26 within ten (10) days of presentation by LANDLORD, TENANT does hereby appoint the LANDLORD as attorney-in-fact, to execute such document on behalf of TENANT.

26.1 NONSUBORDINATION. LANDLORD'S interest in this Lease, and/or the PREMISES, shall not be subordinate to any encumbrances placed upon the PREMISES by, or resulting from, any act of TENANT and nothing contained herein shall be construed to require such subordination by LANDLORD. NOTICE IS HEREBY GIVEN THAT TENANT IS NOT AUTHORIZED TO PLACE, OR ALLOW TO BE PLACED, ANY LIEN, MORTGAGE, DEED, TRUST OR ENCUMBRANCES OF ANY KIND UPON ALL, OR ANY PART, OF THE PREMISES OR TENANT'S LEASEHOLD INTEREST THEREIN AND ANY SUCH PURPORTED TRANSACTION SHALL BE VOID. FURTHERMORE, ANY SUCH PURPORTED TRANSACTION SHALL BE DEEMED A TORTIOUS INTERFERENCE WITH LANDLORD'S RELATIONSHIP WITH TENANT AND LANDLORD'S FEE OWNERSHIP OF THE PREMISES.

27. ESTOPPEL CERTIFICATE / OFFSET STATEMENT.

Each party shall, at the reasonable request of the other, upon not less than fifteen (15) days prior written notice from the requesting party, execute, acknowledge and deliver to the requesting party, a statement in writing certifying that this Lease is unmodified (or state the modifications) and in full force and effect, the date to which the rent and other charges are paid in advance, if any, and acknowledging that there are not, to such party's knowledge, any uncured defaults on the part of the other party hereunder or specifying such defaults, if any are claimed. Any prospective purchaser or encumbrancer of the PREMISES may conclusively rely upon any such statement. The requesting party will bear reasonable expenses. If TENANT shall fail to deliver a certificate, within 15 days following a request by LANDLORD, in accordance with the provisions of Articles 26 and 27, TENANT appoints LANDLORD as its attorney-in-fact to execute and deliver the certificate to any such third party, it being stipulated that such power of attorney is coupled with an interest and is irrevocable and binding.

28. TRANSFER BY LANDLORD.

During the term of this Lease, if LANDLORD transfers fee title or conveys its interest in the PREMISES or this Lease, then from and after the effective date of such conveyance, LANDLORD shall be released and discharged from any and all further obligations and responsibilities under this Lease, provided that any funds in the hands of LANDLORD in which TENANT has an interest, including the security deposit, shall be delivered to the grantee. The obligations to be performed by LANDLORD, contained in this Lease, shall be binding on LANDLORD'S successors and assigns, only during their respective periods of ownership.

29. NOTICES.

Any notice required or permitted to be given hereunder shall be in writing and may be served personally, by facsimile, electronic PDF or by regular mail, addressed to LANDLORD and TENANT respectively at the addresses set forth after their signatures at the end of this Lease. For any legal action taken by LANDLORD, written notice may be served personally or by direct attachment to PREMISES and/or delivered by registered mail to mailing or residence

address, if the TENANT cannot be located in person. Either party hereto may, from time to time, change its mailing address upon ten (10) days written notice to the other.

30. SUCCESSORS AND ASSIGNS.

The terms, covenants and conditions herein contained shall inure to the benefit of, and be binding upon, the heirs, administrators, executors, successors and assigns of each of the parties hereto. This Lease shall be binding upon all assignees, SUBTENANTS, licensees and concessionaires of TENANT.

31. FORCE MAJEURE.

Whenever a period of time is appointed, in which either party is required to complete any act or matter, the time for the completion thereof by such party shall be extended by a period of time equal to the number of days during which the completion of such act is unreasonably interfered with, because of labor disputes, acts of terrorism, civil commotion, war, warlike operations, sabotage, governmental regulations or control, fire or other casualties, inability to obtain any material or to obtain fuel or energy, weather, acts of God or other acts beyond such parties reasonable control (financial inability excepted). However, nothing contained herein shall excuse TENANT from the prompt payment of any rent or charge required of TENANT, nor excuse TENANT from the performance of any of the covenants set forth herein.

32. REMEDIES CUMULATIVE.

The various rights, options, elections and remedies of LANDLORD and TENANT, contained in this Lease, shall be cumulative and no one of them shall be construed as exclusive of any other or of any right, priority or remedy allowed, or provided for, by law and not expressly named in this Lease.

33. ATTORNEYS' FEES.

In the event that any legal proceedings, including Constable fees, are necessary to enforce the terms of this Lease, LANDLORD shall be entitled to recover from TENANT all costs and expenses of such proceedings, including reasonable attorneys' fees and expenses, whether or not any proceedings are prosecuted to judgment. In the event of the bringing of any other action by either party hereto, or by reason of the breach of any term, covenant or condition on the part of the other party, or arising out of this Lease; the prevailing party shall be entitled to recover from the other party, reasonable attorneys' fees to be fixed by the court which renders such judgment.

34. NO PARTNERSHIP.

LANDLORD shall not in any way, or for any purpose, be deemed a partner or a member of any joint enterprise with TENANT. TENANT'S surrender of this Lease, or a mutual cancellation thereof, shall not result in a merger of LANDLORD'S and TENANT'S estates, and shall, at the option of LANDLORD, either terminate any existing subleases or operate as an assignment to LANDLORD of all of such subleases.

35. REMOVAL OF PROPERTY.

Upon the expiration of the term of this Lease, or upon any earlier termination thereof, TENANT shall remove, at its own expense, all trade fixtures, equipment, merchandise and personal property (collectively called "TENANT Property" in this Lease) which are installed by TENANT or any SUBTENANT, concessionaire or licensee in or upon the PREMISES; but if TENANT is in default, TENANT shall not remove TENANT Property, unless notified by LANDLORD so to do. In case of any injury or damage to the building or any portion of the PREMISES, resulting from the removal of TENANT Property, TENANT shall promptly repair or pay to LANDLORD the cost of repairing such injury or damage (including damage from sign removal). TENANT shall be liable for pro-rated payment of rent, until PREMISES are vacated (in clean condition and good repair) and keys returned to LANDLORD, as provided herein. TENANT shall complete such removal by the time provided in this Article 35 and any TENANT Property not so removed from the PREMISES by TENANT, may be construed by LANDLORD as abandoned by TENANT and title thereto shall thereupon vest in LANDLORD, without the execution of documents of sale or conveyance by TENANT. LANDLORD may also order TENANT to remove such TENANT Property from the PREMISES or alternatively have it removed and stored at TENANT'S expense in a public warehouse. TENANT shall pay upon demand, to LANDLORD the actual expense of such removal and storage, together with interest from the date of payment by LANDLORD, until repayment by TENANT.

36. INTERPRETATION.

The captions, by which the Articles and Paragraphs of this Lease are identified, are for convenience only and shall not affect the interpretation of this Lease. Where the context so requires, the singular and/or neuter gender shall include the plural, masculine and feminine genders. If there is more than one signatory hereto as TENANT, the liability of such signatories shall be joint and several.

37. SEVERABILITY.

The invalidity of any provision of this Lease as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof. The waiver by either party hereto, of any breach of any term, covenant or condition of this Lease to be performed by the other, shall not be deemed to be a waiver of any subsequent breach thereof.

38. CONSENT OF LANDLORD.

LANDLORD shall not be deemed to have given any assent or consent to any matter, requiring LANDLORD'S prior consent, unless such consent is in writing.

39. WAIVER AND AMENDMENT.

No provision of this Lease shall be deemed waived or amended, except by a written instrument unambiguously setting forth the matter waived or amended and signed by both parties, including the party against

which enforcement of such waiver is sought. Waiver of any matter shall not be deemed a waiver of the same or any other matter, on any future occasion.

40. SURVIVAL OF OBLIGATIONS.

The provisions of this Lease, with respect to any obligation of TENANT to pay base rent, additional rent or any sum owing during the Term hereof, or to perform any act after the expiration or other termination of this Lease, shall survive the expiration or other termination of this Lease.

41. ENTIRE AGREEMENT.

This Lease contains the entire agreement between the parties hereto and no representations, inducements, promises or agreements (oral or otherwise), entered into prior to the execution of this Lease, will alter the covenants, agreements and undertakings herein set forth. This Lease cannot be modified in any respect, except by an instrument in writing, executed by LANDLORD and TENANT.

42. TIME OF ESSENCE.

Time is of the essence, in all provisions contained herein.

43. RECORDING.

TENANT shall not record this Lease, without LANDLORD'S prior written consent, and such recordation shall, at the option of LANDLORD, constitute a non-curable default of TENANT, hereunder.

44. COVENANTS AND CONDITIONS.

Each provision of this Lease performable by TENANT shall be deemed both a covenant and a condition.

45. CHOICE OF LAW.

The laws of the State of Nevada shall govern this Lease.

46. CORPORATE AUTHORITY / GUARANTY OF LEASE.

If TENANT is a Corporation, Limited Liability Company ("LLC"), Limited Partnership ("LP") or General Partnership ("GP"), each individual executing this Lease, on behalf of said Corporation, LLC, LP or GP, represents and warrants that he is duly authorized to execute and deliver this Lease, on behalf of said legal entity, in accordance with the duly adopted resolution of the board of directors, managers or general partners of said legal entity, or in accordance with the bylaws of said legal entity, and that this Lease is binding upon said legal entity in accordance with the terms. If TENANT is a corporation, TENANT shall, within thirty (30) days after execution of this Lease, deliver to LANDLORD a certified copy of the resolution of the board of directors of said corporation authorizing or ratifying the execution of this Lease. A Guaranty of Lease executed by the Chief Executive Officer, Managing Members or General Partners is required for this Lease, which must be executed simultaneously with Lease documents and attached hereto as "EXHIBIT A", (if applicable).

47. OFAC REPRESENTATION.

Each Party/Entity hereto, represents and warrants to the other that:

A. Each Person owning a ten percent (10%) or greater interest in such entity is (i) not currently identified on the Specifically Designated Nationals and Blocked Persons List, maintained by the Office of Foreign Assets Control, Department of the Treasury ("OFAC") and/or any other similar list maintained by the OFAC, pursuant to any authorizing statute, executive order or regulation ("List") and (ii) is not a Person with whom an American citizen is prohibited to engage in transactions by any trade embargo, economic sanction or other prohibition of U.S. law, regulation or Executive Order of the President of the United States.

B. Each party has implemented procedures and will consistently apply those procedures, to ensure the foregoing representations and warranties remain true and correct at all times. Each party shall comply with all requirements of law relating to money laundering, anti-terrorism, trade embargos and economic sanctions, now or hereafter in effect, and shall use reasonable efforts to notify the other in writing if any of the forgoing representations, warranties or covenants are no longer true or have been breached or if such party has a reasonable basis to believe that they may no longer be true or have been breached.

In addition, at the request of LANDLORD, TENANT shall provide such information as may be requested to determine TENANT'S compliance with the terms hereof.

48. LEGAL COUNSEL.

TENANT acknowledges that it has received, read and understood this Lease, consulting with legal counsel as needed for clarification. Accordingly any rule of law, providing that ambiguities shall be construed against the drafting party, shall be of no force and effect. TENANT further acknowledges that nothing in this Lease creates, or shall be deemed to have created, a fiduciary relationship between LANDLORD and TENANT.

49. CONFIDENTIALITY.

TENANT agrees to maintain in confidence and not to disclose to any third party, the information contained in this Lease, except as provided herein. However, TENANT may disclose such information; (i) to such party's accountants, attorneys, insurance agents, prospective lenders, and other advisors, in connection with the transaction contemplated by this Lease (collectively "Representatives"), to the extent that such Representatives reasonably need to know such information in order to assist and perform services on behalf of TENANT, (ii) to the extent required by any law or court order, (iii) in connection with any securities filings, registration statements or similar filings undertaken by TENANT; and (iv) in connection with any litigation that may arise between the parties in connection with the transactions contemplated by this Lease. TENANT hereby agrees that any breach of any of its obligations, under this Article 49, will cause irreparable harm to LANDLORD, which harm cannot be adequately compensated for by monetary damages, and will constitute an immediate default hereunder. Accordingly, in the event of such a breach, LANDLORD, in addition to whatever other remedies are or might be available in this Lease, at law or in equity, shall

have the right to either compel specific performance by, or to obtain injunctive relief against, TENANT with respect to any such breach.

50. DISCLOSURE.

TENANT acknowledges LANDLORD'S disclosure, that the Managing Members of 1807 WC LLC are Real Estate Licensees. Nevada Real Estate Division Form 525, "Duties Owed by a Nevada Real Estate Licensee", is attached hereto as "ADDENDUM A", as required by law.

IN WITNESS WHEREOF, on the day and year first above written, LANDLORD and TENANT have duly executed this Lease.

TENANT:
OMNIA PHARMACY INC

BY: _____
Aly Molokhia
Title: President
211 E Becon St Unit A
Alhambra, CA 91801
480-577-7919 direct

ADDRESS:
1807 W Charleston Blvd. Suite 110
Las Vegas, NV 89102
480-444-6612 Sam (Manager)

alymolokhia@hotmail.com
evergreenpharmacy20c@gmail.com

LANDLORD:
1807 WC LLC

BY: _____
Adele Josephs Matthews
Title: Managing Member

ADDRESS:
5395 Polaris Ave. Suite #100
Las Vegas, NV 89118
(702) 385-2474 phone
(702) 385-5275 fax

josephsproperties@yahoo.com
jackie@josephsproperties.com

State of
County of

This instrument was acknowledged before me on _____ by

_____.

_____
Signature of Notarial Officer

Notarial Seal

State of
County of

This instrument was acknowledged before me on _____ by

_____.

_____
Signature of Notarial Officer

Notarial Seal

GUARANTY OF LEASE

WHEREAS, a certain Lease dated December 10, 2021 herewith has been executed by and between 1807 WC LLC, a Nevada Limited Liability Company therein and herein referred to as "Landlord", and ALY MOLOKHIA, President d/b/a OMNIA PHARMCY INC, A Nevada Corporation therein and herein referred to as "Tenant", covering certain premises in the City of LAS VEGAS, County of CLARK, State of NEVADA; and

WHEREAS, the Landlord under said Lease requires as a condition to its execution of said Lease that the undersigned guarantee the full performance of the obligations of Tenant under said Lease; and

WHEREAS, the undersigned is desirous that Landlord enter into said Lease with Tenant.

NOW, THEREFORE, in consideration of the execution of said Lease by Landlord, the undersigned hereby unconditionally guarantees the full performance of each and all of the terms, covenants and conditions of said Lease to be kept and performed by said Tenant, including the payment of all rentals and other charges to accrue thereunder. The undersigned further agrees as follows:

1. That this covenant and agreement on its part shall continue in favor of Landlord notwithstanding any extension, modification, or alteration of said Lease entered into by and between the parties hereto, or their heirs, successors or assigns, or notwithstanding any assignment of said Lease, with or without the consent of Landlord, and no extension, modification, alteration or assignment of the above referred to Lease shall in any manner release or discharge the undersigned and it does hereby consent thereto.

2. This Guaranty will continue unchanged by any bankruptcy, reorganization or insolvency of Tenant or any successor or assignee thereof or by any disaffirmance or abandonment by a trustee of Tenant.

3. Landlord may, without notice, assign this Guaranty in whole or in part and no assignment or transfer of the Lease shall operate to extinguish or diminish the liability of the undersigned hereunder.

4. The liability of the undersigned under this Guaranty shall be primary and that in any right of action, which shall accrue to Landlord under the Lease. Landlord may, at its option, proceed against the undersigned without having commenced any action, or having obtained any judgment against Tenant.

5. To pay Landlord's reasonable attorneys' fees and all costs and other expenses incurred in any collection or attempted collection or in any negotiations relative to the obligations hereby guaranteed or enforcing this Guaranty against the undersigned, individually and jointly.

6. That it does hereby waive notice of any demand by Landlord, as well as any notice of default in the payment of rent or any other amounts contained or reserved in the Lease.

The use of the singular herein shall include the plural. The obligation of two (2) or more parties shall be joint and several. The terms and provisions of this Guaranty shall be binding upon and inure to the benefit of the respective successors and assigns of the parties herein named.

IN WITNESS WHEREOF, the undersigned has caused this Guaranty to be executed as of the date set forth on page one of this Lease.

By: _____ Date: _____

Aly Molokhia, Guarantor

DUTIES OWED BY A NEVADA REAL ESTATE LICENSEE

This form does not constitute a contract for services nor an agreement to pay compensation.

In Nevada, a real estate licensee is required to provide a form setting forth the duties owed by the licensee to:

a) Each party for whom the licensee is acting as an agent in the real estate transaction, and
b) Each unrepresented party to the real estate transaction, if any.

Licensee: The licensee in the real estate transaction is Shelly Tabaczynski whose license number is S.0075910. The Licensee is acting for 1807 WC LLC who is/are the [X] Seller/Landlord; [ ] Buyer/Tenant.

Broker: The broker is Adele Josephs, whose company is Josephs Properties.

Are there additional licensees involved in this transaction? **[X] Yes [ ] No If yes, Supplemental form 525A is required.**

Licensee's Duties Owed to All Parties:

A Nevada real estate licensee shall:

1. Not deal with any party to a real estate transaction in a manner which is deceitful, fraudulent or dishonest.
2. Exercise reasonable skill and care with respect to all parties to the real estate transaction.
3. Disclose to each party to the real estate transaction as soon as practicable:
   a. Any material and relevant facts, data or information which licensee knows, or with reasonable care and diligence the licensee should know, about the property.
   b. Each source from which licensee will receive compensation.
4. Abide by all other duties, responsibilities and obligations required of the licensee in law or regulations.

Licensee's Duties Owed to the Client:

A Nevada real estate licensee shall:

1. Exercise reasonable skill and care to carry out the terms of the brokerage agreement and the licensee's duties in the brokerage agreement;
2. Not disclose, except to the licensee's broker, confidential information relating to a client for 1 year after the revocation or termination of the brokerage agreement, unless licensee is required to do so by court order or the client gives written permission;
3. Seek a sale, purchase, option, rental or lease of real property at the price and terms stated in the brokerage agreement or at a price acceptable to the client;
4. Present all offers made to, or by the client as soon as practicable, unless the client chooses to waive the duty of the licensee to present all offers and signs a waiver of the duty on a form prescribed by the Division;
5. Disclose to the client material facts of which the licensee has knowledge concerning the real estate transaction;
6. Advise the client to obtain advice from an expert relating to matters which are beyond the expertise of the licensee; and
7. Account to the client for all money and property the licensee receives in which the client may have an interest.

Duties Owed By a broker who assigns different licensees affiliated with the brokerage to separate parties. Each licensee shall not disclose, except to the real estate broker, confidential information relating to client.

Licensee Acting for Both Parties:

The Licensee
MAY [_____/_____] OR MAY NOT [_____/_____]
in the future act for two or more parties who have interests adverse to each other. In acting for these parties, the licensee has a conflict of interest. Before a licensee may act for two or more parties, the licensee must give you a "Consent to Act" form to sign.

I/We acknowledge receipt of a copy of this list of licensee duties, and have read and understand this disclosure.

~~*Seller*~~/*Landlord*: _____ *Date*: _____ *Time*: _____

~~*Seller*~~/*Landlord*: _____ *Date*: _____ *Time*: _____

OR

~~*Buyer*~~/*Tenant*: _____ *Date*: _____ *Time*: _____

~~*Buyer*~~/*Tenant*: _____ *Date*: _____ *Time*: _____

SUPPLEMENTAL LIST OF LICENSEES PARTY TO THE
DUTIES OWED BY A NEVADA REAL ESTATE LICENSEE

This form does not constitute a contract for services nor an agreement to pay compensation.

Licensee: Shelly Tabaczynski, is acting for 1807 WC LLC.

Broker: Adele Josephs.

Additional licensees on this transaction, listed below, are subject to NRS 645.252, NRS 645.254, and the Duties Owed By A Nevada Real Estate Licensee:

NAME	LICENSE NUMBER
Diana Z Josephs	S.0026129
Jennifer Josephs	S.0063896
Ariel R Matthews	S.0186935

I/We acknowledge receipt of a copy of this Supplemental List of Licensees.

~~*Seller*~~/*Landlord*: _____ *Date*: _____ *Time*: _____

~~*Seller*~~/*Landlord*: _____ *Date*: _____ *Time*: _____

OR

~~*Buyer*~~/*Tenant*: _____ *Date*: _____ *Time*: _____

~~*Buyer*~~/*Tenant*: _____ *Date*: _____ *Time*: _____

Approved Nevada Real Estate Division
525 Replaces all previous versions

Revised 11/7/16

PHARMACY ADDENDUM TO LEASE

This Addendum ("Addendum") is made to that certain 1807 W Charleston Commercial Lease dated December 10, 2021 ("the Lease") by and between 1807 WC LLC, hereinafter ("LANDLORD") and Aly Molokhia, President d/b/a Omnia Pharmacy Inc, hereinafter ("TENANT"), with regard to the following:

A. LANDLORD is the Owner of that certain real property located at 1807 W Charleston Blvd Suite 110 Las Vegas, NV 89102, in which TENANT has Leased approximately 1,215 square feet (the Leased PREMISES"); and
B. LANDLORD and TENANT desire to clarify the Lease with respect to LANDLORD'S ability to access the Leased PREMISES.

NOW THEREFORE, in consideration of the above facts, the mutual covenants and conditions below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree to as follows:

LANDLORD and TENANT, notwithstanding any to the contrary contained in Article 23 of the Lease, or any other term contained therein, and hy way of clarification of the LANDLORD'S right to enter the Leased PREMISES, (i) neither LANDLORD nor any agent of LANDLORD may enter or remain in the Leased PREMISES unless a registered pharmacist or authorized representative of LANDLORD is present at all times, and (ii) no person, other than a pharmacist or authorized representative of LANDLORD, may have possession of a key to the Leased PREMISES. Nothing contained herein shall be construed as an impediment preventing LANDLORD from taking such action as may be reasonable and necessary to protect its property and the safety of its TENANTS, therefore, LANDLORD may have access to a key to the Leased PREMISES secured in a tamper-proof container, available to LANDLORD if emergency entry is required. In the event of an inconsistency between the language set forth herein and that contained in the Lease, the language of this Addendum shall control.

In all other regards, the Lease including any other Addenda thereto remains unchanged, and enforceable according to its terms. In the event of any conflict between the previsions of this Addendum and the printed provisions of the Lease, or any other addendum or addenda, this Addendum shall control.

IN WITNESS WHEREOF, LANDLORD and TENANT have caused this Addendum to be executed.

LANDLORD: 1807 WC LLC

By: _____ Date: _____
Adele Josephs Matthews, Managing Member

TENANT: OMNIA PHARMACY INC

By: _____ Date: _____
Aly Molokhia, President

4CC

This matter has been continued to a future Board Meeting.

4DD

This matter has been continued to a future Board Meeting.

4EE

This matter has been continued to a future Board Meeting.

4FF

This matter has been continued to a future Board Meeting.

4GG

This matter has been continued to a future Board Meeting.

4HH

This matter has been continued to a future Board Meeting.

411

This matter has been continued to a future Board Meeting.

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 (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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH 04323	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics

Physical Address: 10 Herman Avenue Ext., Suite C

City: Asheville State: NC Zip: 28803

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-768-4092 Toll Free # (NAC 639.708, NRS 639.23286): 888-768-4092

Fax: 844-230-5200 Contact Email: kbshort@allergypartners.com

Website: www.allergypartners.com

Nevada Business License # (if applicable) NV20201713398

Supervising/Managing Pharmacist Name (NRS 639.220): Kelly Bridgers Short

Supervising/Managing Pharmacist NV Pharmacist Registration #: Temporary Pharmacist Registration Applied For

Type of Pharmacy (check all applicable)

- ☐ Retail/Community
- ☐ Hospital (# beds _____)
- ☐ Internet
- ☐ Nuclear
- ■ Other: Nonresident

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: Home Infusion

Days of Operation

■ Monday ■ Tuesday ■ Wednesday ■ Thursday ■ Friday ☐ Saturday ☐ Sunday

On Saturday and Sunday, the pharmacy is closed, but an on-call pharmacist who has access to patient record is available through the toll-free number 24/7.

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: Kelly Bridgers Short	NV Pharmacist Registration #: Applied For
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: North Carolina

Parent Company (if any): N/A

Corporation/Organization Name: Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics

Mailing Address: 1978 Hendersonville Road, Suite 130

City: Asheville State: NC Zip: 28803

Telephone: 828-277-1300 Email: kbshort@allergypartners.com

Contact Person Name: David Brown

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 President (title) for Allergy Partners, PLLC d/b/a Allergy Partners / Therapeutics (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 Brown

Print Name of Authorized Person

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

11/9/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, David Brown 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 Allergy Partners, PLLC d/b/a Allergy Partners /Therapeutics (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 4th day of November, 20 21

Notary Public

JENNIFER J. KILLOUGH
NOTARY PUBLIC
McDowell County
North Carolina
My Commission Expires July 15, 2024

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: N/A Pharmacist Registration #: _____

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

_____ 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.

_____ 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.

_____ 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.

_____ 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)).

_____ 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

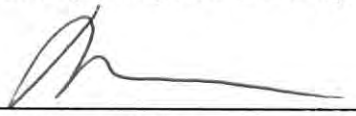
Personal and Professional History	**Yes**	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		
2. Have you been charged, arrested, or convicted 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)

11/4/2021

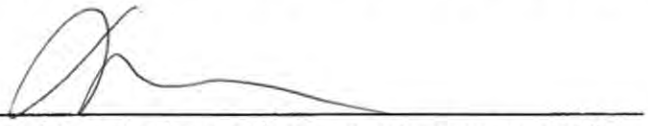
Date

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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded** - The top 4 shareholder/stockholders. b. **For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

David Brown, 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)

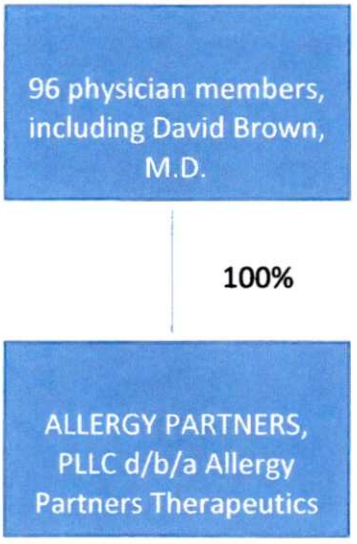
11/4/2021

Date

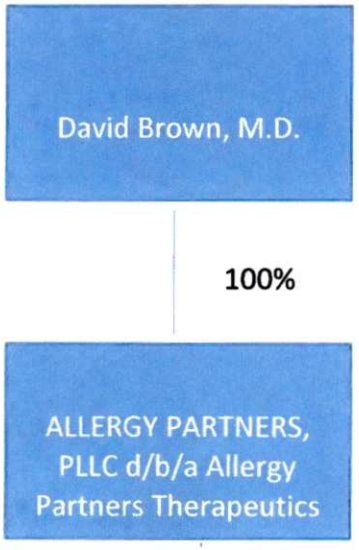
Board Use Only	Date Received: _____	Amount: $500 check 442923

Exhibit A

Before Effective Date:



As of Effective Date:



ALLERGY PARTNERS, PLLC
d/b/a Allergy Partners Therapeutics
10 Herman Avenue Extension, Suite C
Asheville, NC 28803

VIA OVERNIGHT DELIVERY

November 4, 2021

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

Re: Pharmacy Application for Change of Ownership
Nonresident Pharmacy License PH04323

Dear Sir/ Madam:

We hereby enclose an Application for a Nonresident Pharmacy Application for Change of Ownership with respect to Nonresident Pharmacy License PH04323. We are also enclosing a Temporary Pharmacist Registration Request Application for Kelly B. Short, the supervising/ managing pharmacist. Please note that Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics ("Allergy Partners") has not dispensed any prescriptions into the State of Nevada pursuant to its existing license.

Allergy Partners is currently owned by 96 members. As a result of a transaction, David Brown, one of the current 96 members, will become the sole member and own one hundred percent (100%) of the issued and outstanding membership interests of Allergy Partners. Allergy Partners will continue to operate the pharmacy at the same location under its current name, Allergy Partners Therapeutics. The anticipated effective date of this transaction is December 1, 2021 (the "Effective Date"). An organizational chart showing the ownership of Allergy Partners before the Effective Date and as of the Effective Date is attached as Exhibit A.

Please note that there will not be a change in tax identification number of Allergy Partners, and there will not be a change in the entity that operates the pharmacy or a change in the pharmacy's address, personnel (including but not limited to the supervising/ managing pharmacist), policies and procedures, or operations as a result of this change of ownership.

If you have any questions, please contact Kelly B. Short, the supervising/ managing pharmacist, at 919-720-9432. Thank you for your assistance with this matter.

Sincerely,

David Brown, President

List all Officers and Directors

David A. Brown, M.D.	Director, President, CEO, Secretary
Stephen W. Shield, M.D.	Chairman of the Board
Gervinder K. Deogun, M.D.	Director
Nabeel N. Farooqui, M.D.	Director
Colin D. Freccia, M.D.	Director
Joel M. Hartman, M.D.	Director
Ingrid M. Hoffmann, M.D.	Director
Duane Keitel, M.D.	Director
Theodore T. Kim, M.D.	Director
Charles J. Lane, M.D.	Director
Adrienne M. Tiñana, M.D.	Director
Denise C. Yarborough, J.D.	General Counsel
Larry M. Armor	Chief Operating Officer
Jennifer Killough	Chief Financial Officer
Brad K. Powers	Chief Information Officer
William A. McCann, M.D.	Director, CMO, Vice President
R.G. Johnstone, M.D.	Treasurer

List <u>all stockholders</u> who hold 10% or more of the shares

David Brown, 100% owner

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(PROFESSIONAL LIMITED LIABILITY COMPANY)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

ALLERGY PARTNERS, PLLC

is a professional limited liability company duly formed under the laws of the State of North Carolina, having been formed on 25th day of September, 1979.

I FURTHER certify that, as of the date of this certificate, (i) the said professional limited liability company is not dissolved under the terms of its articles of organization, (ii) the said professional limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said professional limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 13th day of October, 2021.

Elaine F. Marshall

Secretary of State

Certification# 111365957-1 Reference# 17816493-ACH Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

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 Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics

Physical Address 10 Herman Ave Ext, Suite C

City Asheville State NC Zip 28803

Mailing Address (if different from physical address) ~~list Corporate Office?~~ NO KBM

City _____ State _____ Zip _____

Telephone 888-768-4092 Website www.allergypartners.com

Licensing Company Email _____

Section 2: Personal Information

First Kelly Middle Bridgers Last Short

Alias(es, nicknames, name changes, etc.) Kelly Bridgers Armstrong (Maiden)

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

Mailing Address [redacted] Glen Cove Road

City Arden State NC Zip 28704

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 KBM

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)		
New England College	Aug 2020 - Oct 2021		
Address	**City**	**State**	**Zip**
98 Bridge St	Henniker	NH	03242
Diploma/Degree obtained, if any			
MBA, Healthcare Management			

School Name	From - To (MM/YY – MM/YY)		
ECU - East Carolina University	Aug ~~2018~~ 2018 - Aug 2019		
Address	**City**	**State**	**Zip**
E 5th St	Greenville	NC	27858
Diploma/Degree obtained, if any			
—			

School Name	From - To (MM/YY – MM/YY)		
University of North Carolina at Chapel Hill	- 5/1999		
Address	**City**	**State**	**Zip**
301 Pharmacy Lane	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Doctorate of Pharmacy, PharmD.			

School Name	From - To (MM/YY – MM/YY)		
University of North Carolina at Chapel Hill	8/1988 - 5/1993		
Address	**City**	**State**	**Zip**
301 Pharmacy Lane	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Bachelors of Science, Pharmacy			

School Name	From - To (MM/YY – MM/YY)		
Plymouth High School	Aug/1984 - June/1988		
Address	**City**	**State**	**Zip**
860 East Main Street	Plymouth	NC	27962
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
07/20 - Present	[redacted] Glen Cove Rd	Arden	NC	28704
6/2008 / 07/20	1910 Stoneytrace Ct	Raleigh	NC	27614

Applicant's initials KPM

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: Allergy Partners Therapeutics			From - To (MM/YY – MM/YY): 8/2020 - present
Business Address: 10 Herman Avenue Ext, Suite C	City: Asheville	State: NC	Zip: 28803
Phone: 888-768-4092	Title: Pharmacy Manager		Number of Employed Hours: 2600
Description of Duties: Oversight of day to day pharmacy operations, prepare + dispense prescription medications, HR responsibilities - oversight technical support			

Business Name: Diplomat Specialty Infusion Group			From - To (MM/YY – MM/YY): 09/2019 - 12/2019
Business Address: 140 Northway Court	City: Raleigh	State: NC	Zip: 27615
Phone: 919-847-9001	Title: Staff Pharmacist - Contract short term		Number of Employed Hours: 520
Description of Duties: Prepared + dispensed specialty Pharmacy medications			

Business Name: UNC REX Hospital			From - To (MM/YY – MM/YY): 01/2011 - 09/2019
Business Address: 4420 Lake Boone Trail	City: Raleigh	State: NC	Zip: 27607
Phone: 919-784-3100	Title: Clinical Coordinator		Number of Employed Hours: 17960
Description of Duties: Clinical Pharmacist specializing in Surgery + Neurology hospital, decentralized practice Policy Development. HR oversight Pharmacist team			

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

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

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

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

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

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 # 1d3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
9/6/1997	11/17/97	NC	Wrightsville Beach	New Hanover County
Case #	**Governing, licensing, Arresting, Presiding Body/Agency/Court**			
97CR26985	Clerk of Superior Court Wilmington - NH Cty			
Reason/Charge				
possession of malt beverage on beach community sidewalk				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Martinez A - Wrightsville Bch Police	fine			
Name of Business/Industry/Entity				
self				

Provide explanation below:

see attached - letter/copy of case

Kelley B Short

Original Signature (electronic, copies or stamps not accepted)

11/2/21

Date

Applicant's initials KBS

STATE OF NORTH CAROLINA
GENERAL COURT OF JUSTICE
CLERK OF SUPERIOR COURT

JAN G. KENNEDY
EX OFFICIO JUDGE OF PROBATE

NEW HANOVER COUNTY
WILMINGTON

Marion Warren, DIRECTOR
Phyllis M. Gorham,
SENIOR RESIDENT JUDGE

RE: Armstrong, Kelly **FILE #:** 97CR26985

DOB: 9/7/1970 **OFFENSE DATE:** 9/6/1997

I, Shauna Nixon, ASST/DEP CLERK OF SUPERIOR COURT for NEW HANOVER COUNTY, NORTH CAROLINA do hereby certify that the case above has been destroyed or purged from our system, in record retention and disposition schedule of Archives and History, Department of Cultural Resources and endorsed by the Administrative Office of the Court.

WITNESS MY HAND AND SEAL THIS 11 DAY OF December, 2020.

Shauna Nixon

Asst/Dep Clerk of Superior Court

640 NEW HANOVER ICA INQUIRY 01 97CR 026985 FILM:
DISPOSED R S DOB/AGE CR FILING DATE: 103097
CITATION W F [redacted] DL#: [redacted] NC
ARMSTRONG,KELLY,BRIDGERS CIT#: C7810276 TRIAL DATE: 112597
[redacted] E GREENSBORO ST APT[redacted] CSLR: CSLRC: AM
WRIGHTSVILLE BE NC 28480 DEF ATTY: WAIVED TYP: W VRA:
CHG/ARRN OFFN: M POSS/CONS BEER/WINE PUBLIC ST LOCAL ORDINANC
COMPLAINANT: MARTINEZ,A CPD ISSUED: 090697 SERVED: 090697
OFFN DATE: 090697 ARRN DATE: MOTIONS DATE: DISP DATE: 111797
CONT. D: S: C: NR: INT?: FRM: RSONCO: GANG REL: DV CV: N

PLEA	VER	MOD	FINE	COSTS	WCC	REST	JUDGE	PAID	TO-BE-PAID
GU	GU	WM	$ 00010.00	$ 80.00		$		YES	

CONV OFFN: M POSS/CONS BEER/WINE PUBLIC ST LOCAL ORDINANC CAB:
SENT LEN: - SENT TYPE: CONS F/JGMT:
PROB: WITHDRAWN: APPEALED TO SUPERIOR:
AREA CD: ACCD: HWY: V LIC: TRANS TO SUPERIOR:
CDL: N CMV: N HAZ: N TRP/DIST: V ST: V TYP: APPELLATE:

ARREST DATE: CHECK DIGIT: SID: LID:
NEXT#: PF2 - NAME INQUIRY ADDTNL CHARGES:

A TRUE COPY
CLERK OF SUPERIOR COURT
NEW HANOVER COUNTY
BY: *Shauna L. Nixon*
Deputy Clerk of Superior Court

I, Kelly Short, **certify that as the designated representative for** Allergy Partners PLLC DBA Allergy Partners Therapeutics **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

Kelly Short
Print Name (First, Last)

Kelley B Short
Original Signature (electronic, copies or stamps not accepted)

11/2/21
Date

Applicant's initials KBS

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.

Kelly Short
Print Name (First, Last)

Kelly B Short — 11/4/21
Original Signature (electronic, copies or stamps not accepted) — Date

---

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

State of North Carolina, ss. County of Buncombe

I, Kelly Short, 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.

Kelly B Short — 11/4/21
Original Signature — **Date**

Subscribed and Sworn to before me this 4th day of November 2021

Brent A Jennings
Notary Public Signature

BRENT A JENNINGS
NOTARY PUBLIC
Buncombe County
North Carolina
My Commission Expires Nov. 25, 2023

(Seal)

Applicant's initials KBS

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: Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics

Physical Address: 10 Herman Avenue Ext. Suite C

City: Asheville State: NC Zip: 28803

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 888-768-4092 Website: www.allergypartners.com

Licensing Company Email: dbrown@allergypartners.com

Section 2: Personal Information

First: David Middle: Allen Last: Brown

Alias(es, nicknames, name changes, etc.): N/A

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

Mailing Address: [redacted] Busbee Road

City: Asheville State: NC Zip: 28803

Telephone: [redacted] Email: dbrown@allergypartners.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 _____

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)	
Clarke Central High School		09/1972-05/1974	
Address	City	State	Zip
Milledge Road	Athens	GA	30601
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina		08/1974-05/1976	
Address	City	State	Zip
Cameron Avenue	Chapel Hill	NC	27514
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Georgia		08/1976-05/1978	
Address	City	State	Zip
220 S. Jackson Street	Athens	GA	30602
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Medical College of Georgia		08/1978-05/1982	
Address	City	State	Zip
Laney Walker Blvd.	Augusta	GA	30904
Diploma/Degree obtained, if any			
MD			

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
10/1992-Present	[redacted] Busbee Road	Asheville	NC	28803
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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: Allergy Partners, PLLC			From - To (MM/YY – MM/YY): 08/1987-Present
Business Address: 1978 Hendersonville Road, Suite 130A	City: Asheville	State: NC	Zip: 28803
Phone: 828-277-1300	Title: 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)	
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 _____

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)

11/4/2021
Date

Applicant's initials _____

Allergy Partners, PLLC d/b/a Allergy Partners Therapeutics ("AP") is a physician practice that specializes in allergy, asthma, and immunology. It was originally incorporated in 1979. It has more than 100 locations in 17 states. In June 2020, AP first obtained a pharmacy permit from the State of North Carolina and is now licensed in 16 states, including the State of Nevada. (Note that AP has not dispensed any prescriptions into the State of Nevada).

AP has not been involved in any lawsuits, arbitrations, administrative proceedings or other actions related to its pharmacy operations, the practice of pharmacy, prescription drugs and/or controlled substances. AP has not been the subject of any administrative proceeding by a state pharmacy board or a state medical board. As would be anticipated for a business of its size, AP has been involved from time to time in lawsuits and arbitrations related to its physician practice operations, including commercial disputes, employment matters, and actions alleging professional malpractice unrelated to the pharmacy. AP has not filed for bankruptcy at any time.

Dr. Brown joined the practice in 1987 and currently serves as its president. (Note that Dr. Brown does not have a Nevada medical license.) He has not been involved individually in any lawsuits, arbitrations, administrative proceedings or other actions related to pharmacy operations, the practice of pharmacy, prescription drugs and/or controlled substances. Dr. Brown has not been the subject of any administrative proceeding by a state pharmacy board or a state medical board nor has he filed for bankruptcy. From time to time, in his capacity as president of AP, he has been named as a plaintiff or defendant in lawsuits and arbitrations involving AP's physician practice operations.

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 A Brown, MD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/4/2021

Date

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

State of North Carolina, ss. County of Buncombe

I, David A. 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

11/4/2021

Date

Subscribed and Sworn to before me this 4 day of November 2021

Notary Public Signature

JENNIFER J. KILLOUGH
NOTARY PUBLIC
McDowell County
North Carolina
My Commission Expires July 15, 2024

(Seal)

Applicant's initials _____

North Carolina Board of Pharmacy

Enforcement
5.0.22.2

Inspection Details

Name	Allergy Partners Therapeutics	**Case #**	N/A	**Permit**	14424
		Person Providing Info	Kelly Bridgers Short #12086	**Inspection Date**	10/15/2020
Address	10 Herman Avenue Extension Asheville, NC 28803	**Person In Charge**	Kelly Bridgers Short #12086	**Inspection User**	Bissell, Megan
		Rx Volume/Date	1/month	**Inspection District**	DISTRICT2
# RPhs	1	**Hours**	M-F 8:30a-5p		
# Techs	1	**Office**	No		
Follow-Up CAP	Yes	**Commercial Use**	No		
CAP Requested	No	**Ship to Other States**	No		
CAP Documentation Received	No	**States Shipped To**			
Non-Sterile Compounding Levels					
Sterile Compounding Levels					

Comments

Pharmacy Notes: The pharmacy opened on August 3, 2020, and inspections were completed on October 5, 2020 and October 15, 2020. The pharmacy did not dispense controlled substances and was in the process of acquiring a DEA permit. The pharmacy had one (1) patient at the time of the inspections, who was dispensed two (2) doses of medication.

The pharmacy was owned by Allergy Partners in a joint venture with Diplomat Specialty Pharmacy (Optum Infusion). RPh. Short stated that Allergy Partners, a physician-owned group of medical offices, owned the pharmacy space. Diplomat Specialty Pharmacy provided the contract employees of the pharmacy and other support. Specifically, Diplomat Specialty Pharmacy provided HR and quality assurance support, such as reviewing adverse events and assisting with quarterly cold chain monitoring. Diplomat Specialty Pharmacy also provided nurses for patients who infused at home. Allergy Partners provided a team to complete an intake and benefits investigation. This team worked in a corporate office adjacent to the pharmacy.

This inspection was a follow-up to the previous inspection on October 5, 2020. After consulting with Jeremy Evans from the Department of Agriculture, it was determined that the pharmacy was not participating in a distribution or wholesale process with Allergy Partners. No violations were noted.

General

	Answer	Question
1)		90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
2)		90-85.25 (b)- PM shall report within 10 days any disaster, accidant, theft.
3)		.1410 (a) - Pharmacy must be directed by a legally qualified pharmacist referred to as Pharmacy Manager (PM).
4)		(b) - Sufficient number of pharmacists and supportive personnel to operate pharmacy competently.
5)		(c) - PM must develop and implement written policies and procedures to specify the duties to be performed by pharmacists.
6)		(d) - Qualified, trained, adequately supervised supportive personnel to provide technical services. Supervising pharmacist must be fully aware of and responsible for all activities involved in the preparation and dispensing of medication.
7)		.1411 (a) - The PM shall establish written procedures for the safe and effective distribution of pharmaceutical products. Procedures periodically reviewed. Copy should be readily available in pharmacy.
8)		(b)(3) - PM is responsible for participation in development and maintenance of a drug formulary when required by the health care facility.
9)		(b)(6) - drugs disp. only by RPh. or others allowed by law & supportive personnel are directed & supervised.
10)		(b)(7) - Policy & Procedure that d/c drugs, outdated drugs, recalled drugs, containers w/ worn, illegible or missing labels are rtnd. to pharmacy for disposition.
11)		(b)(8) - PM must maintain records and reports to ensure patient health, safety & welfare.

General

	Answer	Question
12)	Not Applicable	.1411 (b)(9) - Reports of controlled substance discrepancies including report of action, steps taken to prevent recurrence, recurring losses or mishandling of significant quantities must be reported to the DEA.
13)	Not Applicable	(b)(10) - aux med inventories are inspected.
14)	Not Applicable	(b)(12) - Maintain policy and procedure regarding drug samples and patient's personal medications.
15)		.1412 - Sufficient floor space to ensure that drugs are prepared in sanitary, well lighted, and enclosed places.
16)		(1-2) - Compounding and dispensing areas; physically separate parenteral solution additive area when parenteral solutions are compounded.
17)		(3) - Area for receiving and storage.
18)		(4) - Packaging and repackaging area.
19)		(5) - Office space sufficient to allow for administrative function without interference with the safe compounding and dispensing of medication and security of pharmacy.
20)		(6) - All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination. Controlled Substances shall be stored in compliance with Federal and State laws and regulations.
21)		(7) - Security: All areas in the pharmacy, including auxiliary drug supplies and unit dose carts, shall remain secure at all times.
22)		.1413 (a)(2) - Authorized personnel allowed in the pharmacy after -hours.
23)		.1414 (a)(1) - Policy and procedure to establish a time frame in which oral medication order shall be put into writing and signed.
24)		(a)(2) - Medication orders must contain: patient name, location, medication name, strength, dosage form, route of and directions for administration, date of order written, and prescriber signature.
25)		(a)(3) - Policy and Procedure established for continuing therapy. Information required for patient profile includes patient's name, location, clinical information (height, weight, sex, age, and allergies), medication, strength, dosage form, route of and directions, medication start date, medication discontinue date, and identification of pharmacist responsible.
26)		(a)(4) - Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.
27)		(a)(5) - Protect health care facility patients from indefinite, open-ended medications orders.
28)		(c)(1)- Drugs are labeled and can be identified up to point of administration.
29)	Not Applicable	(d)(1-7) - Auxiliary Medication Inventories
30)		(j)(1) - PM shall develop system of daily accountability for medication compounding & dispensing that permits the identification of the responsible RPh. & pharmacy technicians. Readily retrievable records shall be maintained for thirty (30) days. The system shall identify all personnel who preform these activities & the RPh responsible for: (A-G) (j)(1)(A) - Interpretation & appropriateness of new med orders. (j)(1)(B) - Profile entry of new med orders. (j)(1)(C) - Disp. of new med orders including stat doses. (j)(1)(D) - Daily cart fills.
31)	Not Applicable	(j)(1)(G) - Preparation & release of drugs for replenishment of aux. med inventories & Auto. Disp. Devices in locations outside the pharmacy.
32)		(j)(2) - Documentation of med errors.
33)		(j)(3) - In case of death of patient retain all documents, physical evidence and internal investigative reports related to event; all items made available to North Carolina Board of Pharmacy upon request.
34)	Not Applicable	(j)(4) - Records of ordering, receiving, and dispensing or transferred of controlled substances.
35)	Not Applicable	(j)(4)(E) - Perpetual inventory shall be maintained on all controlled substances awaiting destruction.
36)		.1414 (j)(6) - Records must be maintained for three (3) years.
37)	Not Applicable	.1415 (b)(1) - Drugs will only be dispensed to registered patients of the emergency department
38)	Not Applicable	(b)(2) - The PM develop and supervise a system of control and accountability of all drugs administered in or dispensed from the Emergency Dept.
39)	Not Applicable	(b)(3) - The pharmacy manager in conjunction with the appropriate committee responsible in the emergency department shall develop an emergency department formulary which may be dispensed to patients receiving care from the emergency department. Medications must be limited to no more than a twentyfour (24) hour

General

	Answer	Question
		supply or the smallest commercially available quantity.
40)	Not Applicable	(b)(4) - Drugs shall be prepackaged in safety closure containers and pre-labeled by the pharmacist. Prior to dispensing, the following information must be on the label of the medication: name, address, telephone number of the health care facility pharmacy, dispensing date, full name of patient, generic or trade name, directions for use, the name of physician prescribing and dispensing, and cautionary information for the safety of the patient.
41)	Not Applicable	.1418(b) - PM shall develop written policies and procedures that: (1) - permit a validating technician to validate only the following functions: (A)- stocking of patient care unit medication inventories; (B)- stocking of ancillary drug cabinet inventories (C)- stocking of automated dispensing or drug supply devices; (D)- stocking of emergency kits (E)- prepackaging of prescription drugs within the Hospital pharmacy; (2) - parameters for RPh. supervision of pharmacy technician validation functions; ((3) - facility specific training for technician validation functions; (4) - evaluation and assessment program to ensure functions are performed safely and accurately (5) - recordkeeping system that shall permit the identification of the validating technician. Records are readily retrievable and kept for 3 years.
42)	[illegible]	.1601(a)(3) - Obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical needs of patients. Pharmacy reference library should include medical dictionary, drug interaction reference books, If IV services are provided a reference book on Parenteral Incompatibilities.
43)	[illegible]	(a)(4) - Pharmacy is equipped with sanitary appliances including lavatory with hot and cold running water, well lighted, kept in a clean, and sanitary condition.
44)	[illegible]	(e) - Pharmacy permit is countersigned by rph-mgr. as represented in the application
45)	[illegible]	.2502 (b) - Present in the pharmacy for half the hours open or thirty- two (32) hours a week, whichever is less. Temporary pharmacist in charge should not exceed ninety (90) days, must be present twenty (20) hours a week in the pharmacy.
46)	Not Applicable	(d) - Develop and implement system of inventory record keeping and control to enable detection of shortage or discrepancies of controlled substance medication at earliest time.
47)	[illegible]	(e) - Maintain authority and control over all keys to pharmacy and responsible for security of pharmacy. Pharmacy secured to prohibit entry if no pharmacist in pharmacy for ninety (90) minutes or more.
48)	[illegible]	(j) - Prepare disaster plan.
49)	[illegible]	(k) - Separate drug products more than six (6) months out of date.
50)	[illegible]	(l) - Reporting death of a patient or customer to North Carolina Board of Pharmacy within fourteen (14) days of becoming aware of incident.
51)	Not Applicable	CFR 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.
52)	Not Applicable	CFR 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.
53)	Not Applicable	CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
54)	Not Applicable	CFR 1305.05 (a) - power of attorney on file at registered location.
55)	Not Applicable	CFR 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.
56)	Not Applicable	CFR 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.
57)	Not Applicable	CFR 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.
58)	Not Applicable	CFR 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 for 2 years. (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. Note: Federal law requires 2 years NC Law requires 3 years
59)	Not Applicable	CFR 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
60)	Not Applicable	CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the

General

	Answer	Question
		pharmacy complies with all requirements.
61)	Not Applicable	CFR 1306.11 (a) - a Sch. II order signed by the practitioner.
62)	Not Applicable	CFR 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.
63)	Not Applicable	CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
64)	Not Applicable	CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
65)	Not Applicable	CFR 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.
66)	Not Applicable	CFR 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.
67)	Not Applicable	CFR 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.
68)	Not Applicable	CFR 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.

NORTH CAROLINA BOARD OF PHARMACY

Facility: Allergy Partners Therapeutics
Address: 10 Herman Avenue Extension Suite C
Asheville, NC 28803
Permit Type: Pharmacy
Permit #: 14424
Re-Issue Date: 11/29/2020
Expiration Date: 12/31/2021
Pharmacy Manager: Kelly Bridgers Short (#12086)

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 #: 14424

NORTH CAROLINA BOARD OF PHARMACY

Pharmacy

This is to certify that

Allergy Partners, PLLC

doing business as

Allergy Partners Therapeutics

10 Herman Avenue Extension Suite C Asheville, NC 28803 Buncombe

Has been renewed for the year ending December 31st 2021, 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.

Kelly B Short
Kelly Bridgers Short (#12086)

Ashley H. Duggins 11/29/2020
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

North Carolina Board of Pharmacy

License Verification

Only the top 250 records are shown

This serves as Primary Source Verification of the credential issued by the North Carolina Board of Pharmacy

Name:

Allergy Partners Therapeutics

Permit Number:

14424

Address:

10 Herman Avenue Extension
Suite C

Permit Status:

Active

City:

Asheville

Issue Date:

06/15/2020

State/Zip:

NC 28803

Expire Date:

12/31/2021

Manager:

Kelly Bridgers Short

Discipline:

No

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA9814585	06-30-2023	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-30-2020

ALLERGY PARTNERS, PLLC
DBA ALLERGY PARTNERS THERAPEUTICS
10 HERMAN AVENUE EXT STE C
ASHEVILLE, NC 288038103

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.

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CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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FA9814585	06-30-2023	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-30-2020

ALLERGY PARTNERS, PLLC
DBA ALLERGY PARTNERS THERAPEUTICS
10 HERMAN AVENUE EXT STE C
ASHEVILLE, NC 288038103

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Form DEA-223 (9/2016)

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* ☑ ***Ownership Change*** *(Provide current license number if making changes:* **PH** 03604 *)*
Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: RIVERSIDE PHARMACY ASSOCIATES, LLC (dba APEX SPECIALTY PHARMACY)

Physical Address: 616 NW PLATTE VALLEY DR, RIVERSIDE, MO 64150

Mailing Address: SAME

City: RIVERSIDE State: MO Zip Code: 64150

Telephone: 855 257 2584 Fax: 866 680 3539

Toll Free Number: 855 257 2584 (Required per NAC 639.708)

E-mail: INFO@RXAPEX.COM Website: RXAPEX.COM

Managing Pharmacist: DARREN LEA NV21528 ✓ License Number: 0452609

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☑ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☒ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☒ Community	☐	☑ Long Term Care
☑	☐ Other: SPECIALTY	☐	☒ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

X _____
Original Signature of Person Authorized to Submit Application, no copies or stamps

DARREN LEA _____ 6/8/21 _____
Print Name of Authorized Person Date

Board Use Only	Date Processed: _____	Amount: 500 check # 338558

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: MISSOURI

Parent Company if any: _____

Mailing Address: 614 NW PLATTE VALLEY DR

City: RIVERSIDE State: MO Zip: 64150

Telephone: 855 257 2584 Fax: 864 680 3539

Contact Person: DARREN LEA

For any corporation non publicly traded, disclose the following: NO STOCKHOLDERS. ENTITIES SHOWN BELOW HAVE BENEFICIAL INTEREST IN IVXPRESS, INC.

1) List top 4 persons to whom the shares were issued by the corporation?

a) HEALTH VELOCITY CAPITAL LLP 50 CALIFORNIA ST RIVERSIDE, MO 64150
Name Address

b) McKESSON VENTURES LLC 6535 STATE HIGHWAY 161, IRVING, TX 75039
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 N/A

List any physician shareholders and percentage of ownership. IVXPRESS OWNS 100% OF RIVERSIDE PHARMACY ASSOCIATES LLC (DBA: APEX SPECIALTY PHARMACY)

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours ON CALL

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____ N/A

Must be included 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. ATTACHED

List of officers and directors

ATTACHED

Section 5-C: Corporation Ownership

1. Apex Specialty Pharmacy. – 100% owned by IVXpress, Inc.

IVXpress, Inc. 214 Centerview Drive, Suite 250 Brentwood, TN 37027 FEIN #: 46-1432420

2. IVXpress, Inc. – **Corporate Entity Owners with 10% or Greater INDIRECT OWNERSHIP** are as follows:

McKesson Ventures LLC 1 Post Street #21 San Francisco, CA 94104 FEIN #: 46-5575871
Health Velocity Capital I, LP 1710 S Amphlett Blvd. San Mateo, CA 94402 FEIN #: 82-1941000

****Please see Organizational Chart Following ****

IVXpress, Inc. Individuals with 10% or Greater INDIRECT OWNERSHIP

Name	Address	Title	Email Address	Phone
Douglas Matthew Ghertner	[redacted] Centerview Dr. Suite 250 Brentwood, TN 37027	CEO	dghertner@ivxhealth.com	[redacted]

Precision Healthcare, Inc. Officers:

Name	Address	Title
Douglas Matthew Ghertner	[redacted] Centerview Dr. Suite 250 Brentwood, TN 37027	CEO
William Seibels	[redacted] Centerview Dr. Suite 250 Brentwood, TN 37027	CFO

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, DARREN LEA

Responsible Person of RIVERSIDE PHARMACY ASSOCIATES, LLC (dba APEX SPECIALTY PHARMACY)

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

X _____

Original Signature of Person Authorized to Submit Application, no copies or stamps

DARREN LEA

Print Name of Authorized Person

6/8/21

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Missouri)
) ss.
Platte COUNTY)

I, Darren Lea, 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 for Apex Specialty Pharmacy (the 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 sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product 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 AFFIANT SAYETH NOT.

I, Darren Lea, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
8th day of June, 2021.

NOTARY PUBLIC

JASON BRUMMETT
Notary Public-Notary Seal
STATE OF MISSOURI
Commissioned for Platte County
My Commission Expires: May 15, 2024
ID. #16016212

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, JOHN R. ASHCROFT, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Riverside Pharmacy Associates LLC
LC1144553

was created under the laws of this State on the 26th day of May, 2011, and is active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 10th day of December, 2021.

Secretary of State

Certification Number: CERT-12102021-0015

RIVERSIDE PHARMACY ASSOCIATES, LLC
616 NW PLATTE VALLEY DR
RIVERSIDE, MO 64150-9798

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR2729070	04-30-2023	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-23-2020

RIVERSIDE PHARMACY ASSOCIATES, LLC
DBA APEX SPECIALTY PHARMACY
616 NW PLATTE VALLEY DR
RIVERSIDE, MO 64150-9798

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.

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CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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FR2729070	04-30-2023	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-23-2020

RIVERSIDE PHARMACY ASSOCIATES, LLC
DBA APEX SPECIALTY PHARMACY
616 NW PLATTE VALLEY DR
RIVERSIDE, MO 64150-9798

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Form DEA-223 (9/2016)

STATE OF MISSOURI
BOARD OF PHARMACY

PHARMACY INSPECTION REPORT

MAILING ADDRESS 1277
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY	LICENSE NUMBER	CLASS	INSPECTION DATE
Apex Specialty Pharmacy 616 NW Platte Valley Drive Riverside MO 64150	2011022879	A, J, M	2/13/2020

PHARMACIST-IN-CHARGE	PIC LICENSE NO
Darren Lea	045269

LAST CONTROLLED SUBSTANCES INVENTORY	ADMINISTRATIONS
5/8/2019	☐ Yes ☑ No

PHONE	Fax	Email	STERILE COMPOUNDING
8169310100		darren@rxapex.com	☐ Yes ☑ No

Inspection Type: Routine ***Inspection Result:*** Violation(s) Noted ***Inspector:*** Andi Miller

Start Time: 10:35 AM ***End Time:*** 1:40 PM ***Acknowledged By:*** Darren Lea

This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities. Licensees should review Missouri law to ensure compliance

LICENSES/REGISTRATION

	Y	N	N/A
Pharmacy permit is current and posted [20 CSR 2220-2.020(5)]	☑	☐	☐
Permit has correct class(es) [20 CSR 2220-2.020(10)]	☑	☐	☐
All licenses/registrations current and posted [§ 338.013.3]	☑	☐	☐
Technician list maintained [20 CSR 2220-2.090(2)(BB)]	☐	☐	☑
BOP offsite storage notifications submitted [20 CSR 2220-2.010(1)(I), (J)]	☐	☐	☑
BOP remodel notifications submitted [20 CSR 2220-2.020(4)]	☐	☐	☑

Observations

PHARMACY OPERATIONS

	Y	N	N/A
Pharmacy is clean/sanitary [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Proper sanitation used in dispensing process [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Adequate security maintained to deter drug theft [20 CSR 2220-2.010(H)]	☑	☐	☐
Hot/cold water sewage disposal available and functioning [20 CSR 2220-2.090(2)(V)]	☑	☐	☐
Required drug reference(s) available [20 CSR 2220-2.010(2)(C)]	☐	☐	☑
Dispensing equipment clean/working condition [20 CSR 2220-2.010(2)(C)]	☑	☐	☐
Vacuum-tube delivery system working properly [20 CSR 2220-2.800]	☐	☐	☑
Automated dispensing/storage system meets requirements [20 CSR 2220-2.900]	☐	☐	☑
Automated filling system meets requirements [20 CSR 2220-2.950]	☐	☐	☑

Observations

PHARMACIST SUPERVISION

	Y	N	N/A
Pharmacist on duty or signs posted [20 CSR 2220-2.010(1)(A)]	☑	☐	☐
Technicians supervised, work verified by a pharmacist [20 CSR 2220-2.700(1); 2.010 (1)(B)]	☑	☐	☐

Observations

POLICIES AND PROCEDURES

	Y	N	N/A
Policies and procedures available and followed	☐	☐	☑
Policies and procedures cover required topics	☐	☐	☑

Observations

DRUG INVENTORY/STORAGE

	Y	N	N/A
Drug storage temperature in required range [20 CSR 2220-2.010(2)(G)]	☑	☐	☐
Thermometer/temp measuring device present and functioning [20 CSR 2220-2.010(2)(F)]	☑	☐	☐
Drugs/devices properly separated from food/beverages [20 CSR 2220-2.010(1)(G)]	☑	☐	☐
Expired/misbranded/adulterated drugs separate from active inventory [20 CSR 2220-2.010(6)]	☑	☐	☐
Return to stock prescriptions in original container/properly labeled [20 CSR 2220-3.040(3)]	☐	☐	☑

Observations

RECEIPT/DISTRIBUTION OF DRUGS

	Y	N	N/A
Records maintained for receipt of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐
Receiving legend drugs from licensed entities [§ 338.315]	☑	☐	☐
Records maintained for distribution of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐

Observations

REPACKAGING/PREPACKAGING

	Y	N	N/A
Appropriate containers/packaging used [20 CSR 2220-2.130(1)(B)]	☐	☐	☑
Label contains required elements [20 CSR 2220-2.130(1)(D)]	☐	☐	☑
Expiration date complies with 20 CSR 2220-2.130(1)(D)	☐	☐	☑

Observations

DISPENSING RECORDS

	Y	N	N/A
Prescription files or images properly maintained [20 CSR 2220-2.010(4), 2.083]	☑	☐	☐
Manual prescription records comply with 20 CSR 2220-2.017	☐	☐	☑
Electronic prescription records comply with 20 CSR 2220-2.080	☑	☐	☐

Observations

DISPENSING/LABELING	Y	N	N/A
Sampled prescriptions in required two-line format [§ 338.056]	☐	☐	☑
Sampled prescriptions contain all required information	☑	☐	☐
Sampled prescriptions dispensed as prescribed	☐	☑	☐
Sampled prescriptions comply with other applicable dispensing laws	☑	☐	☐
Generic substitutions comply with 338.056	☑	☐	☐
Prescription labels contain required information [§ 338.059]	☑	☐	☐
Child resistant packaging present [16 CFR 1700.14]	☑	☐	☐
Return to stock items properly reversed in computer system [20 CSR 2220-3.040(3)]	☐	☐	☑
Prescription transfers properly documented [20 CSR 2220-2.120(1)(a)]	☑	☐	☐
Verbal offer to counsel made to each patient [20 CSR 2220-2.190(1)]	☑	☐	☐
Written offer to counsel provided when required [20 CSR 2220-2.190(1)]	☑	☐	☐
Automated Filling System properly checked by pharmacist [20 CSR 2220-2.950(4)]	☐	☐	☑

Observations

- One (1) Quality Assurance Report issued (Rx# 22432)

LONG-TERM CARE DISPENSING	Y	N	N/A
Packaging complies with 20 CSR 2220-2.140	☐	☐	☑
Sampled labels complete [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Proper return and reuse of medication [20 CSR 2220-3.030(1)(2)]	☐	☐	☑
Proper label changes for previously dispensed prescriptions [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

MULTI-MED DISPENSING	Y	N	N/A
Packaging and containers comply with 20 CSR 2220-2.145(2)(C), (D)	☐	☐	☑
Med paks properly labeled [20 CSR 2220-2.145(2)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Return/reuse complies with 20 CSR 2220-2.145(2)(H)	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.145(2)(F); 20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES

	Y	N	N/A
BNDD/DEA registrations current/active [§ 195.030.2; 21 CFR 1301.11]	☑	☐	☐
Sampled prescriptions comply with CS dispensing laws/rules	☐	☐	☑
CS prescriptions manually signed or valid electronic prescription [21 CFR § 1306.8]	☐	☐	☑
Medical reason for dispensing more than a 30-day supply of a C-II documented [§ 195.080.2]	☐	☐	☑
CS prescription quantity limits and partial fill requirements followed [195.080, 19 CSR 30-1.064]	☐	☐	☑
C-II drugs under lock/secure cabinet (19 CSR 30-1.034]	☐	☐	☑
C-III to IV dispersed in inventory or under lock/secure cabinet [19 CSR 30-1.034(1)]	☐	☐	☑
C-III to C-V invoices dated when received [19 CSR 30-1.048(4)]	☐	☐	☑
Loss reports properly filed [19 CSR 30-1.034(2)(B); 21 CFR 1301.76(b)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES INVENTORY

	Y	N	N/A
CS inventory available and taken annually and when required [19 CSR 30-1.042]	☑	☐	☐
CS inventory contains date and time taken [19 CSR 30-1.042(1)(D)]	☑	☐	☐
CS inventory includes C-V pseudoephedrine products [19 CSR 30-1.042]	☐	☐	☑
Pharmacist-in-charge change inventory taken [20 CSR 2220-2.090(2)(T)]	☐	☐	☑

Observations

C-II Ordering

	Y	N	N/A
Sampled CSOS or 222 forms, accessible, executed and complete [21 CFR § 1305.13, .22]	☐	☐	☑
CSOS usernames/passwords not shared [21 CFR §1305.21]	☐	☐	☑

Observations

OTC/PSEUDOEPHEDRINE SALES

	Y	N	N/A
Schedule V OTC PSE products behind counter or under lock [19 CSR 30-1.034]	☐	☐	☑
Combat Meth Act self-certification current [21 CFR 1306.8]	☐	☐	☑
Pseudoephedrine sales properly entered into database and accessible [19 CSR 30-1.074]	☐	☐	☑

Observations

ADMINISTRATION BY PROTOCOL

	Y	N	N/A
Protocol complete, current, signed/dated, and followed [20 CSR 2220-6.050(5)(B)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.050(6)]	☐	☐	☑
Vaccines are authorized by and age limits followed [§338.010]	☐	☐	☑

Observations

ADMINISTRATION BY PRESCRIPTION ORDER

	Y	N	N/A
Prescription requirements met [20 CSR 2220-6.040(5)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.040(6)]	☐	☐	☑

Observations

NON-STERILE COMPOUNDING

	Y	N	N/A
Compounding equipment functioning/maintained [20 CSR 2220-2.400(5)©]	☐	☐	☑
Active/therapeutic ingredients on prescription container [20 CSR 2220-2.400(7)(F)]	☐	☐	☑
Compound log accurately maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Other compounding records properly maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Bulk active ingredients meet compendial standards or certificate of analysis maintained [20 CSR 2220-2.400(8)(A)2]	☐	☐	☑
Return to stock items handled as batched with lot # and BUD on container label and documented in compound log [20 CSR 2220-2.400(7)(A), (D)]	☐	☐	☑
Batch/bulk compounds stored and labeled with lot # and BUD [20 CSR 2220-2.400(7)(A)6.]	☐	☐	☑
Adverse effects/complaints documented and investigated [20 CSR 2220-2.400(8)(B)]	☐	☐	☑
Recalls and prescriber/patient notifications conducted when required [20 CSR 2220-2.400(8)(C)]	☐	☐	☑

Observations

Additional Observations:

Additional Comments:

- Will follow up regarding hub pharmacy relationships

State of Missouri

Division of Professional Registration

Pharmacy
Class A, J, M

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2011022879
RIVERSIDE PHARMACY ASSOCIATES
APEX SPECIALTY PHARMACY
DARREN LEA, PIC
616 NW PLATTE VALLEY DR
RIVERSIDE MO 64150
USA

RIVERSIDE PHARMACY ASSOCIATES
APEX SPECIALTY PHARMACY
DARREN LEA, PIC
616 NW PLATTE VALLEY DR
RIVERSIDE MO 64150
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, J, M

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2011022879
Darren T Lea - 045269
RIVERSIDE PHARMACY ASSOCIATES
APEX SPECIALTY PHARMACY
DARREN LEA, PIC
616 NW PLATTE VALLEY DR
RIVERSIDE MO 64150
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

RECEIVED
JUN 22 2021
MISSOURI BOARD
OF PHARMACY

APEX
SPECIALTY PHARMACY

616 NW Platte Valley Drive
Riverside, Missouri 64150
www.rxapex.com

P :: 855.257.2584
F:: 866.680.3539
info@rxapex.com

Patient care as specialized as the medication prescribed.

17 June 2021

Re :: Letter of Good Standing

Attn: Laura

Our pharmacy is requesting a Letter of good Standing for Riverside Pharmacy Associates LLC (dba Apex Specialty Pharmacy) for an out-of-state pharmacy change of ownership application/documentation for the state of Nevada. I have enclosed a self-addressed, stamped envelope for the letter to be returned directly to the Nevada State Board of Pharmacy. The Nevada State Board of Pharmacy indicates the home state may complete the enclosed License Verification form OR may submit original letter verifying your state license is current and in good standing. The state seal must be embossed on the letter.

Riverside Pharmacy Associates LLC
dba Apex Specialty Pharmacy
License number 2011022879
PIC :: Darren Lea, PharmD (license #45269)
616 NW Platte Valley Drive
Riverside, MO 64150

Your assistance is greatly appreciated.

Sincerely,

Abby Albers
Compliance Officer

Enclosures:
$25 check
Nevada State Board of Pharmacy License Verification form
Return envelope

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: Apex Specialty Pharmacy

Physical Address: 616 NW Platte Valley Drive

City: Riverside State: MO Zip: 64150

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 816-741-8844 Website: www.rxapex.com

Licensing Company Email: info@rxapex.com

Section 2: Personal Information

First: Darren Middle: Todd Last: Lea

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

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

Mailing Address: [redacted] Verona Ct

City: Riverside State: MO Zip: 64150

Telephone: [redacted] Email: darren@rxapex.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: DL

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)	
Lexington High School		08/90 - 05/92	
Address	City	State	Zip
2309 Aull Lane	Lexington	MO	64067
Diploma/Degree obtained, if any			
High School Diploma ✓			

School Name		From - To (MM/YY – MM/YY)	
University of Central Missouri		08/92 - 05/94	
Address	City	State	Zip
116 W. South Street	Warrensburg	MO	64093
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Missouri-Kansas City		08/94 - 05/99	
Address	City	State	Zip
5000 Holmes Street	Kansas City	MO	64110
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
05/10 - present	[redacted]Verona Ct	Riverside	MO	64150
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DL

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)
Apex Specialty Pharmacy			08/12 - present
Business Address	**City**	**State**	**Zip**
616 NW Platte Valley Dr	Riverside	MO	64150
Phone	**Title**	**Number of Employed Hours**	
816-741-8844	Pharmacist in Charge	18,000 ✓	
Description of Duties			

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

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

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description 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 DL 4

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

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

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

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

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 DL

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 DL

I, Darren Todd Lea, certify that as the designated representative for Apex Specialty 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

Darren Lea

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

12/08/2021

Date

Applicant's initials DL

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.

Darren Lea

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/08/2021

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)

Applicant's initials DL

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.

Darren Lea

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/08/2021

Date

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

State of TENNESSEE, ss. County of DAVIDSON

I, DARREN LEA, 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

12/8/21

Date

Subscribed and Sworn to before me this 8th day of December

Notary Public Signature

LASA RUCKER NOTARY PUBLIC STATE OF TENNESSEE DAVIDSON COUNTY My Commission Expires JULY 6, 2022 Seal

Applicant's Initials DL

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Darren T. Lea

Date: 10/06/2021
Amount:
License #: 21528

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:04/06/2022

Darren T. Lea

License #
21528
Temporary

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 #: 21528

Expires: 04/06/2022
STATUS: Temporary

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Darren T. Lea

NONTRANSFERABLE
POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

State of Missouri

Division of Professional Registration
Pharmacist

VALID THROUGH OCTOBER 31, 2022
ORIGINAL CERTIFICATE/LICENSE NO. 045269
DARREN T LEA

DARREN T LEA
[redacted] VERONA COURT
RIVERSIDE MO 64150
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy
Pharmacist

VALID THROUGH OCTOBER 31, 2022
ORIGINAL CERTIFICATE/LICENSE NO. 045269

DARREN T LEA

EXECUTIVE DIRECTOR

Sarah E. Edgerwood
DIVISION DIRECTOR

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Acting Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

This is to certify that the records of the Missouri Division of Professional Registration indicate the following information regarding Lea, Darren T.

LICENSE TYPE:	Pharmacist
LICENSE NUMBER:	045269
ADDRESS:	Riverside, MO 64150
DATE ISSUED:	7/19/1999
STATUS:	Active
EXPIRATION DATE:	10/31/2022
DISCIPLINARY ACTION:	None

Laura Henke
Missouri Board of Pharmacy

June 23, 2021
Date

This is the only form that will be used by the Missouri Board of Pharmacy for the purpose of license verification.

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 (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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH 03856	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Avel eCare, LLC dba Avel eCare Pharmacy

Physical Address: 4103 N Loop 1604 W, Suite 202

City: San Antonio State: TX Zip: 78249

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 210-610-0143 Toll Free # (NAC 639.708, NRS 639.23286): 855-283-7279

Fax: 210-549-4061 Contact Email: Andrea.Darr@avelecare.com

Website: www.avelecare.com

Nevada Business License # (if applicable) NV20181735644

Supervising/Managing Pharmacist Name (NRS 639.220): Jeremy Mueller

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19546 ✓ or exp. 10/31/23

Type of Pharmacy (check all applicable)

- ☐ Retail/Community
- ☐ Hospital (# beds _____)
- ☐ Internet
- ☐ Nuclear
- ■ Other: Remote Med Order Proc

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: See attached list.	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: South Dakota

Parent Company (if any): Rushmore Buyer, LLC

Corporation/Organization Name: Avel eCare, LLC

Mailing Address: 4500 N Lewis Ave

City: Sioux Falls State: SD Zip: 57104

Telephone: 605-606-0240 Email: Deanna.Larson@AveleCare.com

Contact Person Name: Deanna Larson

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 Avel eCare, LLC dba Avel eCare 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).

Deanna Larson

Print Name of Authorized Person

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

12/21/21

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Deanna Larson 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 Avel eCare, LLC dba Avel eCare 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.

Deanna Larson

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21 day of Dec, 2021

Linda L. Robin

Notary Public

Exp: Sept. 12, 2022

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: Jeremy Mueller Pharmacist Registration #: 19546

Pharmacy Name: Avel eCare, LLC dba Avel eCare Pharmacy

Initial each statement below to indicate you have read and agree with the following:

jm 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.

jm 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.

jm 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.

jm 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)).

jm 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 <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?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

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)

12/20/21
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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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/	✓	✓	✓	✓

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) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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)** NR5 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 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)	✓	✓	✓	✓
• **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.

Deanna Larson

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

Deanna Larson — 12/21/21

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

Board Use Only	Date Received: _____	Amount: 500	Check # 1224 ✓ Processed 1/20/22

4500 N. Lewis Avenue
Sioux Falls, SD 57104
(605) 322-2387
Fax: (605) 322-2096
www.AveleCare.com

November 29, 2021

VIA EMAIL AND MAIL

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno, Nevada 89521
Email: pharmacy@pharmacy.nv.gov

Re: Avel eCare, LLC Notification of Change of Ownership (EIN 30-1043916, Pharmacy, License Number PH03856)

Dear Nevada State Board of Pharmacy:

We respectfully submit this letter to the Nevada State Board of Pharmacy ("Board") to report a change in the ownership of Avel eCare, LLC ("Avel"), which holds a Pharmacy License in Nevada. Specifically, Avera Health ("Avera"), the former parent company of Avel, entered into an agreement with Rushmore Buyer, LLC ("Rushmore Buyer") that resulted in the transfer of 100% of the ownership interests in Avel from the Avera to Rushmore Buyer (the "Transaction"). The Transaction that resulted in the change of ownership occurred on November 1, 2021 (the "Closing"). Upon Closing, Rushmore Buyer became the 100% owner of Avel. Avel continues to hold the license, and its name, address, and tax identification number have not changed as a result of the Transaction. Additionally, there has been no change to Avel's day-to-day pharmacy operations, pharmacy staff, or the manner of delivery of pharmacy services.

We understand that the Transaction described above constitutes a change of ownership requiring notice of the change to your Board within thirty (30) days of Closing. As such, we submit this letter as notice to your Board.

If you have any questions or require the completion of any additional documentation, please contact Andrea Darr, Pharmacy Officer, by phone at (605) 322-8358.

Very truly yours,

Deanna Larson, President

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **32217** Expiration Date: **8/31/2022**

Balances: **0**

AVEL ECARE PHARMACY
4103 N LOOP 1604 W STE 202
SAN ANTONIO TX 78249

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

Ownership

Name: Avel eCare, LLC
Ownership Type: Limited Liability Company

List of all Officers and Directors of Avel eCare, LLC:

Name	Title
Douglas Duskin	CEO
Deanna Larson	President
Jay Weems	CFO
Kyle Groteluschen	Secretary
Brian Skow	Chief Medical Officer
Kelly Rhone	Vice President

List of Owners:

Name	Mailing Address	Federal Employer Identification Number (FEIN)	Ownership Percentage	Title
Rushmore Buyer, LLC	535 Madison Ave. New York, NY 10022	87-1193797	100	Member

Note: Avel eCare, LLC is a limited liability company and thus does not have stockholders, but rather has members. Rushmore Buyer, LLC is the sole member of Avel eCare, LLC and holds 100% of the membership interests in Avel eCare, LLC.

We have not completed Personal History Record Application(s) because Avel eCare, LLC does not have any shareholder/stockholders or individual owners. Please let us know if there is any additional documentation that we can provide regarding the membership interests of Avel eCare, LLC.

Pharmacists employed at Avel ePharmacy (License #99-9025)

Jeremy Mueller <Jeremy.Mueller@AveleCare.com>

Wed 12/8/2021 5:35 PM

To: pharmacy@pharmacy.nv.gov <pharmacy@pharmacy.nv.gov>

To whom it may concern,

I am writing to provide you with a current list of Nevada licensed pharmacists employed at our pharmacy, as per NAC 639.540.

Joseph Garcia (20727)
Robert Ibarra (20323)
Tram Le (20377)
Jeremy Mueller (19546)
Michael Olivarez (21786)
Timothy Riordan (19769)
Debra Stewart (19768)
Keith Thomas (19878)
Thao Tran (20376)

Please advise if you need anything further from me in order to comply with this regulatory requirement.

Jeremy

AVEL eCare

Jeremy Mueller, PharmD
Pharmacy Manager

Email: jeremy.mueller@avelecare.com
Phone: 210-610-0413
Cell: 605-370-1438

4103 N Loop 1604 W, Suite 202, San Antonio, TX 78249
www.avelecare.com

State of South Dakota

Office of the Secretary of State

Certificate of Good Standing

Domestic Limited Liability Company

I, Steve Barnett, Secretary of State of the State of South Dakota, hereby certify that

Avel eCare, LLC

Business ID: DL133911

was authorized to transact business in this state on: June 2, 2017.

I, further certify that **Avel eCare, LLC** has complied with the laws of this State relative to the formation of Certificate of Good Standing/Authorizations of its kind and is now regularly and properly organized and existing under the laws of this State and is in Good Standing, as shown by the records of this office. This certificate is not to be construed as an endorsement, recommendation or notice of approval of its financial condition or business activities and practices. Such information is not available from this office.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of South Dakota, in Pierre, the Capital City, this day, October 29, 2021.

Steve Barnett

Steve Barnett
Secretary of State

10/29/2021 2:38 PM

Verification #: 014961427

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Instructions for Amendment/ Restated Articles/Amended and Restated Articles - Limited-Liability Company

IMPORTANT: READ ALL INSTRUCTIONS CAREFULLY BEFORE COMPLETING FORM.

TYPE or PRINT the following information and submit the filing with Customer Order Instruction Form and payment:

1. ENTITY INFORMATION: Enter the current name as on file with the Nevada Secretary of State and enter the Entity or Nevada Business Identification Number (NVID).

2. RESTATED OR AMENDED AND RESTATED ARTICLES: Check the box to indicate that this form is to Accompany Restated or Amended and Restated Articles. Select only one box to indicate Restated Articles or Amended and Restated Articles. Completed sections 1, 2, 5 and 6.

Restated or Amended and Restated Articles must be attached with this filing.

3. TYPE OF AMENDMENT FILING BEING COMPLETED: Indicate what type of amendment is being completed by selecting one box. Completed sections 1, 3, 5 and 6.

Certificate of Amendment pursuant to NRS 86.216 - Before issuance of Members Interest

Must check one of the boxes to indicate the undersigned is at least two-thirds of the organizers or the managers.

Or

Certificate of Amendment pursuant to NRS 86.221

Must check the box that indicates how the Limited-Liability Company is managed.

Or

Amendment to Application for Registration of a Foreign Limited-Liability Company

Enter entity name of Foreign Limited-Liability Company if different then that registered to transact business in Nevada. Check the box to indicate if name changes are to take effect.

4. EFFECTIVE DATE AND TIME: This section is optional. If an effective date and time is indicated the date must not be more than 90 days after the date on which the certificate is filed.

5. INFORMATION BEING CHANGED: Select the appropriate box(es) to indicate what changes are being made. In the field provided indicate what is being amended, provide article number(s) if available. (If necessary, additional pages may be attached to this form.) If adding managers or members, or making changes to the organizer, provide names and addresses.

6. SIGNATURE(S): Must be signed by a Manager, Member or Authorized Signer, if more than 2 signatures an additional page may be attached. Form will be returned if unsigned.

Filing may be submitted at the office of the Secretary of State, by mail, fax or email to the following addresses:

Carson City – Main Office
Regular and Expedited Filings

Mail:
Secretary of State
Commercial Recordings Division
202 North Carson Street
Carson City NV 89701-4201

Phone: 775-684-5708
Fax: 775-684-5725

General Inquires: sosmail@sos.nv.gov

Amendments Division: amendments@sos.nv.gov
New Filings Division: newfilings@sos.nv.gov
Status Division: statusdocs@sos.nv.gov
Certificates & Copies: copies@sos.nv.gov

Las Vegas – Satellite Office
Expedited Filings Only

Mail:
Secretary of State
North Las Vegas City Hall
2250 Las Vegas Blvd. North, Suite 400
North Las Vegas, NV 89030

Phone: 702-486-2880
Fax: 702-486-2888

General Inquires: soslvmail@sos.nv.gov

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Limited-Liability Company:
Certificate of Amendment (PURSUANT TO NRS 86.216, 86.221 and 86.543)
Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 86.221)

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGHLIGHT

1. Entity information:

Name of entity as on file with the Nevada Secretary of State:
Avel eCare, LLC

Entity or Nevada Business Identification Number (NVID): NV20181735644

2. Restated or Amended and Restated Articles (Select one):

(If restating or amending and restating, complete section 1,2 3, 5 and 6.)

☐ **Certificate to Accompany Restated Articles or Amended and Restated Articles**

☐ Articles have been Restated

☐ Articles have been Amended and Restated

* Restated or Amended and Restated articles must be included with this filing type.

3. Type of amendment filing being completed: (Select only one box):

(If amending, complete section 1, 3, 5 and 6.)

☐ **Certificate of Amendment to Articles of Organization For a Nevada Limited-Liability Company Before Issuance of Member's Interest** (Pursuant to NRS 86.216)

The signers thereof are at least two-thirds of the ☐ organizers or the ☐ managers of the limited-liability company

As of the date of the certificate, no member's interest in the limited-liability company has been issued.

☐ **Certificate of Amendment to Articles of Organization For a Nevada Limited-Liability Company** (Pursuant to NRS 86.221)

The limited-liability company is managed by ☐ Managers or ☐ Members

The certificate of amendment must be signed by a manager of the company or, if management is not vested in a manager, by a member.

☒ **Amendment to Application for Registration of a Foreign Limited-Liability Company** (Pursuant to NRS Chapter 86)

Name of Foreign Limited-Liability Company if different than registered to transact business in Nevada:

If amendment is to change the name, the change taking effect: (select all that apply)

☐ The name under which Limited-Liability Company transacts business in this State

☐ Foreign Limited-Liability Company name from home jurisdiction

This form must be accompanied by appropriate fees.

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Limited-Liability Company:
Certificate of Amendment (PURSUANT TO NRS 86.216, 86.221 & 86.543)
Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 86.221)

4. Effective date and time: (Optional)

Date: _____ Time: _____

(must not be later than 90 days after the certificate is filed)

5. Information being changed:

Changes to takes the following effect:

- ☐ The entity name has been amended.
- ☐ The registered agent has been changed. (attach Certificate of Acceptance from new registered agent)
- ☐ The purpose of the entity has been amended.
- ☒ The directors, managers or general partners have been amended.
- ☐ IRS tax language has been added.
- ☐ Articles have been added.
- ☐ Articles have been deleted.
- ☐ Other.

The articles have been amended as follows: (provide article numbers, if available)

6. The street address of principal office has changed to 4500 N. Lewis Ave., Sioux Falls, SD 57104... [continued below]

(attach additional page(s) if necessary)

6. Signature: (Required)

X _____ Authorized Signer - Member
Signature of Manager, Member or Authorized Signer — Title

X _____ _____
Signature of Manager, Member or Authorized Signer — Title

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

...

7. The name and address of the Managing Member:

Rushmore Buyer, LLC,
4500 N. Lewis Ave.,
Sioux Falls, SD 57104

This form must be accompanied by appropriate fees.

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

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

Wolters Kluwer
28 LIBERTY STREET, 26TH FLOOR
New York, NY 10005, USA

Work Order #: W2021082601209
August 26, 2021
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 393953

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Annual List	Fees	20211706169	8/26/2021 12:18:29 PM	Approved	1	$150.00	$150.00
Annual List	Business License Fee	20211706169	8/26/2021 12:18:29 PM	Approved	1	$200.00	$200.00
Total							$350.00

Payments

Type	Description	Payment Status	Amount
Credit Card	630005497010650690307 3	Success	$350.00
Total			$350.00

Credit Balance: $0.00

Wolters Kluwer
28 LIBERTY STREET, 26TH FLOOR
New York, NY 10005, USA

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings 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

Business Entity - Filing Acknowledgement

08/26/2021

Work Order Item Number:	W2021082601209 - 1544668
Filing Number:	20211706169
Filing Type:	Annual List
Filing Date/Time:	08/26/2021 12:18:29 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E0477872018-2

Entity Name: Avel eCare, LLC

Entity Status: Active

Expiration Date: None

Commercial Registered Agent
C T CORPORATION SYSTEM
701 S CARSON ST STE 200, Carson City, NV 89701, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

Avel eCare, LLC
NAME OF ENTITY

NV20181735644
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of Barbara K. Cegavske Secretary of State State Of Nevada	Business Number **E0477872018-2** Filing Number **20211706169** Filed On **08/26/2021 12:18:29 PM** Number of Pages **2**

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☐ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE MEMBER:

Name	Country
Avera Health	USA

Address	City	State	Zip/Postal Code
3900 West Avera Drive	Sioux Falls	SD	57108

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 Adam Deis

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Title	Date
Power of Attorney	08/26/2021

4500 N. Lewis Avenue
Sioux Falls, SD 57104
(605) 322-2387
Fax: (605) 322-2096
www.AveleCare.com

Nevada Board of Pharmacy
c/o Maria Herrera, Licensing Specialist
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

Ms. Herrera,

Thank you for your email letting me know of items still required to complete the Change of Ownership Application for Avel eCare, LLC dba Avel eCare Pharmacy (PH03856).

Attached please find a copy of our home state license in Texas.

In addition, I have attached a copy of the most recent pharmacy inspection by the Texas Board of Pharmacy. Due to Covid, this inspection was done virtually and it appears different than had it been done in person and on site.

Jeremy Mueller will complete the Designated Representative Application and return by mail.

If you have any additional requests or questions, please contact me.

Sincerely,

Andrea Darr, PharmD
VP and General Manager, Pharmacy Services
Avel eCare, LLC
4500 N Lewis Ave
Sioux Falls, SD 57104
(605) 606-0240
Andrea.Darr@avelecare.com

Remarks

Avel Ecare Pharmacy 32217 **Listed Items Discussed – No Deficiencies Noted**

Employment List Verification

No Storage of medications, No dispensing

PIC at only one Pharmacy, must be Full Time

Pharmacist must supervise techs, either in person or electronic

Must be controls to protect security of confidential records

Maintain Records for at least two years

May process orders for A,C, E facilities provided same owner OR have written contract outlining services

P&P, reviewed annually, to include name/address/phone#/license# of all pharmacies servicing

CQIP Program to monitor and evaluate quality and appropriateness of patient care

Documentation of initial and on-going tech training

Facility is orderly and clean and all staff with appropriate name identification

All staff has access to required references, law, Drug Info, Drug Interactions, Injectable Info, etc

Records maintained, separately by each Pharmacy and RPh or able to report accordingly

Action Taken

(1) ☑ Inspection
(2) ☐ Pre-Inspection
(3) ☐ Partial Inspection
(4) ☐ Visit
(5) ☐ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. ~~Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement~~.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

James D Clark RPh
Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

07/13/2021
Date

Distance Inspection
Time of Completion

Jeremy Mueller, Pharmacist In Charge
Printed Name and Title of Authorized Individual

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Avel eCare, LLC

Nevada Business Identification # NV20181735644
Expiration Date: 10/31/2022

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 08/26/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202108261943706
You may verify this certificate online at http://www.nvsos.gov

Form 424—General Information
(Certificate of Amendment)

The attached form is drafted to meet minimal statutory filing requirements pursuant to the relevant code provisions. *This form and the information provided are not substitutes for the advice and services of an attorney and tax specialist.*

Commentary

Sections 3.051 to 3.056 of the Texas Business Organizations Code (BOC) govern amendments to the certificate of formation of a Texas filing entity. A filing entity may amend its certificate of formation at any time and in as many respects as may be desired, *as long as the certificate as amended contains only such provisions as could have been included in the original certificate of formation.* Amendments may be adopted to change the language of an existing provision, to add a new provision, or to delete an existing provision. If extensive amendments are proposed, the entity should consider filing a restated certificate of formation pursuant to section 3.059 of the BOC (Form 414).

Procedural Information by Entity Type

Please note that a document on file with the secretary of state is a public record that is subject to public access and disclosure. Do not include confidential information, such as social security numbers. If amending information relating to directors or governing persons, use a business or post office box address rather than a residence address if privacy concerns are an issue.

For-profit or Professional Corporation

Sections 21.052 to 21.055 of the BOC set forth the procedures for amending the certificate of formation for a for-profit corporation or professional corporation. The board of directors adopts a resolution setting forth the proposed amendment and directing that it be submitted to a vote at a meeting of the shareholders. Written or printed notice setting forth the proposed amendment is given to each shareholder of record entitled to vote not later than the 10th day and not earlier than the 60th day before the date of the meeting, either personally, by electronic transmission, or by mail (BOC § 21.353). (Please refer to chapters 6 and 21 of the BOC for further information.)

Pursuant to section 21.364 of the BOC, the proposed amendment is adopted on receiving the affirmative vote of two-thirds of the outstanding shares entitled to vote. If any class or series of shares is entitled to vote as a class, the amendment must also receive the affirmative vote of two-thirds of the shares within each class or series that is entitled to vote as a class. Any number of amendments may be submitted to the shareholders and voted on at one meeting. Alternatively, amendments may be adopted by unanimous written consent of the shareholders.

If no shares have been issued, the amendment is adopted by a resolution of the board of directors and the provisions for adoption by shareholders do not apply.

An officer must sign the certificate of amendment. If no shares have been issued and the amendment was adopted by the board of directors, a majority of the directors may sign the certificate of amendment.

Professional Association

The provisions of chapters 20 and 21 of the BOC apply to a professional association, unless there is a conflict with a specific provision in title 7. A professional association may amend its certificate of formation by following the procedures set forth in its certificate of formation. If the certificate of

formation does not provide a procedure for amending the certificate, the certificate of formation is amended by a two-thirds vote of its members.

An officer must sign the certificate of amendment.

Nonprofit Corporation

Sections 22.105 to 22.108 of the BOC set forth the procedures for amending the certificate of formation for a nonprofit corporation. If the corporation has members with voting rights, the board of directors adopts a resolution setting forth the proposed amendment and directing that it be submitted to a vote at a meeting of the members, which may be either an annual or special meeting. The proposed amendment is adopted on receiving two-thirds of the votes that members present, in person or by proxy, were entitled to cast (BOC § 22.164). Any number of amendments may be submitted to the members and voted on at one meeting. Alternatively, the amendment may be adopted without a meeting if a written consent, setting forth the action to be taken, is signed by all the members entitled to vote. (Please refer to chapters 6 and 22 of the BOC for further information.)

If the corporation has no members or no members with voting rights, the amendment is adopted by a majority vote of the board of directors.

An officer of the nonprofit corporation must sign the certificate of amendment.

A nonprofit corporation formed for a special purpose under a statute or code other than the BOC may be required to meet other requirements for a certificate of amendment than those imposed by the BOC. This form may not comply with the requirements imposed under the special statute or code governing the special purpose corporation. Please refer to the statute or code governing the special purpose corporation for specific filing requirements for a certificate of amendment.

Cooperative Association

Section 251.052 of the BOC sets forth the procedure for amending the certificate of formation of a cooperative association. The board of directors may propose an amendment to the certificate of formation by a two-thirds vote of the board members. Notice of the meeting to consider the proposed amendment must be provided to the members no later than the 31st day before the date of the meeting. To be approved, the amendment must be adopted by the affirmative vote of two-thirds of the members voting on the amendment. The cooperative association must file the certificate of amendment with the secretary of state within thirty (30) days after its adoption by the members.

An officer of the cooperative association must sign the certificate of amendment.

Limited Liability Company or Professional Limited Liability Company

Chapter 101 of the BOC governs limited liability companies. Pursuant to section 101.356(d), an amendment to the certificate of formation must be approved by the affirmative vote of all of the company's members. If the company has managers, but has yet to admit its initial member, the amendment would be approved by the affirmative vote of the majority of all the company's managers as permitted by section 101.356(e).

If the limited liability company has managers, an authorized manager must sign the certificate of amendment. If the company does not have managers and is managed by its members, an authorized managing-member must sign the certificate of amendment.

Limited Partnership

Chapter 153 of the BOC governs limited partnerships. A certificate of limited partnership may be amended at any time for any proper purpose determined by the general partners. However, section 153.051 *requires* a certificate of amendment when there is:

(1) a change of name of the partnership;
(2) an admission of a new general partner; or
(3) a withdrawal of a general partner.

Section 153.051 of the BOC also requires that a limited partnership amend its certificate of formation when there is a change of address for the registered office or a change of name or address of the registered agent of the partnership. However, rather than filing an amendment, the partnership may file a statement of change pursuant to section 5.202 of the BOC to effect a change to its registered agent or registered office.

Pursuant to section 153.553, at least one general partner must sign the certificate of amendment. In addition, each general partner designated as a new general partner also must sign the certificate of amendment. A withdrawing general partner need not sign the certificate of amendment. The execution of a certificate by a general partner is an oath or affirmation, under a penalty of perjury, that to the best of the executing party's knowledge and belief, the facts contained in the certificate are true and correct (BOC §153.553(c)).

Instructions for Form

- **Entity Information:** The certificate of amendment must contain the legal name of the entity and identify the type of filing entity. *If the amendment changes the name of the entity, the name as it currently appears on the records of the secretary of state should be stated.* It is recommended that the date of formation and file number assigned by the secretary of state be provided to facilitate processing of the document.

- **Amendments: 1. Amended Name.** This form is designed to provide a standardized amendment form to effect a change of name for the filing entity. If the legal name of the entity is to be changed, state the new name of the entity in section 1. Please note that the legal name of the entity must include an appropriate organizational designation for the entity type.

  The new entity name will be checked for availability on submission of the certificate of amendment. Under section 5.053 of the BOC, if the new name of the entity is the same as, deceptively similar to, or similar to the name of an existing domestic or foreign filing entity, or any name reservation or name registration filed with the secretary of state, the document cannot be filed. The administrative rules adopted for determining entity name availability (Texas Administrative Code, title 1, part 4, chapter 79, subchapter C) may be viewed at *www.sos.state.tx.us/tac/index.shtml*. If you wish the secretary of state to provide a preliminary determination on name availability, you may call (512) 463-5555, dial 7-1-1 for relay services, or e-mail your name inquiry to *corpinfo@sos.state.tx.us*. A final determination cannot be made until the document is received and processed by the secretary of state. Do not make financial expenditures or execute documents based on a preliminary clearance. Also note that the preclearance of a name or the issuance of a certificate under a name does not authorize the use of a name in violation of another person's rights to the name.

- **Amendments: 2. Changes to Registered Agent and/or Registered Office.** It is not necessary to file a certificate of amendment if the entity seeks only to change its registered agent or its

registered office. A filing entity may file a statement of change of registered agent/registered office pursuant to section 5.202 of the BOC.

However, if the entity is changing its name or making other changes to its certificate of formation, any changes to the registered agent or registered office may be included in a certificate of amendment. Section 2 can be completed to effect a change to the registered agent or registered office address. The registered agent can be either (option A) a domestic entity or a foreign entity that is registered to do business in Texas or (option B) an individual resident of the state. The filing entity cannot act as its own registered agent.

Consent: Effective January 1, 2010, a person designated as the registered agent of an entity must have consented, either in a written or electronic form, to serve as the registered agent of the entity. Although the consent of the person designated as registered agent is required, a copy of the written or electronic consent need not be submitted with a certificate of correction that corrects the name of the registered agent. *The liabilities and penalties imposed by sections 4.007 and 4.008 of the BOC apply with respect to a false statement in a filing instrument that names a person as the registered agent of an entity without that person's consent.* (BOC § 5.207)

Amendment to Registered Office: The registered office address must be located at a street address where service of process may be personally served on the entity's registered agent during normal business hours. Although the registered office is not required to be the entity's principal place of business, the registered office may not be solely a mailbox service or telephone answering service (BOC § 5.201).

- **Amendments: 3. Other Provisions to be Added, Altered, or Deleted.** Section 3 of this form contains three text areas that may be used to make alterations or changes to other provisions in the certificate of formation or to identify those provisions to be deleted. If the space provided in a text area is insufficient, include the provisions as an attachment to this form.

  ➢ **Add:** If the amendment is an addition to the certificate of formation, check the "Add" statement and provide an identification or reference for the added provision and the full text of each provision added in the text area.
  ➢ **Alter:** If the amendment alters or changes an existing article or provision in the certificate of formation, check the "Alter" statement and provide an identification of the article number or description of the altered provision and the text of the article or provision as it is amended to read in the text area.
  ➢ **Delete:** If the amendment deletes an existing article or provision in its entirety, check the "Delete" statement and provide a reference to the article number or provision being deleted in the text area.

- **Statement of Approval:** As required by section 3.053 of the BOC, the form includes a statement regarding the approval of the amendment. In general, amendments are adopted and approved in the manner set forth in the title of the BOC governing the entity. General procedural information relevant to each filing entity that may use this form precedes the instructions for completing the form.

- **Effectiveness of Filing:** A certificate of amendment becomes effective when filed by the secretary of state (option A). However, pursuant to sections 4.052 and 4.053 of the BOC the effectiveness of the instrument may be delayed to a date not more than ninety (90) days from the date the instrument is signed (option B). The effectiveness of the instrument also may be delayed on the occurrence of a

future event or fact, other than the passage of time (option C). If option C is selected, you must state the manner in which the event or fact will cause the instrument to take effect and the date of the 90th day after the date the instrument is signed. In order for the certificate to take effect under option C, the entity must, within ninety (90) days of the filing of the certificate, file a statement with the secretary of state regarding the event or fact pursuant to section 4.055 of the BOC.

On the filing of a document with a delayed effective date or condition, the computer records of the secretary of state will be changed to show the filing of the document, the date of the filing, and the future date on which the document will be effective or evidence that the effectiveness was conditioned on the occurrence of a future event or fact.

- **Execution:** Pursuant to section 4.001 of the BOC, the certificate of amendment must be signed by a person authorized by the BOC to act on behalf of the entity in regard to the filing instrument. Please refer to the procedural information relating to the specific entity type for further information on execution requirements. Generally, a governing person or managerial official of the entity signs a filing instrument.

  The certificate of amendment need not be notarized. However, before signing, please read the statements on this form carefully. The designation or appointment of a person as the registered agent by a managerial official is an affirmation by that official that the person named in the instrument has consented to serve as registered agent. (BOC § 5.2011, effective January 1, 2010)

  A person commits an offense under section 4.008 of the BOC if the person signs or directs the filing of a filing instrument the person knows is materially false with the intent that the instrument be delivered to the secretary of state for filing. The offense is a Class A misdemeanor unless the person's intent is to harm or defraud another, in which case the offense is a state jail felony.

- **Payment and Delivery Instructions:** The filing fee for a certificate of amendment is **$150**, unless the filing entity is a nonprofit corporation or a cooperative association. The filing fee for a certificate of amendment for a nonprofit corporation or a cooperative association is **$25**. Fees may be paid by personal checks, money orders, LegalEase debit cards, or American Express, Discover, MasterCard, and Visa credit cards. Checks or money orders must be payable through a U.S. bank or financial institution and made payable to the secretary of state. Fees paid by credit card are subject to a statutorily authorized convenience fee of 2.7 percent of the total fees.

  Submit the completed form in duplicate along with the filing fee. The form may be mailed to P.O. Box 13697, Austin, Texas 78711-3697; faxed to (512) 463-5709; or delivered to the James Earl Rudder Office Building, 1019 Brazos, Austin, Texas 78701. If a document is transmitted by fax, credit card information must accompany the transmission (Form 807). On filing the document, the secretary of state will return the appropriate evidence of filing to the submitter together with a file-stamped copy of the document, if a duplicate copy was provided as instructed.

Revised 05/11

Form 424 **(Revised 05/11)** Submit in duplicate to: Secretary of State P.O. Box 13697 Austin, TX 78711-3697 512 463-5555 FAX: 512/463-5709 **Filing Fee: See instructions**	**Certificate of Amendment**	This space reserved for office use.

Entity Information

The name of the filing entity is:

Avel eCare, LLC

State the name of the entity as currently shown in the records of the secretary of state. If the amendment changes the name of the entity, state the old name and not the new name.

The filing entity is a: (Select the appropriate entity type below.)

- ☐ For-profit Corporation
- ☐ Nonprofit Corporation
- ☐ Cooperative Association
- ☑ Limited Liability Company
- ☐ Professional Corporation
- ☐ Professional Limited Liability Company
- ☐ Professional Association
- ☐ Limited Partnership

The file number issued to the filing entity by the secretary of state is: 803024488

The date of formation of the entity is: June 2, 2017 (SD Domicile); April 23, 2018 (TX Qualification)

Amendments

1. Amended Name

(If the purpose of the certificate of amendment is to change the name of the entity, use the following statement)

The amendment changes the certificate of formation to change the article or provision that names the filing entity. The article or provision is amended to read as follows:

The name of the filing entity is: (state the new name of the entity below)

The name of the entity must contain an organizational designation or accepted abbreviation of such term, as applicable.

2. Amended Registered Agent/Registered Office

The amendment changes the certificate of formation to change the article or provision stating the name of the registered agent and the registered office address of the filing entity. The article or provision is amended to read as follows:

Registered Agent
(Complete either A or B, but not both. Also complete C.)

☐ A. The registered agent is an organization (cannot be entity named above) by the name of:

OR

☐ B. The registered agent is an individual resident of the state whose name is:

First Name *M.I.* *Last Name* *Suffix*

The person executing this instrument affirms that the person designated as the new registered agent has consented to serve as registered agent.

C. The business address of the registered agent and the registered office address is:

Street Address (No P.O. Box) *City* *State* *Zip Code*

TX

3. Other Added, Altered, or Deleted Provisions

Other changes or additions to the certificate of formation may be made in the space provided below. If the space provided is insufficient, incorporate the additional text by providing an attachment to this form. Please read the instructions to this form for further information on format.

Text Area (The attached addendum, if any, is incorporated herein by reference.)

☐ **Add** each of the following provisions to the certificate of formation. The identification or reference of the added provision and the full text are as follows:

☑ **Alter** each of the following provisions of the certificate of formation. The identification or reference of the altered provision and the full text of the provision as amended are as follows:

See attached revision to Section 11 of the Application for Registration of a Foreign Limited Liability Company.

☐ **Delete** each of the provisions identified below from the certificate of formation.

Statement of Approval

The amendments to the certificate of formation have been approved in the manner required by the Texas Business Organizations Code and by the governing documents of the entity.

Effectiveness of Filing (Select either A, B, or C.)

A. ☑ This document becomes effective when the document is filed by the secretary of state.

B. ☐ This document becomes effective at a later date, which is not more than ninety (90) days from the date of signing. The delayed effective date is: _____

C. ☐ This document takes effect upon the occurrence of a future event or fact, other than the passage of time. The 90th day after the date of signing is: _____

The following event or fact will cause the document to take effect in the manner described below:

Execution

The undersigned signs this document subject to the penalties imposed by law for the submission of a materially false or fraudulent instrument and certifies under penalty of perjury that the undersigned is authorized under the provisions of law governing the entity to execute the filing instrument.

Date: 12/17/2021

By: _____

Signature of authorized person

Kyle Groteluschen, General Counsel and Secretary

Printed or typed name of authorized person (see instructions)

11. The name, title, and address of each governing person is as follows:

Doug Duskin, CEO
4500 N. Lewis Ave,
Sioux Falls, SD 57104

Deanna Larson, President
4500 N. Lewis Ave,
Sioux Falls, SD 57104

Jay Weems, CFO
4500 N. Lewis Ave,
Sioux Falls, SD 57104

Kyle Groteluschen, Secretary
4500 N. Lewis Ave,
Sioux Falls, SD 57104

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 Avel eCare Pharmacy

Physical Address 4103 N Loop 1604 West, Suite 202

City San Antonio State TX Zip 78249

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-283-7279 Website www.avelecare.com

Licensing Company Email pharmacy@avelecare.com

Section 2: Personal Information

First Jeremy Middle Myron Last Mueller

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

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

Mailing Address 4103 N Loop 1604 West, Suite 202

City San Antonio State TX Zip 78249

Telephone [redacted] Email jeremy.mueller@avelecare.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 JM

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

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.

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)	
Sunshine Bible Academy		09/87 - 05/90	
Address	**City**	**State**	**Zip**
400 Sunshine Drive	Miller	SD	57362
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Oklahoma Wesleyan University		08/90 - 05/94	
Address	**City**	**State**	**Zip**
2201 Silver Lake Road	Bartlesville	OK	74006
Diploma/Degree obtained, if any			
BS in Biology			

School Name		From - To (MM/YY – MM/YY)	
South Dakota State University		09/01 - 05/05	
Address	**City**	**State**	**Zip**
1175 Medary Avenue	Brookings	SD	57006
Diploma/Degree obtained, if any			
PharmD			

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
08/17 - present	[redacted] Robinwood Lane	San Antonio	TX	78248
10/15-08/17	2408 E Marson Drive	Sioux Falls	SD	57103
07/08-10/15	5804 W 53rd Street	Sioux Falls	SD	57106

Applicant's initials JM

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)	
Avel eCare Pharmacy			09/17 - present	
Business Address		**City**	**State**	**Zip**
4103 N Loop 1604 W, Suite 202		San Antonio	TX	78249
Phone	**Title**		**Number of Employed Hours**	
855-283-7279	Pharmacy Manager		9,000	
Description of Duties				
Responsible for oversight & management of all pharmacy activities as we provide remote support to hospitals in multiple states, including order review/entry/verification, drug information consults with providers and nurses, patient monitoring, etc.				

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

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

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

Applicant's initials JM

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 JM

I, Jeremy Myron Mueller, **certify that as the designated representative for**

Avel eCare 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

Jeremy Mueller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/27/2022

Date

Applicant's initials JM

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 Mueller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/28/22

Date

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

State of Texas, ss. County of Bexar

I, Jeremy Mueller, 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

1/28/22

Date

Subscribed and Sworn to before me this 28 day of January 2022

Notary Public Signature

SOFIA MERCADO
Notary Public, State of Texas
My Comm. Exp. 02-03-2025
ID No. 13291006-4

(Seal)

Applicant's initials JM

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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH 03951	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: CTCA/Rx

Physical Address: 610 Celebrate Life Pkwy

City: Newnan State: GA Zip: 30265

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 678-552-2013 Toll Free # (NAC 639.708, NRS 639.23286): 833-570-4736

Fax: 678-552-2014 Contact Email: licensing@maxor.com

Website: N/A

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Valeana Dawn Domercant

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21428

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: Valeana Dawn Domercant	NV Pharmacist Registration #: 21428
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): CTCA Pharmacy Holdings, LLC (see attached chart for ownership structure)

Corporation/Organization Name: CTCA Rx, LLC

Mailing Address: 610 Celebrate Life Pkwy

City: Newnan State: GA Zip: 30265

Telephone: 678-552-2013 Email: ctcarx@ctca-hope.com

Contact Person Name: Preston Sisler (outside consultant, Advis, Inc.; 708-478-7030; psisler@advis.com)

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, Enterprise Pharmacy (title) for CTCA/Rx (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).

Christopher Marcum

Print Name of Authorized Person

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

12/20/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Christopher Marcum 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, Enterprise Pharmacy (title) for CTCA/Rx (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 20th day of December, 2021

Parul Jain
Notary Public

PARUL JAIN
NOTARY PUBLIC
STATE OF OHIO
MY COMMISSION EXPIRES
05/17/2026

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: Valeana Dawn Domercant Pharmacist Registration #: 21428

Pharmacy Name: CTCA/Rx

Initial each statement below to indicate you have read and agree with the following:

VD 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.

VD 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.

VD 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.

VD 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)).

VD 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 <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?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

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.

Valeana Domercant
Original signature of Managing Pharmacist (copies or stamps not accepted)

12/27/2021
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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded** - The top 4 shareholder/stockholders. b. **For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Christopher Marcum, Vice President, Enterprise Pharmacy

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)

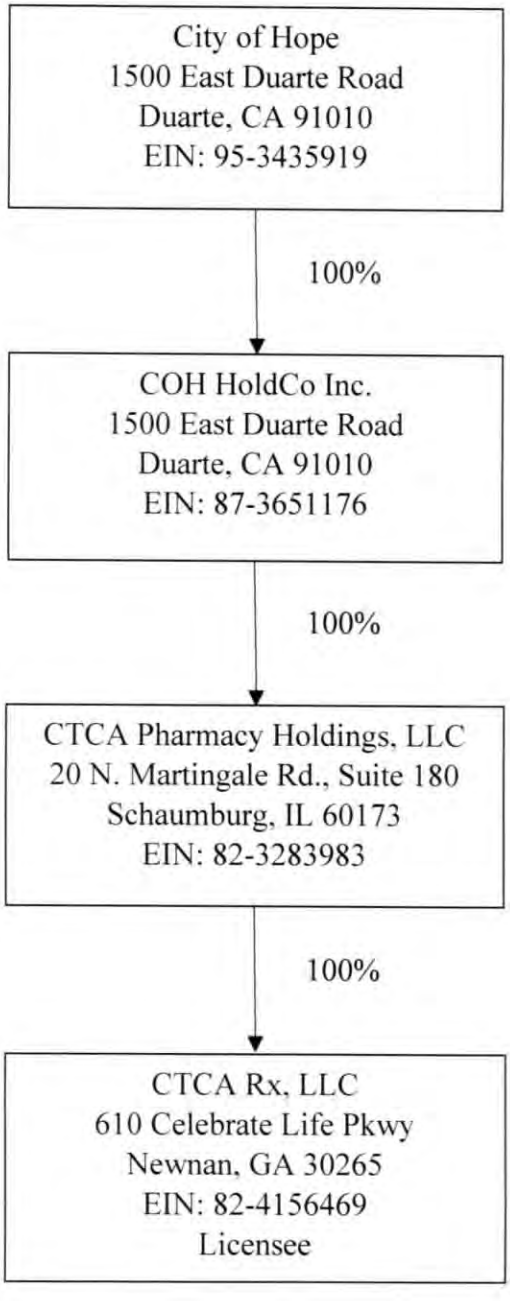
12/20/2021

Date

Board Use Only	Date Received: _____	Amount: 500 Check# 36456

Pharmacy Application

Disclosure of Ownership and Officers



- LLC Manager (CTCA Rx, LLC): Timothy Flanigan
- Officers (CTCA Rx, LLC): Christopher Marcum – Vice President, Enterprise Pharmacy

Submitted for:
CTCA Rx, LLC

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CTCA RX, 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 FIFTEENTH DAY OF DECEMBER, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CTCA RX, LLC" WAS FORMED ON THE THIRTY-FIRST DAY OF OCTOBER, A.D. 2017.

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

Jeffrey W. Bullock, Secretary of State

6598372 8300

SR# 20214107821

Authentication: 204990526

Date: 12-15-21

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

Control Number : 17122923

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

CTCA Rx, LLC
a Foreign Limited Liability Company

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 22099727
Date Inc/Auth/Filed	: 11/22/2017
Jurisdiction	: Delaware
Print Date	: 12/01/2021
Form Number	: 211

Brad Raffensperger

Brad Raffensperger
Secretary of State

STATE OF GEORGIA
Georgia Board of Pharmacy
Retail Pharmacy
LICENSE NO. PHRE010615 Status: Active

CTCA/Rx,
610 Celebrate Life Pkwy
Newnan GA 30265

Expires: 06/30/2023
Issued: 03/26/2018

Pharmacist in Charge RPH026437
Valeana Dawn Domercant

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Retail Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Retail Pharmacy
LICENSE NO. PHRE010615 Status: Active
CTCA/Rx,
610 Celebrate Life Parkway
Newnan GA 30265

Expires: 06/30/2023 Pharmacist in Charge RPH026437
Issued: 03/26/2018 Valeana Dawn Domercant
Real-time license verification is available at gadch.mylicense.com/verification

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC7726764	08-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-23-2021

CTCA/RX
CTCA RX, LLC
610 CELEBRATE LIFE PKWY
NEWNAN, GA 302653026

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
FC7726764	08-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-23-2021

CTCA/RX
CTCA RX, LLC
610 CELEBRATE LIFE PKWY
NEWNAN, GA 302653026

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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)

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: CTCA Rx, LLC d/b/a CTCA/Rx

Physical Address: 610 Celebrate Life Parkway

City: Newnan State: GA Zip: 30265

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 678-552-2013 Website: N/A

Licensing Company Email: licensing@maxor.com

Section 2: Personal Information

First: Valeana Middle: Dawn Last: Domercant

Alias(es, nicknames, name changes, etc.): Valeana Dawn Ruffin

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

Mailing Address: [redacted] Oak Valley Cir SE

City: Smyrna State: GA Zip: 30265

Telephone: [redacted] Email: vddomercant@maxor.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 VD

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	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
The University of Tennessee Health Science Center - College of Pharmacy	881 Madison Ave	Memphis	TN	38163	08/07 - 05/11	Doctor of Pharmacy
The University of Tennessee, Knoxville	320 Student Services Building	Knoxville	TN	37996	08/02 - 05/06	B.S. Biochemistry Cellular and Molecular Biology
Campbell High School	5265 Ward Street	Smyrna	GA	30080	08/98 - 05/02	H.S. 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
09/20 - present	[redacted]Oak Valley Cir SE	Smyrna	GA	30082
06/16 - 09/20	2532 Bridlewood Ln SE	Atlanta	GA	30339
02/13 - 06/16	3833 Peachtree Rd NE	Atlanta	GA	30319
07/11 - 02/13	10820 Snapdragon Way	Knoxville	TN	37931

Applicant's initials _____

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)
CTCA/Rx			06/18 - present
Business Address	**City**	**State**	**Zip**
610 Celebrate Life Parkway	Newnan	GA	30265
Phone	**Title**		**Number of Employed Hours**
678-552-2013	Pharmacist in Charge		7200
Description of Duties			

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

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

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

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

Directs and coordinates all pharmacy activities, including clinical services, performance improvement, dispensing and the purchasing, receipt and storage of pharmaceuticals.

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 WD

I, Valeana Domercant, **certify that as the designated representative for** CTCA/Rx,

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

Valeana Domercant

Print Name (First, Last)

Valeana Domercant

Original Signature (electronic, copies or stamps not accepted)

12-27-2021

Date

Applicant's initials VD

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.

Valeana Domercant

Print Name (First, Last)

Valeana Domercant

Original Signature (electronic, copies or stamps not accepted)

12-27-2021

Date

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

State of Georgia, ss. County of Cowetа

I, Valeana D Domercant, 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.

Valeana Domercant

Original Signature

12/27/2021

Date

Subscribed and Sworn to before me this 27 day of December 21

Notary Public Signature

C HAYES JR
NOTARY PUBLIC
Douglas County
State of Georgia
My Comm. Expires July 19, 2022

(Seal)

Applicant's initials VD

Georgia Drugs and Narcotics Agency
254 Washington Street SW - G2000
Atlanta, Georgia 30334

RETAIL

Pharmacy Permit Inspection Form

Board Office: 404-651-8000
Board Fax: 470-386-6137
GDNA Office: 404-656-5100
GDNA Fax: 404-651-8210
GDNA Toll Free: 800-656-6568

Pharmacy Information

Inspection Type:	Routine Inspection						
Permit Type Primary:	Independent 10-01	Permit Type Secondary:					
Pharmacy Name	CTCA/Rx					County:	Coweta
						Date:	6/17/2020
Pharmacy Permit #:	PHRE010615	Exp Date:	6/30/2021	DEA:	FC7726764	Exp Date:	12/31/2021
Street Address:	610 Celebrate Life Pkwy						
City:	Newnan	State:	GA	Zip:	30265	Hours:	MF 8-6
Phone:	678-552-2013	Fax:	678-552-2014	Pharmacy Email:		not available	
Pharmacist-in-Charge:	Valeana Dawn Domercant			License #:	RPH026437	Exp Date:	12/31/2020
Other Employees							
Full-Time Pharmacist	Dustin Ray Hirsh			License #	RPH027445	Exp Date:	12/31/2020
Pharmacy Technician	Catilin Jarvis			Registration #	PHTC049195	Exp Date:	6/30/2021
Pharmacy Technician	Hamshana Aleena Griffin-Ranson			Registration #	PHTC049246	Exp Date:	6/30/2021
Last GDNA Inspection Date	9/25/2018			Inspected By:	Mathis		
Recommendations Made:	N/A			Corrections Made:	N/A		

Criteria	Satisfactory	Comments
1. Pharmacy License	Yes	
2. DEA Permit	Yes	
3. Pharmacist/Intern License	Yes	
4. Dangerous Drug Rxs	Yes	
5. Schedule II Rxs	N/A	No Controlled substance dispensing/stock
6. Schedule III, IV, V Rxs	N/A	No Controlled substance dispensing/stock
7. Refill Records / Computer Printout Records	Yes	
8. Exempt Narcotic Book	N/A	No exempt narcotics sold
9. PSE Logbook and Combat Meth Certificate	N/A	No OTC PSE sales
10. Drug Distribution Records (Non-Rx Sales)	N/A	No non-rx drug distribution
11. DEA Biennial Inventory	Yes	5/1/2020
12. Drug Purchase Records (Invoices/Order Forms)	Yes	
13. Rx Department Security / Authorized Access Only	Yes	
14. Rx Department Sanitation / Orderly	Yes	
15. Adequate Pharmacy Temperature Control	Yes	
16. Rx Drug Stock (Adulterated / Misbranded)	Yes	
17. Laws / Rules / Appropriate Reference Material	Yes	
18. Required Equipment for Pharmacy Type	Yes	
19. Exemption Documentation / Other Reports	N/A	
20. Policies & Procedures Manual (if required)	N/A	
21. Patient Counseling / Patient Profile Records	Yes	Review 480-31-.01 & 26-4-85 for patient counseling.
22. Safety Concerns, i.e. Adequate Staffing	Yes	
23. Proper Supervision of Pharmacy Technicians	Yes	Review 480-15-.03 & 26-4-82 for pharmacist to pharmacy technician ratio.
24. List Drug Suppliers and Reverse Distributors:	Amerisource	HerculesRx Oncology Supply

Georgia Drugs and Narcotics Agency
254 Washington Street SW - G2000
Atlanta, Georgia 30334

RETAIL

Pharmacy Permit Inspection Form

Board Office: 404-651-8000
Board Fax: 470-386-6137
GDNA Office: 404-656-5100
GDNA Fax: 404-651-8210
GDNA Toll Free: 800-656-6568

Compounding	Does this Pharmacy Compound Medication?						No			
	Type of Compounding Conducted				No Compounding Conducted					
25. Was a GDNA non-sterile compounding inspection conducted during this visit?							No			
26. Was a GDNA sterile compounding inspection conducted during this visit?							No			
27. Is this pharmacy registered with the FDA as a 503B Outsourcing Facility?							No			
28. Does this pharmacy receive compounded products from outside sources?							No			
	If yes, provide names of suppliers:	N/A								
Vaccinations	Does this pharmacy administer vaccinations via protocol?						No			
29. Types of vaccinations adminstered:										
	Influenza	N/A	Shingles	N/A	Pneumococcal	N/A	Meningitis	N/A	Other	

	Satisfactory	Comments
30. Vaccination Protocol Agreement	N/A	
31. Signed & Notarized Affidavit	N/A	
32. Liability Insurance for each Vaccinating Pharmacist	N/A	
33. Immunization cards issued	N/A	
34. Attempt to contact PCP within 72hrs	N/A	
35. Reporting vaccinations to G.R.I.T.S.	N/A	
36. Supervision during administration	N/A	

Delivery by Mail	Does the pharmacy deliver prescription mediations to the patient via mail or common carrier?	Yes	

	Satisfactory	Comments
37. Controlled substance prescriptions sent signature required	Yes	
38. Temperature sensitive Rxs packed correctly	Yes	
39. Proper documentation maintained by pharmacy	Yes	
40. Replacement of compromised Rx shipment	Yes	

Recommendations / Comments

N/A

This inspection report has been read and explained to the pharmacist whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do affirm the information I have given pursuant to this inspection is true and correct to the best of my knowledge. This inspection report is not intended to be all inclusive, and there may be deficiencies, non-compliance, or violations of the laws and rules not detected and noted in this report.

Pharmacist's Email: n/a

Printed Name: Valeana Dawn Domercant

Signature: Pharmacist-in-Charge or on Duty

Today's Date 6/17/2020

Printed Name: Jordan Khail

Special Agent, Georgia Drugs & Narcotics Agency

advis

December 29, 2021

VIA FEDEX

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

RE: Notice of Organizational Change
Pharmacy Application
CTCA Rx, LLC
610 Celebrate Life Pkwy
Newnan, GA 30265
Nevada License Number: PH03951

To Whom it May Concern:

Enclosed please find a completed Pharmacy Application (the "Application"), submitted on behalf of CTCA Rx, LLC.

CTCA Rx, LLC is 100% owned by CTCA Pharmacy Holdings, LLC. On or around **February 1, 2022**, COH HoldCo Inc., of which City of Hope is the sole corporate member, will acquire 100% of the membership interests in CTCA Pharmacy Holdings, LLC. This organizational change will have no impact on CTCA Rx, LLC's legal name, federal tax identification number, location, supervising personnel, operating procedures, or services. CTCA Rx, LLC also sent a license verification request to the Georgia Board of Pharmacy, which is currently pending.21

We will promptly communicate any changes in the transaction closing date. In the meantime, should you need anything further, please do not hesitate to contact me at (708) 478-7030 or at psisler@advis.com.

Sincerely,

Preston Sisler, J.D.
Vice President

Enclosures

cc (via email): Cynthia Filippone, Deputy General Counsel, Ci

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 (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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH_____	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Healthcare Pharmacy LLC

Physical Address: 2320 West Peoria Ave , Suite D132-A

City: Phoenix State: AZ Zip: 85029

Mailing Address (if different from physical address): 2320 West Peoria Ave., Suite D132-A

City: Phoenix State: Az Zip: 85029

Telephone: 602.704.0044 Toll Free # (NAC 639.708, NRS 639.23286): 888.348.3010

Fax: 602.767.5522 Contact Email: apjones@healthcare.com

Website: Pharmacy.Healthcare.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Apral Jones-Ford

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18989 ✓ok exp. 10/31/2023

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: Apral Jones-Ford	NV Pharmacist Registration #: 18989
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: Arizona

Parent Company (if any): Healthcare, Inc.

Corporation/Organization Name: Healthcare Pharmacy LLC

Mailing Address: 2320 West Peoria Ave., Suite D132-A

City: Phoenix State: AZ Zip: 85029

Telephone: 602 704.0044 Email: apjones@healthcare.com

Contact Person Name: Apral Jones-Ford

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: _____

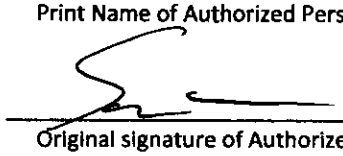
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Healthcare 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).

Scott Lake

Print Name of Authorized Person



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

1/5/2022

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Scott Lake 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 Healthcare 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 7th day of January, 2022.

Notary Public

VICTORIA PORTILLO
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 615126
Expires September 23, 2025

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: NA _____ Pharmacist Registration #: _____

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

_____ 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.

_____ 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.

_____ 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.

_____ 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)).

_____ 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) 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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/. NAC 639.500S. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded** - The top 4 shareholder/stockholders. b. **For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Scott Lake

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)

1/5/2022

Date

Board Use Only	Date Received: _____	Amount: 500 CHECK # 872515

HealthCare Pharmacy

Healthcare Pharmacy LLC Member and Officer

Scott Lake (President)
Address: [redacted] West Black Ridge Circle, Herriman, UT 84096

Healthcare, Inc. (Sole Member)
Address: 3401 N. Miami Avenue, Ste. 205, Miami, Florida 33127
Office Number: (239) 282-4600
FEIN: 45-2731251

21081613455759

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

HEALTHCARE PHARMACY, LLC

ACC file number: 23236662

was incorporated under the laws of the State of Arizona on 06/16/2021, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **08/16/2021**

Matthew Neubert, Executive Director

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH0981109	10-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-18-2021

HEALTHCARE PHARMACY LLC
2320 W PEORIA AVE STE D132-A
PHOENIX, AZ 850294753

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
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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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HEALTHCARE PHARMACY LLC
2320 W PEORIA AVE STE D132-A
PHOENIX, AZ 850294753

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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)

Arizona State Board of Pharmacy

Physical Address: 1616 W. Adams, Suite 120, 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 :	Healthcare Pharmacy
Address :	2320 West Peoria Avenue Suite D132-A Phoenix AZ 85029
License No :	Y009026
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	10/25/2021
Expiration Date :	10/31/2022
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 01/11/2022

NEVADA STATE BOARD OF PHARMACY

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

y

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Healthcare Pharmacy LLC

Physical Address: 2320 West Peoria Ave., Suite D132-A

City: Phoenix State: AZ Zip: 85029

Mailing Address (if different from physical address): 2320 West Peoria Ave., Suite D132-A

City: Phoenix State: AZ Zip: 85029

Telephone: 602.704.0044 Website: Pharmacy.Healthcare.com

Licensing Company Email: apjones@healthcare.com

Section 2: Personal Information

First: Apral Middle: Dawn Last: Jones-Ford

Alias(es, nicknames, name changes, etc.): Jones or Ford

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

Mailing Address: [redacted] North 54th Court

City: Phoenix State: AZ Zip: 85018

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 _____

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 University		01/91 - 05/95	
Address	**City**	**State**	**Zip**
4600 Sunset Ave.	Indianapolis	IN	46208
Diploma/Degree obtained, if any: Bachelor of Science, Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Auburn University		08/89 - 12/90	
Address	**City**	**State**	**Zip**
23 Samford Hall	Auburn	AL	36849
Diploma/Degree obtained, if any: None			

School Name		From - To (MM/YY – MM/YY)	
Southeast Missouri State University		01/88 - 05/89	
Address	**City**	**State**	**Zip**
One University Plaza	Cape Girardeau	MO	63701
Diploma/Degree obtained, if any: None			

School Name		From - To (MM/YY – MM/YY)	
Cape Central High School		08/84 - 06/88	
Address	**City**	**State**	**Zip**
1000 S. Silver Springs Rd.	Cape Girardeau	MO	63703
Diploma/Degree obtained, if any: High School Diploma in General Studies			

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
07/18 - Present	[redacted] N. 54th Court	Phoenix	AZ	85018
10/16 - 07/18	3655 N. 59th Place	Phoenix	AZ	85018
05/15 - 10/16	5841 E. Indian Bend Rd	Paradise Valley	AZ	85253
03/12 - 05/15	3010 N. 34th St.	Phoenix	AZ	85018
10/10 - 03/12	8004 W. Foothill Dr.	Peoria	AZ	85383

Applicant's initials _____

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)	
Summit Pharmacy			11/2008 to 11/2019	
Business Address		**City**	**State**	**Zip**
2320 West Peoria Ave., Suite D132		Phoenix	AZ	85029
Phone	**Title**		**Number of Employed Hours**	
602.678.5400	Pharmacist In Charge and VP of Business Development		24,960 hours	
Description of Duties				
Managing pharmacist and technicians. Compliance with rules and regulations in the pharmacy. Typed new prescriptions, utilization review of processed prescription, filled prescriptions, and verification of final product dispensed.				

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

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

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

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?		✓

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 # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
September 2012	6/10/2020	NJ		Gloucester

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
GLO-L-1138-13.	See attached.

Reason/Charge
See attached.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
See attached.	See attached.

Name of Business/Industry/Entity
See attached.

Provide explanation below:

See attached.

Original Signature (electronic, copies or stamps not accepted)

1/4/2022
Date

Applicant's initials

HealthCare Pharmacy

Question 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.)

Response:
On or around August of 2013, Allstate New Jersey Insurance Company (et al.) filed suit against, among others, Summit Pharmacy, Inc. ("Summit"), myself Apral Jones (at the time an employee of Summit), and Sherri Oxford, a pharmacist who, at one time, worked for Summit. The complaint included counts under the New Jersey Insurance Fraud Prevention Act – there were no allegations of fraud with regard to Medicare, Medicaid or government or government-funded payer (rather, the matter related solely to claims submitted to Personal Injury Protection (PIP) carriers). One or more of the counts concerned the submission of claims to the Plaintiff by Summit, which included paperwork on which the name of Sherri Oxford, a pharmacist then-working for Summit, appeared. As Summit and its agents later learned, Ms. Oxford had concealed from others the fact that her pharmacist licensure had been suspended for a brief period. Upon Summit's determination of Ms. Oxford's status, she was promptly terminated, and internal remedial measures taken. Note that at all times, Ms. Oxford's work was also subject to another pharmacist's review so prescriptions in question were all reviewed by a licensed pharmacist. However, Allstate's principal claim was predicated on those PIP claims submitted containing Ms. Oxford's name. Ultimately, the case was resolved by way of confidential settlement agreement, as between Plaintiffs on the one hand and Summit, Sherri Oxford, and myself (among others), on the other, in which none of the parties admitted wrongdoing.

2320 West Peoria Avenue, Suite D132-A, Phoenix, Arizona 85029
TF: 888-348-3010 P: 602-704-0044 F: 602-767-5522
W: Pharmacy.Healthcare.com

I, Apral Jones-Ford, **certify that as the designated representative for**

Healthcare Pharmacy 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

Apral Jones-Ford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/4/2022

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.

Apral Jones-Ford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 1/4/2022

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

State of Arizona, ss. County of Maricopa

I, Apral Jones-Ford, 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** 1/5/2022

Subscribed and Sworn to before me this 5th day of 2022.

Notary Public Signature

VINCENT NAVARRO
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 561673
Expires March 17, 2023

(Seal)

Applicant's initials

HealthCare Pharmacy

Summary of Disciplinary History

As of the date of this application, applicant (Healthcare Pharmacy LLC), its officers, and its parent company Healthcare, Inc. have no sanctions or discipline. However, we wanted to note that on November 8, 2021, Healthcare, Inc., parent company of Healthcare Pharmacy LLC, completed the purchase of and became sole owner of Summit Pharmacy, Inc. ("Summit Pharmacy"). Summit Pharmacy has disciplinary history, which occurred prior Healthcare, Inc.'s acquisition and is included in the materials included below.

Alabama State Board of Pharmacy

- Alabama State Board of Pharmacy license was issued on 10/19/2011.
- Summit Pharmacy was not dispensing controlled substances, and not submitting, "zero reports" to the Alabama Prescription Monitoring Program.
- Summit Pharmacy did not realize zero reports were required.
- Mid 2012, Summit Pharmacy was fined $1,000.

Hawaii State Board of Pharmacy

- On 2013 license renewal application, Summit Pharmacy disclosed Alabama State Board of Pharmacy's disciplinary action.
- Hawaii State Board of Pharmacy had no record of Summit Pharmacy disclosing the Alabama State Board of Pharmacy disciplinary action within the 30-day reporting period required by law, nor did Summit Pharmacy.
- In 2015, Hawaii State Board of Pharmacy filed disciplinary action for not reporting discipline in a timely manner.
- Summit Pharmacy was fined $1,500.

Florida State Board of Pharmacy

- Florida State Board of Pharmacy received disclosure of disciplinary action against Summit Pharmacy from Alabama State Board of Pharmacy.
- The Alabama State Board of Pharmacy fine was for not reporting zero fill to the Alabama Prescription Monitoring Program, which in turn would have been a violation if zero fill was not reported to Florida Prescription Monitoring Program.
- In November of 2016, Florida State Board of Pharmacy imposed disciplinary action against Summit Pharmacy for being fined by Alabama State Board of Pharmacy.
- Summit Pharmacy was fined $250 plus $1,359.89 in administrative costs.

HealthCare Pharmacy

Michigan State Board of Pharmacy

- Michigan State Board of Pharmacy received disclosure of disciplinary action taken against Summit Pharmacy by Alabama State Board of Pharmacy.
- It is a violation of Michigan Pharmacy law for a license to be disciplined by another professional board.
- In December of 2016, Michigan State Board of Pharmacy fined Summit Pharmacy for being disciplined by Alabama State Board of Pharmacy.
- Summit Pharmacy was fined $1,000.

Texas State Board of Pharmacy

- On the 2012 renewal application, a box was checked indicating no disciplinary action occurred within the last 36 months since the application date.
- No renewal application needed in 2013.
- On the 2014 renewal application, a box was checked indicating no disciplinary action occurred within the last 36 months since the application date.
- Both of the above statements were incorrect. Summit Pharmacy is unsure why these were answered incorrectly, but believe it to be an accidental oversight.
- Texas State Board of Pharmacy initiated disciplinary procedures against Summit Pharmacy for incorrect statements on the 2012 and 2014 renewal applications.
- In May of 2018, Texas State Board of Pharmacy assessed an administrative penalty of $2,000.

2320 West Peoria Avenue, Suite D132-A, Phoenix, Arizona 85029
TF 888-348-3010 P 602-704-0044 F 602-767-5522
W Pharmacy Healthcare.com

IN THE MATTER OF	)	BEFORE THE ALABAMA
SUMMIT PHARMACY, INC.	)	
Non- Resident Pharmacy	)	STATE BOARD OF PHARMACY
Permit Number 113820/201946	)	

CONSENT ORDER

This matter is before the Alabama State Board of Pharmacy (the "Board") on a complaint against *SUMMIT PHARMACY, INC.* alleging a failure to report the dispensing of controlled substances as required by and in violation of Code of Alabama (1975) §20-2-213. This alleged failure constitutes grounds for discipline as set forth in Code of Alabama (1975) §20-2-213 (e).

The Board and *SUMMIT PHARMACY, INC.* pursuant to the provisions of Code of Alabama (1975) §41-22-12(f) have agreed to informally resolve the pending matter through the entry of a Consent Order, which shall include the following terms:

1. *SUMMIT PHARMACY, INC.* is guilty of violating Code of Alabama (1975) §34-23-33(2) as a result of failing to report to the Prescription Drug Monitoring Program database all controlled substances dispensed in violation of Code of Alabama (1975) §20-2-213.
2. *SUMMIT PHARMACY, INC.* shall pay an administrative fee to the Board in the amount of One Thousand Dollars ($1,000.00) within ten (10) days from the effective date of this Consent Order, which is the date it is signed on behalf of the Board. The obligation for payment of this fine shall not be dischargeable in bankruptcy nor shall *SUMMIT PHARMACY, INC.* attempt to do so.

3. *SUMMIT PHARMACY, INC.* expressly waves its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975) §34-23-34 and §34-23-92(12), Code of Alabama (1975) §41-22-12 and §41-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity to receive Notice of the applicable charges, a hearing before the Board in connection with any charges against you and any judicial review. *SUMMIT PHARMACY, INC.* further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.
4. By execution of this Consent Order, *SUMMIT PHARMACY, INC.* hereby releases the Board, its members, agents, representative, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.
5. *SUMMIT PHARMACY, INC.* acknowledges and agrees that any future violation of the Alabama Pharmacy Practice , the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state of any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license, including, but not limited to revocation.

6. *SUMMIT PHARMACY, INC.* acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. *SUMMIT PHARMACY, INC.* acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and are signing this Consent Order either on advice of counsel or with the understanding such advice could be sought.

DONE this the 13th day of June 2012.

Representative
SUMMIT PHARMACY, INC.

DONE this the 2 day of July 2012.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Donnie Calhoun, RPh, President

_____
James S. Ward, Attorney
For the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
Telephone: 205/871-5404
Facsimile: 205/871-5758

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2016 JAN 20 A 9:58
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS
2016 APR -1 P 2:38
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of	)	PHA 2015-38-L
	)	
SUMMIT PHARMACY, INC.,	)	SETTLEMENT AGREEMENT PRIOR TO
	)	FILING OF PETITION FOR DISCIPLINARY
Respondent.	)	ACTION AND BOARD'S FINAL ORDER;
	)	EXHIBIT "1"
	)	

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent SUMMIT PHARMACY, INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under permit number PMP 629. The

I HEREBY CERTIFY THAT THE ATTACHED
IS A TRUE AND CORRECT COPY OF THE
ORIGINAL ON FILE IN THE DEPARTMENT
OF COMMERCE & CONSUMER AFFAIRS.
Carli Fogle

permit was issued on or about January 26, 2010. The permit will expire or forfeit on or about December 31, 2015.

2. Respondent's mailing address for purposes of this action is c/o Michael A. Galpern, Esq., Locks Law Firm, 801 North Kings Hwy., Cherry Hill, New Jersey, 08034.

3. On or about December 20, 2013, Respondent submitted a renewal application indicating disciplinary action had been taken against Respondent.

4. Respondent attached a copy of a July 2, 2012 Consent Order with the Alabama State Board of Pharmacy in In the Matter of Summit Pharmacy, Inc./Permit Number 113820/201946 (hereinafter "the July 2, 2012 Consent Order") (Exhibit "1").

5. The July 2, 2012 Consent Order alleged Respondent failed to timely file controlled substance report(s) in violation of Alabama licensing laws, and assessed a $1,000 fine.

6. RICO alleges that disciplinary action was taken against Respondent by the State of Alabama and that Respondent failed to timely report this action.

7. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to report).

8. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is represented by Michael A. Galpern, Esq., Locks Law Firm, 801 North Kings Hwy., Cherry Hill, New Jersey, 08034 for purposes of this Settlement Agreement.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the July 2, 2012 Consent Order with the Alabama State Board of Pharmacy in In the Matter of Summit Pharmacy, Inc./Permit Number 113820/201946.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO No. PHA 2015-38-L.

10. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND FIVE-HUNDRED AND NO/100 DOLLARS ($1,500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again,

Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C. 5, C. 6, C. 7 and C. 8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Dec. 11, 2015

SUMMIT PHARMACY, INC
Respondent

By: _____
Its Attorney - NJ

DATED: Honolulu, Hawaii, January 19, 2016.

DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

APPROVED AS TO FORM:

MICHAEL A. GALPERN, ESQ.
Attorney for Respondent

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF SUMMIT PHARMACY, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO(S). PHA 2015-38-L; EXHIBIT "1"

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF SUMMIT PHARMACY, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO(S). PHA 2015-38-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

KERRI OKAMURA
Chairperson

3/31/16
DATE

GARRETT A. LAU
Vice Chairperson

MARCELLA CHOCK

MARY JO KEEFE

CAROLYN S. J. MA

PVL 07/01/15

STATE OF New Jersey }
} SS.
COUNTY OF Camden }

On this 11 day of Dec., 2015 before me personally appeared Michael Galperin ~~to me~~ known to be the person described, and who executed the foregoing instrument and acknowledged that he/she executed the same as his/her free act and deed.

This 9 -page Settlement Agreement document dated Dec. 11, 2015 was acknowledged before me by Michael Galperin this 11th day of Dec, 2015, in the City of Cherry Hill, in the County of Camden, in the State of ~~Hawaii~~ New Jersey.

Michelle Lyn Clark
Name:
Notary Public, State of ~~Hawaii~~ New Jersey

My Commission expires: ____

MICHELLE LYN CLARK
NOTARY PUBLIC
STATE OF NEW JERSEY
My Commission Expires Feb. 7, 2017

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

Celeste Philip, MD, MPH
Surgeon General and Secretary

Vision: To be the Healthiest State in the Nation

December 22, 2016

Summit Pharmacy
2320 West Peoria Ave
Suite D-132
Phoenix, AZ 85029

DEC 27 2016

Final Order filed: 11/15/2016
Case Number: 201607759
License Number: 22580

Dear Sir/Madam:

The Compliance Management Unit has received your payment of the fines and/or costs imposed in the Final Order for Case Number 201607759.

Amount Paid: $849.70

Date Received: 12/16/2016

Receipt Number: 116001738

Balance Paid in Full: Yes

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268, select option 3 or by fax at (850) 488-0796.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

Final Order No. DOH-16-2235-9 -MQA
FILED DATE NOV 15 2016
Department of Health
BY Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH, PETITIONER, vs. SUMMIT PHARMACY, INC., RESPONDENT.	CASE NO.: 2016-07759 LICENSE NO.: PH 22580

FINAL ORDER
APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), *Florida Statutes*, on October 19, 2016, in Kissimmee, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby **Ordered** and **Adjudged**:

1. The Settlement Agreement as submitted is hereby approved, adopted, and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.
2. Costs of investigation and prosecution are $599.70.

This Final Order shall takes effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 31 day of October, 2016.

BOARD OF PHARMACY

Jennifer L. Wennhold, MSW
Interim Executive Director
On Behalf of
Debra B. Glass, PharmB, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to **Summit Pharmacy, Inc.**, 2320 West Peoria Avenue, Suite D-132, Phoenix, Arizona 85029 ; and via electronic mail to **Karen B. Schapira, Esquire,** kbs@flhealthlaw.com ; **Christopher Jurich,** Assistant General Counsel, Prosecution Services Unit, christopher.jurich@flhealth.gov; and to **David D. Flynn,** Assistant Attorney General, Department of Legal Affairs, david.flynn@myfloridalegal.com this 15th day of November, 2016.

DEPUTY AGENCY CLERK

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2016-07759**

SUMMIT PHARMACY, INC.

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy ("Board") as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **Summit Pharmacy, Inc.** was a permitted special non-resident pharmacy in the state of Florida, having been issued permit number **PH 22580**. Respondent's mailing address of record is 2320 West Peoria Avenue, Suite D-132, Phoenix, Arizona 85029.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health ("Department") and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that it is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance** - Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine** - The Board of Pharmacy shall impose an administrative fine of **TWO HUNDRED FIFTY DOLLARS ($250.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **one (1) year** from the date the Final Order

approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs** - The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND THREE HUNDRED FIFTY-NINE DOLLARS AND EIGHTY-NINE CENTS ($1,359.89)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **one (1) year** from the date the Final Order is filed with the Department Clerk.

4. **Future Conduct** - Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms** - It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of

an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

6. **No Force or Effect until Final Order** - It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

7. **Purpose of Agreement** - This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any

of its members from further participation, consideration, or resolution of these proceedings.

8. **Not Preclude Additional Proceedings** - Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

9. **Waiver of Attorney's Fees and Costs** - Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

10. **Waiver of Procedural Rights** - Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

11. **Current Addresses** - Respondent shall keep current its mailing address and its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement In resolution of this matter.

SIGNED this 16th day of June, 2016.

Legal Representative for
Summit Pharmacy, Inc.
CASE NO. 2016-07759

STATE OF Florida

COUNTY OF Broward

Before me personally appeared Karen Schapira, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 16 day of June, 2016.

Notary Public
My Commission Expires:

TRISHA SPILLER
MY COMMISSION # EE 838912
EXPIRES: March 10, 2017
Bonded Thru Notary Public Underwriters

APPROVED this 17th day of June, 2016.

Celeste Philip, M.D., M.P.H.
Surgeon General and Secretary

Amy C. Thorn
Assistant General Counsel

Counsel for Petitioner
Amy C. Thorn
Florida Bar No. 0092097
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444 ext. 8154
Fax: (850) 245-4662

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

SUMMIT PHARMACY INC.
License Number: 53-01-009717

File Number: 53-16-141213
CONSENT ORDER AND STIPULATION

CONSENT ORDER

On June 16, 2016, the Department of Licensing and Regulatory Affairs (Department) executed an Administrative Complaint (Complaint) charging Summit Pharmacy Inc (Respondent Pharmacy) with violating section(s) 17768(2)(d) of the Public Health Code, MCL 333.1101 et seq.

Respondent Pharmacy has admitted that the facts alleged in the Complaint are true and constitute violation(s) of the Public Health Code. The Disciplinary Subcommittee of the Michigan Board of Pharmacy has reviewed this Consent Order and Stipulation (Order) and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violation(s) of section(s) 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS ORDERED that, for the cited violation(s) of the Public Health Code, Respondent is FINED $1,000.00, 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, Legal Affairs Division, Compliance Section, 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 **53-16-141213**

IT IS FURTHER ORDERED that, if Respondent Pharmacy fails to comply with the terms and conditions of this Order, Respondent Pharmacy's license shall be automatically suspended for a minimum of one day. If, within six months of the suspension of the license, Respondent Pharmacy complies with the terms of this Order, the license shall be automatically reinstated.

IT IS FURTHER ORDERED that if Respondent Pharmacy's license remains suspended for more than six months, Respondent Pharmacy must apply for reinstatement of the license. If Respondent Pharmacy applies for reinstatement of the license, application for reinstatement shall be in accordance with sections 16245 and 16247 of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

Dated 12-7-16

STIPULATION

1. The facts alleged in the Complaint are true and constitute violation(s) of section(s) 17768(2)(d) of the Public Health Code, supra

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, MCL 24.201 et seq., to require the 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. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231

et seq., and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Nichole Penny, R.Ph., a member of the Board 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 Order.

5. This 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 matter.

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent Pharmacy and the Department expressly reserve the right to further proceedings, should this Order be rejected.

AGREED TO BY:

Kim Gaedeke, Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 8/11/2016

AGREED TO BY:

Stephen Persons, R.Ph.
Authorized Representative for
Summit Pharmacy Inc.
Respondent Pharmacy

Dated: 8/29/16

This is the final page of a Consent Order and Stipulation in the matter of Summit Pharmacy Inc. File Number 53-16-141213, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included

SDM

AGREED BOARD ORDER #F-17-029

RE: IN THE MATTER OF
SUMMIT PHARMACY, INC
(PHARMACY LICENSE #27277)

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 pharmacy license number 27277 issued to Summit Pharmacy, Inc. (Respondent), 2320 West Peoria Avenue, Suite D-132, Phoenix, Arizona 85029.

By letter dated December 21, 2017, 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:

> Sections 565.002(a)(3) and (10); and 565.002(c) of the Texas Pharmacy Act, TEX OCC CODE ANN. Title 3, Subtitle J (2013); and
>
> Section 281.8(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014), in that allegedly,

COUNTS

(1) On or about July 2, 2012, the Alabama Board of Pharmacy entered a Consent Order against the Alabama non-resident pharmacy permit number 113870201946, held by Summit Pharmacy, Inc. The Order was based on failure to timely report controlled substance data to Alabama's prescription drug monitoring program database. The Consent Order imposed a $1,000 fine.

On or about December 19, 2012, Summit Pharmacy, Inc. submitted an application for renewal of its license as a nonresident pharmacy to the Texas State Board of Pharmacy. On the application it was falsely indicated that the pharmacy had not been subject to any disciplinary action by any regulatory authority within the last 36 months, when, on July 2, 2012 it was subject to the Alabama Board of Pharmacy Consent Order previously described.

(2) On or about December 15, 2014, Summit Pharmacy, Inc. submitted an application for renewal of its license as a non-resident pharmacy. On the application it was falsely indicated that the pharmacy had not been subject to any disciplinary action by any regulatory authority within the last 36 months, when in July 2012, it was subject to the Alabama Board of Pharmacy Consent Order described in Count (1).

An informal conference was held in the Board's office on March 6, 2018, with Apral Jones, Vice President Business Development; and Bruce Hayden, Chief Financial Officer,

Summit Pharmacy, Inc., on behalf of Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Bradley A. Miller, Ph.D., Board Member; Dennis E. Wiesner, R.Ph., Board Member; and Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary; with Kerstin Arnold, General Counsel. Alissa Zachary, Staff Attorney, was also in attendance.

At the aforementioned conference, Bruce Hayden, on behalf of Respondent, waived the right to be represented by legal counsel. By signing this Order, Bruce Hayden, 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:

(1) Respondent shall pay an administrative penalty of two thousand dollars ($2,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018).

And it is so ORDERED

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of May, 2018.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Bruce Hayden, Chief Financial Officer, Summit Pharmacy, Inc.
On behalf of Summit Pharmacy, Inc.

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 10/25/2021 for Healthcare Pharmacy

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y009026	10/31/2022	Healthcare Pharmacy
Address :		
2320 West Peoria Avenue		
Zip :	City :	State :
85029	Phoenix	AZ
Phone :	Email :	Inspection Date :
(623) 261-3711	apraljones@me.com	10/25/2021
PIC :	Pic License Exp Date :	Inspection Reviewed With :
Apral Jones	10/31/2022	Apral Jones
Reviewers License# :	Inspection type :	
S012316	Opening	
Inspection Conducted By :		
Elizabeth Dodge		

ACTIVITIES

1	Nonsterile Compounding	○YES ◉NO
2	Nonsterile Hazardous Compounding	○YES ◉NO
3	Sterile Compounding	○YES ◉NO
4	Sterile Hazardous Compounding	○YES ◉NO

Hospital Facility Data

# Licensed Beds	DHS License #

PHARMACY DEPARTMENT

1	Size/Personnel Measured: 2180 sf	◉S ○C/P ○U ○N/A R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	◉S ○C/P ○U ○N/A R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	◉S ○C/P ○U ○N/A R4-23-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

4	Counter	◉S ○C/P ○U ○N/A R4-23-609(B); R4-23-672(A), R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	◉S ○C/P ○U ○N/A R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area	○S ○C/P ○U ◉N/A R4-23-609(D)
7	Enclosed (barrier)	◉S ○C/P ○U ○N/A R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	◉S ○C/P ○U ○N/A R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	◉S ○C/P ○U ○N/A R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation	◉S ○C/P ○U ○N/A R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier	◉S ○C/P ○U ○N/A R4-23-609(H)
12	Receiving/checking area	◉S ○C/P ○U ○N/A R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	○S ○C/P ○U ◉N/A R4-23-610(F)
14	Walls	◉S ○C/P ○U ○N/A R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	◉S ○C/P ○U ○N/A R4-23-611(A)(2); R4-23-672(A), R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	○S ○C/P ○U ◉N/A R4-23-611(A)(2); R4-23-672(A), R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	◉S ○C/P ○U ○N/A R4-23-611(A)(2); R4-23-672(A), R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	◉S ○C/P ○U ○N/A R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	◉S ○C/P ○U ○N/A R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area	○S ○C/P ○U ◉N/A R4-23-410(E)

SECURITY

Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 10/25/2021 for Healthcare Pharmacy

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Controlled substances	◉S ○C/P ○U ○N/A
	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
2	Pharmacist access	◉S ○C/P ○U ○N/A
	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
3	Additional pharmacy drug storage areas	○S ○C/P ○U ◉N/A
	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
4	Filled Rx medication storage	◉S ○C/P ○U ○N/A
	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)	
5	Remote drug storage (hospitals)	○S ○C/P ○U ◉N/A
	R4-23-654(D); R4-23-672(C)	

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	◉S ○C/P ○U ○N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
	Clinical Pharmacology	
2	Therapeutics reference	◉S ○C/P ○U ○N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
3	Drug compatibility reference	◉S ○C/P ○U ○N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
4	Drug product equivalency reference	◉S ○C/P ○U ○N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
5	Sterile products reference	○S ○C/P ○U ◉N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)	
6	Policy and procedure manual-pharmacy operations	○S ◉C/P ○U ○N/A
	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)	
7	Policy and procedure manual-technicians	○S ◉C/P ○U ○N/A
	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D	
8	Policy and procedure manual-automation	○S ○C/P ○U ◉N/A
	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04	
9	Policy and procedure manual-compounding	○S ○C/P ○U ◉N/A
	R4-23-410; R4-23-670	
10	Arizona statutes/rules	◉S ○C/P ○U ○N/A
	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	
11	Current antidote/drug interaction information	◉S ○C/P ○U ○N/A
	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	

Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 10/25/2021 for Healthcare Pharmacy

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12	Poison Control # displayed	◉S ○C/P ○U ○N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	◉S ○C/P ○U ○N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	○S ○C/P ○U ◉N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage	◉S ○C/P ○U ○N/A	R4-23-408
4	Computer-patient profiles	◉S ○C/P ○U ○N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	◉S ○C/P ○U ○N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	◉S ○C/P ○U ○N/A	R4-23-408(C)(4)
7	Prescription label	◉S ○C/P ○U ○N/A	ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)
8	Federal transfer labels	◉S ○C/P ○U ○N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
9	Warning labels	◉S ○C/P ○U ○N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information	◉S ○C/P ○U ○N/A	R4-23-402(C)(4); R4-23-402(I)
11	Consultation log	◉S ○C/P ○U ○N/A	R4-23-402(G)
12	Federal medication guides	◉S ○C/P ○U ○N/A	21 CFR part 208
13	Hospital IV label	○S ○C/P ○U ◉N/A	R4-23-658
14	Generic Rx blanks	◉S ○C/P ○U ○N/A	R4-23-402(A); R4-23-407(D)
15	Immunization administration recordkeeping	○S ○C/P ○U ◉N/A	R4-23-411(F)
16	Schedule V register	○S ○C/P ○U ◉N/A	R4-23-612(A)(2)

Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 10/25/2021 for Healthcare Pharmacy

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

17	Methamphetamine precursor sales log	○S ○C/P ○U ◉N/A	ARS 32-1977
18	Red C stamp	◉S ○C/P ○U ○N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting The pharmacy will begin reporting to the CSPMP daily, including zero reports, as soon as they receive the DEA registration.	◉S ○C/P ○U ○N/A	R4-23-502
20	Graduates	◉S ○C/P ○U ○N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	◉S ○C/P ○U ○N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	◉S ○C/P ○U ○N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	◉S ○C/P ○U ○N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	◉S ○C/P ○U ○N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	○S ○C/P ○U ◉N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	◉S ○C/P ○U ○N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	○S ○C/P ○U ◉N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	○S ○C/P ○U ◉N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device	○S ○C/P ○U ◉N/A	R4-23-615
30	Mechanical counting device	○S ○C/P ○U ◉N/A	R4-23-616
31	Emergency drug supply units (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.04

Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 10/25/2021 for Healthcare Pharmacy

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	○S ○C/P ○U ◉N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	○S ○C/P ○U ◉N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	○S ○C/P ○U ◉N/A	R4-23-670(A)(2)
4	Restricts entry/access	○S ○C/P ○U ◉N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	○S ○C/P ○U ◉N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
9	Environment ISO 7	○S ○C/P ○U ◉N/A	R4-23-670(A)(6)
10	Hood ISO 5	○S ○C/P ○U ◉N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	○S ○C/P ○U ◉N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Hours: M-F (8-5p), Sat (7-12p)
The pharmacy does not compound. This is a closed-door pharmacy.

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 (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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH 04203	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: HomeCare Rx, Inc.

Physical Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Mailing Address (if different from physical address): PO Box 2578

City: Secausus State: NJ Zip: 07096

Telephone: 877-920-2090 Toll Free # (NAC 639.708, NRS 639.23286): 877-920-2090

Fax: 877-920-0466 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Ami Patel Temp. 22-1558 exp. 6/15/22

Supervising/Managing Pharmacist NV Pharmacist Registration #: 28RI03752700 (NJ); NV temp application submitted

Type of Pharmacy (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Retail/Community	☒ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
☐ Other: _____	☐ 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: _____	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 #: _____
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 Jersey

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: HomeCare Rx, Inc.

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: 877-828-3940 Email: licensing@infucarerx.com

Contact Person Name: Daynee Perez

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 Corporate Secretary (title) for HomeCare Rx, 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).

Tiffany Samantha Scheppers

Print Name of Authorized Person

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

12/2/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Tiffany Samantha Scheppers 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 Corporate Secretary (title) for HomeCare Rx, Inc. (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 02 day of Dec., 2021

Notary Public Brayan Loor

BRAYAN LOOR NOTARY PUBLIC MECKLENBURG COUNTY, NC

Comm Exp. June 19 2026

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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Tiffany Samantha Scheppers

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)

12/2/2021

Date

Board Use Only	Date Received: _____	Amount: 500 check # 1000000508 ✓

Processed 12/9/21

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

HOMECARE RX INC
0400722426

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on February 06, 2015.

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:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 21st day of September, 2021

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6123317456

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

HOMECARE RX INC.
AMI D PATEL
695 US Hwy. 46, Ste. 100
Fairfield NJ 07004

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
HOMECARE RX INC
Pharmacy
05/18/2021 TO 06/30/2022
VALID
SIGNATURE

PLEASE DETACH HERE
IF YOUR LICENSE/REGISTRAT
CERTIFICATE ID CARD IS LOS
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

05/18/2021 TO 06/30/2022
VALID

28RS00739900
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

ACTING DIRECTOR

PLEASE DETACH HERE

HOMECARE RX INC.

EXPIRATION DATE **2022**

YOUR LICENSE/REGISTRATION/CERTIFICATE NUMBER IS **28RS 00739900** . PLEASE USE IT IN ALL CORRESPONDENCE TO THE DIVISION OF CONSUMER AFFAIRS USE THIS SECTION TO REPORT ADDRESS CHANGES YOU ARE REQUIRED TO REPORT ANY ADDRESS CHANGES IMMEDIATELY TO THE ADDRESS NOTED BELOW

Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PRINT YOUR NEW **ADDRESS OF RECORD** BELOW
YOUR ADDRESS OF RECORD IS THE ADDRESS THAT WILL PRINT ON YOUR LICENSE/REGISTRATION/CERTIFICATE AND IT MAY BE MADE AVAILABLE TO THE PUBLIC

HOME ☐
BUSINESS ☐

TELEPHONE
INCLUDE AREA CODE

PRINT YOUR NEW **MAILING ADDRESS** BELOW
YOUR MAILING ADDRESS IS THE ADDRESS THAT WILL BE USE THE DIVISION OF CONSUMER AFFAIRS TO SEND YOU CORRESPONDENCE

HOME ☐
BUSINESS ☐

TELEPHONE
INCLUDE AREA CODE

If the law governing your profession requires the current license/registration/certificate to be displayed, it shou within reasonable proximity of your original license/registration/certificate at your principal office or place of busin

NEW JERSEY DIVISION OF CONSUMER AFFAIRS

Sean P. Ne
Acting Dir
Rea

License Information

Accurate as of December 01, 2021 9:38 AM

Return to Search Results

Name: HOMECARE RX INC.

Address: Fairfield,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00739900

License Status: Active

Status Change Reason: License Issuance

Issue Date: 4/15/2015

Expiration Date: 6/30/2022

NO Board Actions. For more information contact New Jersey State Board of Pharmacy (973)504-6450.

Documents

No Public Documents

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HomeCare Rx, Inc.

List of stockholders who hold 10% or more of the shares

InfuCare Rx, Inc. 100%
695 US Highway 46, Suite 100
Fairfield, NJ 07004
877-828-3940

HomeCare Rx, Inc.

List of officers

Dhara Patel, President
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

Tiffany Samantha Scheppers, Secretary and General Counsel
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

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 HomeCare Rx Inc. dba InfuCare Rx

Physical Address 695 US Hwy 46 STE 100

City Fairfield State NJ Zip 07004

Mailing Address (if different from physical address) PO Box 2397

City Secaucus State NJ Zip 07096

Telephone 877-920-2090 Website WWW.InfuCareRx.com

Licensing Company Email Licensing@infucarerx.com

Section 2: Personal Information

First Ami Middle Dinesh Last Patel

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

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

Mailing Address [redacted] Vincent Road

City Cedar Grove State NJ Zip 07009

Telephone [redacted] Email APatel@homecarerx.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: N/A to:

Military Occupation/Specialty N/A

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 AP

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. Louis College of Pharmacy		08/04 - 05/10	
Address	**City**	**State**	**Zip**
1 Pharmacy Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shawnee Mission Northwest		08/00 - 05/04	
Address	**City**	**State**	**Zip**
12701 W 67th Street	Shawnee	KS	66216
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
06/18 - Present	[redacted]Vincent Road	Cedar Grove	NJ	07009
11/12 - 06/18	818 7th Street Unit B	Secaucus	NJ	07009
05/10 - 11/12	14203 West 72nd St.	Shawnee	KS	66216

Applicant's initials AP

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)	
HomeCare Rx Inc.			12/2015 - Present	
Business Address		**City**	**State**	**Zip**
695 US Hwy 46, Suite 100		Fairfield	NJ	07004
Phone	**Title**		**Number of Employed Hours**	
877-920-2090	National Director of Pharmacy / Pharmacist in Charge		11,888	
Description of Duties				
Oversee pharmacy operations for all branches. For pharmacist in charge role, making sure pharmacy is adhering to rules and regulations; maintain close control over pharmacy operations; managing all pharmacists and technicians on 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.

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

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

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

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

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 AP

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

N/A

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/3/24
Date

Applicant's initials AP

I, Ami Patel, **certify that as the designated representative for** HomeCare Rx 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

Ami Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/3/21

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.

Ami Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/3/21

Date

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

State of New Jersey, ss. County of Essex

I, Ami D. Patel, 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

12/3/21

Date

Subscribed and Sworn to before me this 12th day of December 2021

Notary Public Signature

ADELA LUNGU
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2423604
My Commission Expires 8/3/2022

(Seal)

Applicant's initials

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 HomeCare Rx, Inc.

Physical Address 695 US Highway 46, Suite 100

City Fairfield State NJ Zip 07004

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 877-920-2090 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Dhara Middle _____ Last Patel

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

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

Mailing Address 695 US Highway 46, Suite 100

City Fairfield State NJ Zip 07004

Telephone [redacted] Email dbpatel@infucarerx.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: n/a to: n/a

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 DP

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)	
Armstrong Atlantic State University			
Address: 11935 Abercorn St.	City: Savannah	State: GA	Zip: 31419
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School			
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			

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
present	[redacted]Vincent Rd.	Cedar Grove	NJ	07009
From - To (MM/YY – MM/YY)	818 7th St.	Secaucus	NJ	07094
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DK

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)
InfuCare Rx, Inc.			present
Business Address	**City**	**State**	**Zip**
695 US Highway 46, Suite 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	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)
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 DL

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 DR.

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)

12/7/21
Date

Applicant's initials DP

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.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/7/21

Date

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

State of New Jersey, ss. County of Essex

I, Dhara Patel, 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

12/7/21

Date

Subscribed and Sworn to before me this 7th day of December, 2021

Notary Public Signature

ADELA LUNGU
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2423604
My Commission Expires 8/3/2022

(Seal)

Applicant's initials DP.

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 HomeCare Rx, Inc.

Physical Address 695 US Highway 46, Suite 100

City Fairfield State NJ Zip 07004

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 844-773-6779 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Tiffany Middle Samantha Last Scheppers

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

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

Mailing Address 695 US Highway 46, Suite 100

City Fairfield State NJ Zip 07004

Telephone [redacted] Email tscheppers@infucarerx.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: n/a to: n/a

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 TSS

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 Missouri St Louis			
Address	**City**	**State**	**Zip**
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law			
Address	**City**	**State**	**Zip**
100 N Tucker Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University			
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus			
Address	**City**	**State**	**Zip**
2323 W Broadway	Anaheim	CA	92804
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] Lookout Circle	Waxhaw	NC	28173
From - To (MM/YY – MM/YY)	[redacted] Jones Crossing, #213	Charlotte	NC	28277
From - To (MM/YY – MM/YY)	[redacted] Polo Lake Dr	Ellisville	MO	63021
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 TS

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)
Infucare Rx Inc.			03/2021 - present
Business Address	**City**	**State**	**Zip**
695 US Highway 46, Suite 100	Fairfeild	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secr		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.
• Current Officer acting as Corporate Secretary.
• Advised executive leadership and Board of Directors on a variety of complex regulatory compliance matters

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
	Outside General Counsel		

Description of Duties

• Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, consisting of health care, pharma, biotech and CRO/CSO companies on all legal and regulatory

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

• Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel

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 TSB

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)

12/2/2021
Date

Applicant's initials JBS

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.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2021

Date

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

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, 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

12/2/2021

Date

Subscribed and Sworn to before me this 02 day of Dec. 2021.

Notary Public Signature Brayan Loor

BRAYAN LOOR NOTARY PUBLIC MECKLENBURG COUNTY, NC

Comm Exp. June 19 2026

(Seal)

Applicant's initials TS

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 6-22-2021
File number: 8-6531-21-722

Board of Pharmacy Inspection Report

Home Care Rx Inc.
Pharmacy trade name

Corporation name (if not the same)

Owner (as identified on the occasion of this inspection)

695 US Highway 46
Street address

Fairfield, NJ 07004
City State ZIP code

HomeCare Rx, Inc.
695 Route 46 West, Suite 100
Fairfield, NJ 07004-1692 877-920-2090
Rx #: 30010103 Date: 05/13/2020 RPh: ES
Patient, Test
695 Rt 46 W Fairfield, NJ 07004
H. Abdelrazek, MD
Drug: Acetaminophen 325mg Tablet
Take 2 Tablets (650 mg) by mouth
30 minutes prior to infusion.
Generic for Tylenol
Qty: 4 Original Rx: 05/13/2020
Refills: 2 Use By: 05/13/2021
Mfr: GERI-CARE NDC: 57896-0102-01
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

HomeCare Rx Inc (Name of permit holder) 28RS00739900 (Certificate number) 6-30-2022 (Expiration date)

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

D10573100 (Certificate number) 10-31-2021 (Expiration date)

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

FH 5185738 (Certificate number) 10-31-2023 (Expiration date)

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Ami D. Patel
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

28RT03544600 (Permit number) 4-30-2023 (Expiration date) 40 hr/wk (Hours worked per week)

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☑ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
			☐ Yes ☐ No	
			☐ Yes ☐ No	
SEE ATTACHED			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☑ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☑ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R. 1700.14/15] Is a representative inventory of safety closures present? ☑ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☑ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☑ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☑ Yes ☐ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☐ Yes ☐ No N/A but waiver no controls.
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☐ Yes ☐ No

Ami Patel
Print the name of the registered pharmacist who was present for the survey

Ami Patel
Signature of the registered pharmacist who was present for the survey

Signature of the Enforcement Bureau representative

Form EB-02 (10/12)

Date: 10-22-2021
Time entered: 10:30am
Time departed: 11:45 am

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy

Report of Inspection

Name of Pharmacy Home Care Rx Inc

Address 695 Us Highway 46 Fairfield, NJ

Name and registration number of the Pharmacist-in-Charge
Ami Patel 28RI03544600
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

Inspection revealed the following deficiencies as denoted by a check-mark (✓) in the corresponding boxes (☐):

Inventory

The medications that were present for the filling of prescriptions were examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could have potentially been dispensed, and did not include any segments of the inventory that may have been already separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the Inspector, and then recorded on the attached EB Form 23A. The line entries on the EB Form 23A are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite.

✓	Cite	Description	Comment
☐	N.J.A.C. 13:39-7.18/13:39-6.2(f)7	Expired Medication from 1 day to 4 months	For specifics see attached Exhibit No.:
☐		Expired Medication from 4 months to 1 year	
☐		Expired Medication over 1 year	
☐		Misbranded Medications	
☐	N.J.A.C. 13:39-7.18/13:39-6.2(f)7	Sample Medications	
☐	N.J.A.C. 13:39-6.2(f)7, 8	Improperly Stored Medications	
☐	N.J.A.C. 13:39-7.16(c)2,3	Over-filled Medications	

Compliance surveying activity was conducted utilizing standardized Enforcement Bureau Forms which address various requirements. This portion of the inspection revealed the following deficiencies as denoted by check-marks (✓) in the corresponding boxes (☐):

✓	Cite	Description	Comment
☐	[N.J.A.C. 13:39-4.3]	Board of Pharmacy (B.O.P.) Store Permit	
☐	[21C.F.R.1301.11-1301.12]	D.E.A. (Drug Enforcement Administration) Certificate	
☐	[N.J.S.A.24:21-10] [13:45H-1.2(c) and 13:45H-1.5(e)]	N.J. C.D.S. (Controlled Dangerous Substance) Registration	
☐	[13:39-3.1(b)]	Display of R.P. Current Renewal for full-time Pharmacists	
☐	[13:39-5.3(b)] [13:39-5.3(c)]	Public display of name of present-day designated R.P.-in-Charge (R.P.I.C.) and hours Pharmacy is open.	
☐	[13:39-6.3]	Name Tag worn by R.P.(s) and Supportive Personnel	
☐	[16C.F.R.1700.14/15]	The presence of safety closure containers	
☐	[13:39-5.8(c)]	Cleanliness, orderliness, sanitary condition (see comments if checked)	
☐	[13:39-7.12(a)12]	Prescription label "use by" deficiency	
☐	[13:45H-5.5 and 5.7]	C.D.S. Biennial Inventory requirement not satisfactorily met.	
☐	[13:39-5.8(a)7]	Pharmacy refrigerator not being utilized exclusively for pharmaceuticals.	
☐	[13:39-5.9]	Pharmacy balances/scales not currently inspected/sealed by Office of Weights and Measures personnel.	
☐	[13:39-10 et seq.]	Notification to B.O.P. of Automated RX Med. Dispensing System (A.D.S.) presence	
☐	[13:39-10.4(c)]	A.D.S. "Policies & Procedures Manual" unavailable.	
☐	[13:39-10.3(b)2]	A.D.S. bi-monthly inspection documentation not present regarding "use by" dating, misbranding, etc.	
☐	[13:39-10.6(a)2]	A.D.S. inspection for accuracy checking (every 6 months) documentation not present.	
☐	[13:39-5.9] [13:39-10 et seq.]	A.D.S. not currently inspected/sealed by Weights and Measures personnel.	
☐	[13:39-4.15(c)4]	Pharmacy Dept. requirement not met regarding the telephone number of the Pharmacist-in-Charge being present in the store manager's office.	
☐	[13:39-4.15]	Miscellaneous "Pharmacy Department" requirement deficiency, specifically:	
☐	[13:39-5.8(a)1]	Comprehensive Pharmaceutical Reference Text	
☐	The Pharmacy's library was deficient in the following reference text categories.	Drug Interactions	
☐		Drug Product Composition	
☐		Patient Counseling	
☐		Specialized Compounding Preparations (As applicable)	

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following comments, if any.

Comments: No Deficiencies

Ami Patel
(Signature of the Pharmacist identified above)

(Signature of Investigator)

Form: EB-33A (12/13 version)

Date: 6-22-2021
Time entered: 10:30 am
Time departed: 11:45 am

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: Home Care Rx
Address: 695 US highway 46 Suite 100 Fairfield, NJ

Name and registration number of pharmacist-in-charge:
Ami Patel (PIC) 28RI0 3544600
(If the Pharmacist-In-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted:

NO DEFICIENCIES FOUND

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: Home Care Rx Inc. Date: 6-22-2021

Street Address: 695 Highway 46

City, State, ZIP: Fairfield, NJ 07004

Kapetanakis / Patel
Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39–7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												

NO Deficiencies Found

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 (9/22/2021)

Y

Where is the facility located?

- ☐ Nevada
- ☒ Out-of-State

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New Pharmacy	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Ownership Change*	PH 03995	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA

Physical Address: 2400 Veterans Memorial Blvd ., Ste 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): PO Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Toll Free # (NAC 639.708, NRS 639.23286): 877-828-3940

Fax: 844-504-3278 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Richard Anderson NV Temp 22161

Supervising/Managing Pharmacist NV Pharmacist Registration #: PST.020664 (LA)

Type of Pharmacy (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Retail/Community	☒ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
☐ Other: _____	☐ 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: _____	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 #: _____
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: Louisiana

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: 877-828-3940 Email: licensing@infucarerx.com

Contact Person Name: Daynee Perez

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 Corporate Secretary (title) for Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA (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).

Tiffany Samantha Scheppers

Print Name of Authorized Person

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

12/2/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Tiffany Samantha Scheppers 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 Corporate Secretary (title) for Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA (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 02 day of Dec., 2021

Notary Public Brayan Loor

BRAYAN LOOR NOTARY PUBLIC MECKLENBURG COUNTY, NC

Comm Exp. June 19 2026

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 <u>all</u> Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the <u>top four</u> stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List <u>all stockholders</u> 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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Tiffany Samantha Scheppers

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)

12/2/2021

Date

Board Use Only	Date Received: _____	Amount: 50	Check # 1000000507

Processed 12/9/21

Alabama State Board of Pharmacy Action
Re: Case No: 21-L-0071
Fast Access Specialty Pharmacy LLC dba InfuCare Rx of LA

On or about January 18, 2021 Sajal Roy, PharmD ("Roy"), the Alabama Supervising Pharmacist ("PIC") at Fast Access Specialty Pharmacy LLC dba InfuCare Rx of LA ("Pharmacy") submitted his resignation as AL PIC of the Pharmacy to the Alabama Board of Pharmacy ("Board"). His employment resignation was submitted to the Pharmacy on or about January 18th, and his last day of employment was March 4, 2021. Roy was asked by the Pharmacy to rescind his PIC resignation until such time as a replacement could be found, since his employment with the Pharmacy continued through March 4th. The Pharmacy believed that Roy had rescinded his resignation, and as a result, it mistakenly did not notify the Board within 10 days with an action plan to designate another PIC. A new PIC was designated March 3, 2021. The Board cited the Pharmacy for being unable to maintain a PIC and failing to notify the Board within 10 days with an action plan. The Pharmacy's license was not affected and remained and is in good standing.

DocuSign Envelope ID: 84F74718-96B5-4A6C-8085-438A8B2BDCFD

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
FAST ACCESS SPECIALTY	)	**BOARD OF PHARMACY**
THERAPEUTICS LLC dba INFUCARE	)	
RX OF LA	)	
	)	
Non-Resident Pharmacy	)	**CASE NO: 21-L-0071**
Permit Number: 113920	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA has violated the provisions of law based upon the conduct set out in Count One of the Statement. Counts Two and Three shall be dismissed.

2. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Consent Order, that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA attempt to discharge

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the same.

3. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA's permit, including, but not limited to revocation.

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6. That Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of October, 2021.

FAST ACCESS SPECIALTY THERAPEUTICS LLC DBA INFUCARE RX OF LA

DocuSigned by:

BY: Dhara Patel

ITS: President

Jerry Moore, Attorney for Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA

DONE this the 12th of October, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Brenda Denson, PharmD, President

By: _____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
FAST ACCESS SPECIALTY THERAPEUTICS LLC dba INFUCARE RX OF LA	)	
	)	
Non-Resident Pharmacy Permit Number: 113920	)	**CASE NO: 21-L-0071**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Fast Access Specialty Therapeutics LLC
dba Infucare Rx of La
2400 Veterans Memorial Boulevard
Suite 480
Kenner, Louisiana 70062

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on November 16, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Fast Access Specialty Therapuetics LLC dba Infucare Rx of LA should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Fast Access Specialty Therapuetics LLC dba Infucare Rx of LA has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by you being unable to maintain a designated Supervising Pharmacist and failing to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Sajal Kumar Roy ceased to be your Supervising Pharmacist on or about January 18, 2021 and you, as of the date hereof, have not submitted the referenced action plan to the Board.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT THREE

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and

Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 3rd day of March 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ICRX LLC
0600468095

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Pennsylvania Foreign Limited Liability Company was registered by this office on June 02, 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:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CTR.
SUITE 160
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 7th day of September, 2021

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6122865323

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

UNITED STATES OF AMERICA

State of Louisiana

R. Kyle Ardoin

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

FAST ACCESS SPECIALTY THERAPEUTICS, L.L.C.

A limited liability company domiciled in METAIRIE, LOUISIANA,

Filed charter and qualified to do business in this State on September 17, 2009,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

October 26, 2021

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Secretary of State

Web 40011784K

Certificate ID: 11475184#3PK73

To validate this certificate, visit the following web site, go to **Business Services, Search for Louisiana Business Filings, Validate a Certificate,** then follow the instructions displayed.
www.sos.la.gov

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
Infucare Rx of LA	2400 Veterans Memorial Blvd Ste 480 Kenner, LA 70062-8728

Credential Information with supervision

License	License Type	Issue Date	Expiration Date	Status	Pharmacist In Charge
PHY.007442-IR	Pharmacy - Community ~ Independent	03/07/2017	12/31/2022	Current, without restriction or limitation	Richard P. Anderson Jr.

List of Current Employees

Name	License	License Type	Expiration Date	Status
Aris M. Christophe	CPT.008500	Certified Pharmacy Technician	06/30/2022	ACTIVE
Jennifer B. Hays	CPT.011588	Certified Pharmacy Technician	06/30/2022	ACTIVE
Kim Lien T. Nguyen	PST.018325	Pharmacist	12/31/2022	ACTIVE
Richard P. Anderson Jr.	PST.020664	Pharmacist	12/31/2021	ACTIVE - IN RENEWAL
Thu Hoang Nguyen	PST.019875	Pharmacist	12/31/2021	ACTIVE - IN RENEWAL
Tiffany J. Lawson	PST.019662	Pharmacist	12/31/2021	ACTIVE - IN RENEWAL

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Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA

List of stockholders who hold 10% or more of the shares

InfuCare Rx, Inc. 100%
695 US Highway 46, Suite 100
Fairfield, NJ 07004
877-828-3940

Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA

List of officers

Dhara Patel, President
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

Tiffany Samantha Scheppers, Secretary and General Counsel
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

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: Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA

Physical Address: 2400 Veterans Memorial Blvd STE 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Website: WWW.InfuCareRx.com

Licensing Company Email: Licensing@infucarerx.com

Section 2: Personal Information

First: Richard Middle: Paul Last: Anderson

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

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

Mailing Address: [redacted] Lizabeth Dr.

City: Morgan City State: LA Zip: 70380

Telephone: [redacted] Email: RAnderson@infucarerx.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: N/A to:

Military Occupation/Specialty: N/A

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: PK

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)	
Xavier University of Lousiana College of Pharmacy		08/08 - 05/14	
Address	**City**	**State**	**Zip**
1 Drexel Drive	New Orleans	LA	70125
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Xavier University of Louisiana		08/04-05/08	
Address	**City**	**State**	**Zip**
1 Drexel Drive	New Orleans	LA	70125
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Morgan City High School		08/00-05/04	
Address	**City**	**State**	**Zip**
2400 Tiger Dr	Morgan City	LA	70380
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
01/10 - Present	[redacted] Lizabeth Dr	Morgan City	LA	70380
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA			06/21-Pres.&11/17-06/19
Business Address	**City**	**State**	**Zip**
2400 Veterans Memorial Blvd STE 480	Kenner	LA	70062
Phone	**Title**	**Number of Employed Hours**	
877-327-8881	Pharmacist in Charge	'21 =1000 hr Prev = 5248	

Description of Duties

Supervise the pharmacy staff to ensure accurate and safe job performance Directs, coordinates, and supervises all pharmacy activities. Works with VP of operations to facilitate and coordinate pharmacy operations Performs performance

Business Name			From - To (MM/YY – MM/YY)
Factor One Source Pharmacy dba InfuCare Rx of MD			06/19 - 10/20
Business Address	**City**	**State**	**Zip**
217 Glenn Street STE 300	Cumberland	MD	21502
Phone	**Title**	**Number of Employed Hours**	
877-327-8881	Pharmacy Manager/Clinical Pharmacist	2808	

Description of Duties

Supervise the pharmacy staff to ensure accurate and safe job performance Directs, coordinates, and supervises all pharmacy activities. Works with VP of operations to facilitate and coordinate pharmacy operations Performs performance

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

Description of Duties

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

Description 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.

Applicant's initials RAS

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)

8/2/21
Date

Applicant's initials RA

I, Richard Anderson, **certify that as the designated representative for**

Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA,

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

Richard Anderson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/21

Date

Applicant's initials RA

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.

Richard Anderson

Print Name (First, Last)

Richard Anderson 12/21/21

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

---

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

State of Louisiana, ss. County of Jefferson

I, Richard Anderson, 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.

Richard A 12/21/21

Original Signature **Date**

Subscribed and Sworn to before me this 2 day of December, 2021

Carl Butler

Notary Public Signature

Carl A. Butler
Notary Public # 12025
State of Louisiana
My Commission is for life.
La. Bar No. 17261

(Seal)

Applicant's initials RA

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Richard P. Anderson Jr

Date: 12/13/2021
Amount:
License #: 22161

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:06/13/2022

Richard P. Anderson Jr

License #
22161
Temporary

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

License Type: Pharmacist
License #: 22161

Expires: 06/13/2022
STATUS: Temporary

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Richard P. Anderson Jr

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Fast Access Specialty Therapeutics LLC d/b/a Infucare Rx of LA

Physical Address: 2400 Veterans Memorial Blvd

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 844-773-6779 Website: www.fosrxfast.com; www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

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

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

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: [redacted] Email: tscheppers@infucarerx.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: n/a to: n/a

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: TB

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 Missouri St Louis			
Address	**City**	**State**	**Zip**
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law			
Address	**City**	**State**	**Zip**
100 N Tucker Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University			
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus			
Address	**City**	**State**	**Zip**
2323 W Broadway	Anaheim	CA	92804
Diploma/Degree obtained, if any			
Diploma Received			

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] Lookout Circle	Waxhaw	NC	28173
	[redacted] Jones Crossing, #213	Charlotte	NC	28277
	[redacted] Polo Lake Dr	Ellisville	MO	63021

Applicant's initials TSB

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)
Infucare Rx Inc.			03/2021 - present
Business Address	**City**	**State**	**Zip**
695 US Highway 46, Suite 100	Fairfeild	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secr		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.
• Current Officer acting as Corporate Secretary.
• Advised executive leadership and Board of Directors on a variety of complex regulatory compliance matters

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
	Outside General Counsel		

Description of Duties

• Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, consisting of health care, pharma, biotech and CRO/CSO companies on all legal and regulatory

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

• Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel

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 RS

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:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/2/2021
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.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2021

Date

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

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, 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

12/2/2021

Date

Subscribed and Sworn to before me this 02 day of Dec. 2021.

Notary Public Signature Brayan Loor

BRAYAN LOOR
NOTARY PUBLIC
MECKLENBURG COUNTY, NC

Comm Exp.
JUNE 19 2026

(Seal)

Applicant's initials TS

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: Fast Access Specialty Therapeutics, d/b/a InfuCare Rx of LA

Physical Address: 2400 Veterans Memorial Blvd., Ste 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 877-327-8881 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Dhara Middle: Last: Patel

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

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

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: [redacted] Email: dbpatel@infucarerx.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: n/a to: n/a

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: DP.

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)	
Armstrong Atlantic State University			
Address	City	State	Zip
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School			
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			

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
present	[redacted] Vincent Rd.	Cedar Grove	NJ	07009
	[redacted] 7th St.	Secaucus	NJ	07094
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DP.

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)
InfuCare Rx, Inc.			present
Business Address	**City**	**State**	**Zip**
695 US Highway 46, Suite 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	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)	
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 DP.

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 DP.

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)

12/7/21
Date

Applicant's initials DP.

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.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 12/7/21

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

State of New Jersey, ss. County of Essex

I, Dhara Patel, 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:** 12/7/21

Subscribed and Sworn to before me this 7th day of December, 2021

Notary Public Signature

ADELA LUNGU
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2423604
My Commission Expires 8/3/2022

(Seal)

Applicant's initials DP.

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

Permit Data	Report No. 079	Inspected by: Dennis	Territory: Dennis	Date: 6/4/2021

Reason for Visit: ☐ Initial Survey ☒ Service Review ☐ Follow-Up Survey ☐ Compliance Check

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Infucare Rx of LA	7442	49472	IR	2021

6. Physical Address	7. Mailing Address	8. City, State, Zip
2400 Veterans Memorial Blvd., Suite 480	Same	Kenner, La. 70062

9. Phone No.	10. Fax No.	11. E-mail Address	12. Accreditation Joint Commission/ACHC
504-885-3378	504-844-3278	pandrews@infucarerx.com	Yes ☒ (6/2021) No ☐ N/A ☐

13. Compounding	14. AMS Permit No.	15. Rx Software	16. DEA No.	DEA Expiration
Sterile ☐ Non-Sterile ☐ N/A ☒	N/A	CPR+	FF6607280	9/30/2022

17. Store Hours	18. Pharmacy Hours
N/A ☒	9a-5p Mon-Fri; Closed Sat and Sun

Pharmacist-in-Charge

19. PIC Name	20. Sex	21. License No.	22. Renewal Year	23. CE Compliance
Amanda S. Bercey	Female	19517	2021	Yes ☒ No ☐ N/A ☐

24. Address of Record	25. City, State, Zip	26. Phone
6022 N. Rampart St.	New Orleans, La. 70117	asbercey@gmail.com

27. Pharmacy Staff	License No.	Renewal Year	CE Compliance		
Philip P. Andrews, PST	15873	2021	Yes ☒	No ☐	N/A ☐
Tiffany J. Lawson, PST	19662	2021	Yes ☒	No ☐	N/A ☐
Thu H. Nguyen, PST	19875	2021	Yes ☒	No ☐	N/A ☐
Bianca P. Jackson, CPT	10075	2020-2021	Yes ☒	No ☐	N/A ☐
Naiomi Hernandez-Arroyo, CPT	13212	2020-2021	Yes ☒	No ☐	N/A ☐
Aris M. Christophe, CPT	8500	2020-2021	Yes ☒	No ☐	N/A ☐
Dawn M. Birden, CPT	3679	2020-2021	Yes ☒	No ☐	N/A ☐
			Yes ☐	No ☐	N/A ☐
			Yes ☐	No ☐	N/A ☐

Professional and Occupational Standards

	Compliance Yes	No	N/A		Compliance Yes	No	N/A
28. Credentials Displayed	☒	☐	☐	39. Emergency Drug Cabinet	☐	☐	☒
29. Premises Clean/Orderly	☒	☐	☐	40. Electronic Record Keeping	☒	☐	☐
30. Adequate Lighting/Ventilation	☒	☐	☐	41. Required Info. on CDS Rxs	☐	☐	☒
31. Adequate Refrigeration/Temperature	☒	☐	☐	42. CDS Invoices Retrievable/Dated	☐	☐	☒
32. Min. Rx Dept. Size/Aisle Space	☒	☐	☐	43. C-II Order Forms	☐	☐	☒
33. Sterile Compounding – ( )	☐	☐	☒	44. Perpetual CII/CDS Annual Inventory			
34. Sink (Location & Temperature)	☒	☐	☐	Inventory Date ( )	☐	☒	☐
35. Required References	☒	☐	☐	45. Policy & Procedure Manual	☒	☐	☐
36. Security (Alarm) (Restricted Access)	☒	☐	☐	46. Pharmacist Register/Positive Identification	☒	☐	☐
37. Adequate Equipment	☒	☐	☐	47. Patient Counseling	☒	☐	☐
38. Meds. Misbranded, Non-Labeled, Exp.	☒	☐	☐	48. Intern/CPT/Tech Trainee I.D.	☒	☐	☐

52. Prior Inspection Date:	53. Deficiencies/Non-Compliance on Prior Inspection	54. Correction(s) Observed
8/15/19	None	None

(continued)

In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, La. 70809; 225.925.6496; info@pharmacy.la.gov. (2) Committee on House & Governmental Affairs; Louisiana House of Representatives; P.O. Box 44486; Baton Rouge, La. 70804; 225.342.2403; h&ga@legis.la.gov. (3) Committee on Senate & Governmental Affairs; Louisiana Senate; P.O. Box 94183; Baton Rouge, La. 70804; 225.342.9845; s&g@legis.la.gov.

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Fast Access Specialty Therapeutics	**7442**	**49472**	**IR**	**2021**

55. Comments: NOTE: A finding of satisfactory compliance is not indicative of a detailed inspection/investigation and does not exclude the permit and/or staff from possible future violations of compliance.
-Inspection report emailed to pandrews@infucarerx.com per PST. Andrews.
-Permit has non-resident permits in all 50 states. (See Universal Inspection Form for compliance)
44-Permit does not procure or stock CDS medications. Ensure "0" inventory sheet is dated and signed annually.
13-Permit is in process of constructing a sterile compounding room suite. Permit to have rooms and hoods certified when completed. Permit to then email CO Dennis for an inspection of sterile compounding prior to commencing.
-Reminder to obtain annual CE hours and ensure they are uploaded into NABP CE monitor prior to renewing credential.
-Reminder to update with Board office any changes of address/employment for licensees.

Authorized Signature & Title

Compliance Officer, Louisiana Board of Pharmacy

Form No. 601 Rev. 08-23-2018

In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, La. 70809; 225.925.6496; info@pharmacy.la.gov. (2) Committee on House & Governmental Affairs; Louisiana House of Representatives; P.O. Box 44486; Baton Rouge, La. 70804; 225.342.2403; h&ga@legis.la.gov. (3) Committee on Senate & Governmental Affairs; Louisiana Senate; P.O. Box 94183; Baton Rouge, La. 70804; 225.342.9845; s&g@legis.la.gov.

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 (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	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*	PH 03505	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD

Physical Address: 217 Glenn St., Ste 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): PO Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 844-773-6779 Toll Free # (NAC 639.708, NRS 639.23286): 844-773-6779

Fax: 844-533-1131 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Nathan Schaffer nathan Shaffer

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23949 (MD); NV temp application submitted NV21203

Type of Pharmacy (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Retail/Community	■ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
☐ Other: _____	☐ 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: Nathan Shaffer	NV Pharmacist Registration #: 21203
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: Maryland

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: 877-828-3940 Email: licensing@infucarerx.com

Contact Person Name: Daynee Perez

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 Corporate Secretary (title) for Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD (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).

Tiffany Samantha Scheppers

Print Name of Authorized Person

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

12/2/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Tiffany Samantha Scheppers 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 Corporate Secretary (title) for Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD (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 02 day of Dec, 2021

Notary Public Brayan Loor

BRAYAN LOOR
NOTARY
PUBLIC
MECKLENBURG COUNTY, NC

Comm Exp.
June 19 2026

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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Tiffany Samantha Scheppers

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)

12/2/2021

Date

Board Use Only	Date Received: _____	Amount: 500 check# 1000000506

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Nathan R. Shaffer

Date: 11/23/2021
Amount:
License #: 21203

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:10/31/2023

Nathan R. Shaffer

License #
21203
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

License Type: Pharmacist
License #: 21203

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

Expires: 10/31/2023
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Nathan R. Shaffer

NONTRANSFERABLE
POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

PHARMACY WAIVER REGISTRATION

112057

STATE OF MARYLAND
DEPARTMENT OF HEALTH

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Factor One Source Pharmacy Llc Dba Infucare Rx Of Md
217 Glenn Street
Suite #300
Cumberland MD 21502

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Factor One Source Pharmacy Llc Dba Infucare Rx Of Md
IS A REGISTERED **Active**
License Expiration Date
Pharmacy Waiver 05/31/2022

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0521	05/31/2022

SIGNATURE OF BEARER

112057

112057

State of Maryland

DEPARTMENT OF HEALTH

SIGNATURE OF BEARER

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT **Factor One Source Pharmacy Llc Dba Infucare Rx Of Md**
IS A REGISTERED **Active**
License Expiration Date
Pharmacy Waiver 05/31/2022

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO	EXPIRATION DATE
PW0521	**05/31/2022**

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Pharmacy Waiver Change of Information

A Pharmacy Waiver must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

Details

Demographic Information

Name: FACTOR ONE SOURCE PHARMACY LLC dba INFUCARE RX OF MD

Address Information

Address: 217 Glenn Street
Suite #300

City: Cumberland **State:** MD **Zip:** 21502

Maryland License\Permit Information

Number:	PW0521	**Type:**	Pharmacy Waiver	**Status:**	Home InfusionActive
Original Issued:	12/27/2018	**Date Renewed:**	4/2/2020	**Expires:**	5/31/2022

No Speciality Information
No Related Documents

****Please refer to the Board's Formal Disciplinary Action page for the listing of all disciplinary actions.****

Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD

List of stockholders and percent ownership

InfuCare Rx, Inc. 100%
695 US Highway 46, Suite 100
Fairfield, NJ 07004
877-828-3940

Factor One Source Pharmacy, LLC, d/b/a InfuCare Rx of MD

List of officers

Dhara Patel, President
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

Tiffany Samantha Scheppers, Secretary and General Counsel
965 US Hwy 46, Ste 100
Fairfield, NJ 07004
877-828-3940

MARYLAND
Department of Health
Larry J. Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Robert R Neall, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Kevin M. Morgan, Board President, Deena Speights-Napata, Executive Director

PHARMACY OPENING INSPECTION FORM

Maryland Pharmacy Permit Number	:	PW0521
Inspection Date	:	01/30/2020
Corporate Pharmacy Name	:	FACTOR ONE SOURCE PHARMACY
Pharmacy Name-Doing Business as (d/b/a) or Trade Name	:	
Street Address	:	217 Glenn Street, Cumberland, MD, 21502
Business Telephone Number	:	844 773-6779
Business Fax Number	:	301 876-4395
Arrival Time	:	09:35
Departure Time	:	09:58
Name of Inspector	:	Nancy Richard

1. PHYSICAL REQUIREMENTS AND EQUIPMENT

(•) Yes ( ) No ( ) N/A	The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
(•) Yes ( ) No ( ) N/A	The pharmacy has a refrigerator(s), solely for the storage of drugs requiring refrigeration, with a thermometer or a temperature monitoring device. COMAR 10.34.07.01B
(•) Yes ( ) No ( ) N/A	The pharmacy has additional equipment to enable it to prepare and dispense prescriptions properly consistent with its scope of practice. COMAR 10.34.07.02
(•) Yes No N/A	The pharmacy has hot and cold running water.
(•) Yes No ( ) N/A	The pharmacy has a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03
(•) Yes ( ) No ( ) N/A	The pharmacy has online resources. HO §12-403(b)(15)
(•) Yes ( ) No ( ) N/A	The pharmacy possesses the current edition of The Maryland Pharmacy Laws and Regulations. HO §12-403(b)(10)(ii)

2. SECURITY COMAR 10.34.05

( ) Yes (•) No	The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

Has the same hours.

(•) Yes No	The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Opening Inspection:

- (•) **Pass**
- ( ) **Fail**
- ( ) **Pending for Review**

INSPECTOR'S COMMENTS:

Reviewed entire remodel inspection with pharmacist Danielle M Neupauer. This pharmacy expanded into the existing finance office space for production. See attached alarm report.

Inspector Signature:

Harry Rutherford

Pharmacist Name (Print): 20721 20721: DANIELLE M NEUPAUER Date: 01/30/2020

Received a copy of this inspection report:

Supporting Documents.
PW0521_01302020_345_alarm for Factor One.pdf
PW0521_01302020_345_Factor One Remodel PW0521.pdf

410-764-4755 - Fax 410-384-4137 - Toll Free 800-542-4964
MDH 1-877-463-3464 - Maryland Relay Service 1-800-735-2258
Web site: https://health.maryland.gov/pharmacy/Pages/index.aspx

TWR Communications

Alarm Activity Report - for CSID# '0842'

For the Period 1/30/2020 To 1/30/2020

Based on Customer Time

710 ***Factor One Source Pharmacy;*** ***CSID:0842***

UL Grade :

Event Occurred / *Incident #*	*Condition* / *Incident Details*	*Description*	*Signal ID*	*Zone*	*Area*	*User*	*User Name*	
Thu 01/30/20 09:24:10	Panic Area: 1	Silent Panic -	E122	099	1			
708443	01/30 09:24:32	Opr. Note: SC						OPR
	01/30 09:24:38	Signal completed - Resolution: User Testing						

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: Factor One Source Pharmacy LLC, d/b/a InfuCare Rx of MD

Physical Address: 217 Glenn Street, Suite 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 877-828-3940 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Dhara Middle: Last: Patel

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

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

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: [redacted] Email: dbpatel@infucarerx.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: n/a to: n/a

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: DP

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)	
Armstrong Atlantic State University			
Address	**City**	**State**	**Zip**
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School			
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			

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
present	[redacted] Vincent Rd.	Cedar Grove	NJ	07009
From - To (MM/YY – MM/YY)	[redacted] 7th St.	Secaucus	NJ	07094
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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: InfuCare Rx, Inc.			From - To (MM/YY – MM/YY): present
Business Address: 695 US Highway 46, Suite 100	City: Fairfield	State: NJ	Zip: 07004
Phone: 877-828-3940	Title: 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)
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 _____

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 DP

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)

12/7/21

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.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 12/7/21

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

State of New Jersey, ss. County of Essex

I, Dhara Patel, 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:** 12/7/21

Subscribed and Sworn to before me this 7th day of December, 2021

Notary Public Signature

ADELA LUNGU
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2[illegible]
My Commission Expires [illegible]2

(Seal)

Applicant's initials DP.

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: Factor One Source Pharmacy LLC, d/b/a Infucare Rx of MD

Physical Address: 217 Glenn Street, Suite 300

City: Cumberland State: MD Zip: 46062

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 844-773-6779 Website: www.fosrxfast.com; www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

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

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

Mailing Address: 695 US Highway 46, Suite 100

City: Fairfield State: NJ Zip: 07004

Telephone: [redacted] Email: tscheppers@infucarerx.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: n/a to: n/a

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: TS

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 Missouri St Louis			
Address	City	State	Zip
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law			
Address	City	State	Zip
100 N Tucker Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University			
Address	City	State	Zip
1 N Grand Blvd	St Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus			
Address	City	State	Zip
2323 W Broadway	Anaheim	CA	92804
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] Lookout Circle	Waxhaw	NC	28173
	[redacted] Jones Crossing, #213	Charlotte	NC	28277
	[redacted] Polo Lake Dr	Ellisville	MO	63021

Applicant's initials _____

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)
Infucare Rx Inc.			03/2021 - present
Business Address	**City**	**State**	**Zip**
695 US Highway 46, Suite 100	Fairfeild	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secr		

Description of Duties

• Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.
• Current Officer acting as Corporate Secretary.
• Advised executive leadership and Board of Directors on a variety of complex regulatory compliance matters

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
	Outside General Counsel		

Description of Duties

• Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, consisting of health care, pharma, biotech and CRO/CSO companies on all legal and regulatory

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

• Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel

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 _____

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 JSS

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)

12/2/2021
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.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2021

Date

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

State of North Caroline, ss. County of Mecklenburg

I, ~~Brayan Loor~~ BL Tiffany Scheppers TS 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

12/2/2021

Date

Subscribed and Sworn to before me this 02 day of Dec 2021.

Notary Public Signature Brayan Loor

BRAYAN LOOR NOTARY PUBLIC MECKLENBURG COUNTY, NC

Comm Exp. June 19 2026

(Seal)

Applicant's initials TS

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: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Physical Address: 217 Glenn St STE 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): PO Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Website: WWW.InfuCareRx.com

Licensing Company Email: Licensing@infucarerx.com

Section 2: Personal Information

First: Christina Middle: Marie Last: Nutter

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

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

Mailing Address: [redacted] Point Cedar Dr.

City: Martinsburg State: WV Zip: 25404

Telephone: [redacted] Email: CNutter@infucarerx.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: N/A to:

Military Occupation/Specialty: N/A

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: CMN

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)	
Bernard J Dunn School of Pharmacy at Shenandoah University		08/03 - 06/07	
Address	**City**	**State**	**Zip**
1775 N. Sector Ct	Winchester	VA	22601
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
North Harris Community College		08/97 - 12/00	
Address	**City**	**State**	**Zip**
2700 W. W Thorne Dr	Houston	TX	77073
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Montgomery Community College		08/01 - 06/03	
Address	**City**	**State**	**Zip**
51 Mannakee Street	Rockville	MD	20850
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Montgomery Community College		08/01 - 06/03	
Address	**City**	**State**	**Zip**
20200 Observation Dr #4067	Germantown	MD	20876
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY	
Damascus High School		08/93 - 06/97	
Address	**City**	**State**	**Zip**
25921 Ridge Rd	Damascus	MD	20872
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
07/20 - Present	[redacted] Point Cedar Dr	Martinsburg	WV	25404
05/12 - 07/20	[redacted] Magellan Dr	Martinsburg	WV	25404
05/11 - 05/12	[redacted] Creighton Ct	Martinsburg	WV	25404
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 CMJ

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)	
Factor One Source Pharmacy, LLC dba InfuCare Rx of MD			11/20 - Present	
Business Address		**City**	**State**	**Zip**
217 Glenn St STE 300		Cumberland	MD	21502
Phone	**Title**		**Number of Employed Hours**	
877-327-8881	Pharmacist in Charge / Staff pharmacist		2128	

Description of Duties

Supervise all aspects of the Maryland Branch (Pharmacist in Charge). Head the operations of the Hemophilia Center of Excellence at the Maryland branch. Clinical pharmacist for hemophilia, IVIG/SCIG, and Speciality Injectables.

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			07/2004 - 11/2020	
Business Address		**City**	**State**	**Zip**
1631 Dual Highway		Hagerstown	MD	21740
Phone	**Title**		**Number of Employed Hours**	
240-313-9165	Pharmacy Manager		33,280	

Description of Duties

Manage pharmacy staff; create schedule for staff; Monitor customer service; maintain patient charts; achieve corporate pharmacy metrics; collaborate with store manager; enter, enter, fill, verify patient prescriptions; medication therapy management; drug utilization review; answer phones; communicate with other providers; compound

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

Description of Duties

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

Description 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 CMN

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

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

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

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description 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 _____ 5

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 CMW

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)

12/3/21
Date

Applicant's initials CMW

I, Christina Nutter, **certify that as the designated representative for**

Factor One Source Pharmacy, LLC dba InfuCare Rx of MD,

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

Christina Nutter

Print Name (First, Last)

Christina Nutter, PharmD

Original Signature (electronic, copies or stamps not accepted)

12/3/21

Date

Applicant's initials CMN

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.

Christina Nutter

Print Name (First, Last)

Christina Nutter, PharmD — 12/3/21

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

---

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

State of West Virginia, ss. County of Berkeley

I, Christina Nutter, 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.

Christina Nutter — 12/3/21

Original Signature — **Date**

Subscribed and Sworn to before me this 3 day of December.

Andrea Uquillas-C.

Notary Public Signature

OFFICIAL SEAL
NOTARY PUBLIC
STATE OF WEST VIRGINIA
Andrea Elizabeth Uquillas
THE UPS STORE #2458
484 Williamsport Pike
Martinsburg, WV, 25404
My Commission Expires August 13, 2026

(Seal)

Applicant's initials CNN

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* ☑ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** 03241

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: ~~IV Solutions Rx~~ PSG of Sarasota LLC dba IV Solutions Rx

Physical Address: 5315 Avion Park Drive Suite 120 Tampa, Florida 33607-1461

Mailing Address: 5315 Avion Park Drive Suite 120

City: Tampa State: Florida Zip Code: 33607-1461

Telephone: 1-844-650-5802 Fax: 1-844-277-0049

Toll Free Number: 1-844-650-5802 (Required per NAC 639.708)

E-mail: sgrant@ivsolutionsrx.com Website: www.ivsolutionsrx.com

Managing Pharmacist: Sharon Grant License Number: 21795 Temp

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☑	☐ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☐	☑ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☑	☐ Other: Specialty/Home Infusion	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☐ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* ☑ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** 03241

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: IV Solutions Rx

Physical Address: 5315 Avion Park Drive Suite 120 Tampa, Florida 33607-1461

Mailing Address: 5315 Avion Park Drive Suite 120

City: Tampa State: Florida Zip Code: 33607-1461

Telephone: 1-844-650-5802 Fax: 1-844-277-0049

Toll Free Number: 1-844-650-5802 (Required per NAC 639.708)

E-mail: sgrant@ivsolutionsrx.com Website: www.ivsolutionsrx.com

Managing Pharmacist: Sharon Grant License Number: Florida PS59193

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral **
☐	☑ Internet	☑	☐ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☐	☑ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☑	☐ Other: Specialty/Home Infusion	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☐ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Sharon M. Grant

Date: 10/28/2021
Amount:
License #: 21795

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:04/28/2022

Sharon M. Grant

License #
21795
Temporary

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 #: 21795

Expires: 04/28/2022
STATUS: Temporary

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Sharon M. Grant

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Ronald McFarlane
Original Signature of Person Authorized to Submit Application, no copies or stamps

Ronald McFarlane
Print Name of Authorized Person

~~08/24/2021~~ 9/1/2021
Date

Board Use Only Date Processed:_____ Amount: 500 CHECK# 0300573108 Processed 9/16/21

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General _____ Limited X (company is LLC)

Partnership Name: PSG of Sarasota LLC

Mailing Address: 5315 Avion Park Drive Suite 120

City: Tampa State: Florida Zip Code: 33607-1461

Telephone Number: 1-844-650-5802 Fax Number: 1-844-277-0049

Contact Person: Ronald McFarlane

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
IV Solutions Holdings LLC	G	100%

List names of 4 largest partners and percentage of ownership:

Name: IV Solutions Holdings LLC %: 100

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:00 am 5:30 pm Saturday closed am _____ pm

Sunday closed am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20212145273

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Ronald McFarlane

Responsible Person of IV Solutions Rx

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Ronald McFarlane

Original Signature of Person Authorized to Submit Application, no copies or stamps

Ronald McFarlane

Print Name of Authorized Person

9/1/2021

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF North Carolina
WAKE COUNTY) ss.)

I, Ronald McFarlane, 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 OWNER for IV Solutions Rx (the 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 sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product 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 AFFIANT SAYETH NOT.

I, Ronald McFarlane do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Ronald McFarlane
Name

SUBSCRIBED AND SWORN TO before me, a notary public this 1st day of September, 2021.

NOTARY PUBLIC

TYLER COLE NOTARY PUBLIC WAKE COUNTY, NC My Comm. Expires October 23rd, 2022

Managing Pharmacist

Pharmacist Name: Sharon Grant License #: 21795 Temp.

Pharmacy Name: PSG of Sarasota LLC dba IV Solutions Rx

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

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 the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

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.

	Yes	No
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?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature _____ Date 09/21/2021

State of Florida
Department of State

I certify from the records of this office that PSG OF SARASOTA, LLC is a limited liability company organized under the laws of the State of Florida, filed on August 8, 2013, effective December 10, 2012.

The document number of this limited liability company is L13000112694.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on April 23, 2021, 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-sixth day of July, 2021

Secretary of State

Tracking Number: 7516693392CU

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

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

Department of Health

License Verification

Printer Friendly Version

PSG OF SARASOTA, LLC IV SOLUTIONS RX

License Number: PH33457

Data As Of 7/13/2021

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners

Profession	Pharmacy
License	PH33457
License Status	CLEAR/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2023
License Original Issue Date	07/08/2021
Address of Record	5315 AVION PARK DRIVE SUITE 120 TAMPA, FL 33607
Discipline on File	No
Public Complaint	No

Back

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

Primary Source Verified

Privacy Statement | Disclaimer | Email Advisory | Accessibility

© 2021 FL HealthSource, All Rights Reserved Florida Department of Health | Division of Medical Quality Assurance Search Services

PSG of Sarasota, LLC dba IV Solutions Rx

5315 Avion Park Drive Suite 120 Tampa, Florida 33607-1461

Phone: 844-650-5802 Fax: 844-277-0049

List of Officers

Title: Manager/CEO of PSG of Sarasota LLC

Ronald McFarlane

rmcfarlane@ivsolutionsrx.com

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV355 - Community Pharmacy (New Business / Change of Owner)

File # 27878
Insp # 179114

NAME	PERMIT NUMBER	DATE OF INSPECTION
PSG OF SARASOTA, LLC		07/06/2021
DOING BUSINESS AS		
IV SOLUTIONS RX		
STREET ADDRESS	**TELEPHONE #**	**EXT**
5315 AVION PARK DRIVE SUITE 120	844-650-5802	
CITY	**COUNTY**	**STATE/ZIP**
TAMPA	HILLSBOROUGH	FL/33607

Additional Information

Business Operation Hours

M-T-W-TH-F N	Monday Y
Monday Hours 9:00 am to 5:30pm	Tuesday Y
Tuesday Hours 9:00 am to 5:30pm	Wednesday Y
Wednesday Hours 9:00 am to 5:30pm	Thursday Y
Thursday Hours 9:00 am to 5:30pm	Friday Y
Friday Hours 9:00 am to 5:30pm	Saturday Y
Saturday Hours on call	Sunday Y
Sunday Hours on call	

Registered Pharmacist / Intern / Tech

License # 58062	Licensee Name Reema Rifaie
License Type Registered Pharmacists	
License # 62436	Licensee Name Kristin Malone
License Type Registered Pharmacists	
License # 52620	Licensee Name Parag Choksi
License Type Registered Pharmacists	
License # 59193	Licensee Name Sharon Grant
License Type Registered Pharmacists	
License # 74527	Licensee Name Candace Convington
License Type Pharmacy Tech	
License # 81132	Licensee Name Ada Maldonado
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP5195525	

License Relations

Pharmacy Affiliate

MCFARLANE, RONALD	License #
SCHERL, ZEV	License #

RX DPT MGR/COR/POR

GRANT, SHARON MEI	License # 59193

INV355 - Community Pharmacy (New Business / Change of Owner)

Insp # 179114 PSG OF SARASOTA, LLC File # 27878

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.]	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
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.] *Amerisource and Mckession*	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.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

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:

I have read and have had this inspection raport 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

GORDON, TAKARA

Date:7/6/2021

Representative:

SHARON GRANT

Date:7/6/2021

Registrant Verification For

PSG OF SARASOTA, LLC

DEA Number:	FP5195525
Expiration Date:	03/31/2024
Additional Company Info:	IV SOLUTIONS RX
Registered Address:	5315 AVION PARK DR STE 120
City:	TAMPA
State:	FL
Zip Code:	33607
Business Activity:	RETAIL PHARMACY
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	06/30/2021

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

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 PSG of Sarasota LLC dba IV Solutions Rx

Physical Address 5315 Avion Park Drive Suite 120

City Tampa State Florida Zip 33607-1461

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 1-844-650-5802 Website www.ivsolutionsrx.com

Licensing Company Email sgrant@ivsolutionsrx.com

Section 2: Personal Information

First Ronald Middle Howard Last McFarlane

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

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

Mailing Address [redacted] Williamsborough Court

City Raleigh State NC Zip 27609

Telephone [redacted] Email rmcfarlane@ivsolutionsrx.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 RHM

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)	
Cave Spring High School		8/69-6/73	
Address	City	State	Zip
3712 Chaparral Drive	Roanoke	Va	24018
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Roanoke College		9/73 - 5/74	
Address	City	State	Zip
221 College Lane	Salem	Va	24153
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Virginia		8/74 - 6/77	
Address	City	State	Zip
1827 University Avenue	Charlottesville	Va	22903
Diploma/Degree obtained, if any			
B.S. in Science Eduction			

School Name		From - To (MM/YY – MM/YY)	
Virginia Commonwealth University		9/77 - 6/80	
Address	City	State	Zip
1111 W. Broad Street	Richmond	Va	23220
Diploma/Degree obtained, if any			
B.S. in Pharmacy			

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
12/13 - Current	[redacted] Williamsborough Court	Raleigh	NC	27609
04/89 - 08/15	8016 Selfridge Court	Raleigh	NC	27615
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 RHM

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)
PSG of Sarasota LLC dba IV Solutions Rx			05/21 - Current
Business Address	**City**	**State**	**Zip**
5315 Avion Park Drive, Suite 120	Tampa	FL	33607
Phone	**Title**		
919 414 9977	Owner		
Description of Duties			
Provide capital to run this specialty pharmacy and also business advice to my management team.			

Business Name			From - To (MM/YY – MM/YY)
Fairlane Investors LLC			2/20 - Current
Business Address	**City**	**State**	**Zip**
3620 Williamsborough Court	Raleigh	NC	27609
Phone	**Title**		
919 414 9977	Manager		
Description of Duties			
Real Estate Investments			

Business Name			From - To (MM/YY – MM/YY)
Selfridge Investments LLC			06/06 - Current
Business Address	**City**	**State**	**Zip**
3620 Williamsborough Court	Raleigh	NC	27609
Phone	**Title**		
919 414 9977	Manager		
Description of Duties			
Real Estate Investments			

Business Name			From - To (MM/YY – MM/YY)
Williamsborough Investors LLC			08/13 - Current
Business Address	**City**	**State**	**Zip**
3620 Williamsborough Court	Raleigh	NC	27609
Phone	**Title**		
919 414 9977	Manager		
Description of Duties			
Real Estate Investments			

Business Name			From - To (MM/YY – MM/YY)
Diplomat Pharmacy			06/14 - 12/16
Business Address	**City**	**State**	**Zip**
4100 S. Saginaw Street	Flint	MI	98507
Phone	**Title**		
919 414 9977	VP, Specialty Pharmacy Services		
Description of Duties			
Managed Sales and Pharmacy Operations for the Specialty Pharmacy Division of Diplomat Pharmacy			

Continue on next page if additional space is needed.

Applicant's initials RHM

Business Name			From - To (MM/YY – MM/YY)
MedPro Rx			05/02 - 06/14
Business Address	**City**	**State**	**Zip**
140 Northway Court	Raleigh	NC	27615
Phone	**Title**		
919 414 9977	Chief Operating Officer/Co-owner		
Description of Duties			
Managed Sales and Pharmacy Operations for a Specialty 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			

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 RHM

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
12/18/03 Event	12/10/04	NC	Raleigh	Wake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
03 CVS 17025	General Court of Justice, Superior Court, Wake County, North Carolina

Reason/Charge
Caremark sued MedPro Rx over a disputed Noncompete employment issue.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
The plaintiff was Caremark. The defendant was MedPro Rx	This dispute was settled by mediation

Name of Business/Industry/Entity
Our company, MedPro Rx, was the defendant. We were a specialty pharmacy.

Provide explanation below:

Caremark sued MedPro Rx on December 18, 2003 over a disputed Noncompete issue regarding an employee that MedPro Rx had hired. The matter was settled on December 10, 2004 with the Plaintifs agreeing to a voluntary dismissal with prejudice per the terms of a mutually agreed upon mediated settlement. MedPro Rx agreed to follow the terms of the mutually to settlement from the period dating December 10, 2004 and ending on September 1, 2006. In that settlement, MedPro Rx agreed to follow all guidelines, rules, limitations, non-solicitation agreements and other restrictions as agreed to in the mediated settlement. MedPro Rx followed all those guidelines and met the mediated settlement criteria without further comment or legal intervention by Caremark.

Ronald H. McFarlane
Original Signature (electronic, copies or stamps not accepted)

12/31/2021
Date

Applicant's initials RHM

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.

Ronald McFarlane

Print Name (First, Last)

Ronald McFarlane — 12/31/2021

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

---

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

State of NC, ss. County of Wake

I, ~~Tammy Goetchius~~ Ronald McFarlane, 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.

~~Tammy Goetchius~~ Ronald McFarlane — 12/31/21

Original Signature — **Date**

Subscribed and Sworn to before me this 31 day of December 2021

~~Tammy Goetchius~~

Notary Public Signature

TAMMY GOETCHIUS NOTARY PUBLIC WAKE COUNTY, NC My Comm. Expires September 14, 2022

(Seal)

Applicant's initials RHM

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 PSG of Sarasota LLC dba IV Solutions Rx

Physical Address 5315 Avion Park Drive Suite 120

City Tampa State Florida Zip 33607-1461

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 1-844-650-5802 Website www.ivsolutionsrx.com

Licensing Company Email sgrant@ivsolutionsrx.com

Section 2: Personal Information

First Sharon Middle Mei Last Grant

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

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

Mailing Address 5315 Avion Park Drive Suite 120

City Tampa State FL Zip 33607-1461

Telephone 1-844-650-5802 ext 211 Email sgrant@ivsolutionsrx.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 SMG

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)	
Howard University College of Pharmacy		08/04-05/08	
Address	**City**	**State**	**Zip**
2300 4th Street NW	Washington	DC	20059
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
The Pennsylvania State University		08/99-05/03	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science--Life Science major, Nutrition Minor			

School Name		From - To (MM/YY – MM/YY)	
Fairfield High School		08/95-05/99	
Address	**City**	**State**	**Zip**
205 East Atlantic Avenue	Fairfield	CA	94533
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
09/20-present	[redacted]113th Street Unit [redacted]	Seminole	FL	33775
06/18-09/20	628 Kinglet Street	Suisun City	CA	94585-2314
07/16-06/18	7845 Westside Drive Apt 425	San Diego	CA	92108
03/16-07/16	11260 Overland Avenue #28C	Culver City	CA	90230
09/11-03/16	2451 Midtown Avenue Unit 908	Alexandria	VA	22303

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)	
PSG of Sarasota LLC dba IV Solutions Rx			06/21-present	
Business Address		**City**	**State**	**Zip**
5315 Avion Park Drive Suite 120		Tampa	FL	33607-1461
Phone	**Title**		**Number of Employed Hours**	
1-844-650-5802	Production Services Manager/Pharmacist in Charge		500	
Description of Duties				
Clinical oversight and pharmacist-in-charge of day to day operations of IV Solutions Rx.				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Rx Pharmacy 063			09/20-06/21	
Business Address		**City**	**State**	**Zip**
5315 Avion Park Drive Suite 120		Tampa	FL	33607-1461
Phone	**Title**		**Number of Employed Hours**	
1-844-650-5802	Pharmacist		1,280	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Hillcrest Pharmacy			07/16-05/18	
Business Address		**City**	**State**	**Zip**
120 University Drive		San Diego	CA	92103
Phone	**Title**		**Number of Employed Hours**	
619-260-1010	Executive Director of Pharmacy		3,640	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Preston's Pharmacy			06/08-02/16	
Business Address		**City**	**State**	**Zip**
5101 Lee Highway		Arlington	VA	22207
Phone	**Title**		**Number of Employed Hours**	
703-522-3412	Pharmacist in Charge		15,950	
Description 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

Applicant's initials SMG

I, SHARON GRANT, **certify that as the designated representative for**

PSG of Sarasota LLC dba IV Solutions Rx,

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

Sharon Grant

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/21/2021

Date

Applicant's initials SMG

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.

SHARON GRANT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/21/2021

Date

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

State of FLORIDA, ss. County of HILLSBOROUGH

I, JOSEPH F ALBRECHT, 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

9/23/2021

Date

Subscribed and Sworn to before me this 23RD day of SEPTEMBER 2021

Notary Public Signature

JOSEPH F. ALBRECHT
MY COMMISSION # HH 145780
EXPIRES: June 27, 2025
Bonded Thru Notary Public Underwriters

(Seal)

Applicant's initials SMG

PSG of Sarasota LLC dba IV Solutions Rx
5315 Avion Park Dr. Ste. 120
Tampa, Florida 33607-1461

August 24, 2021

Nevada Board of Pharmacy
Change of Ownership Application

Re: PSG of Sarasota, LLC d/b/a IV Solutions Rx Licenses

To Whom It May Concern:

PSG of Sarasota, LLC, d/b/a IV Solutions Rx (the "Company"), is sending you this letter to update you on a number of developments involving the Company. We hope that the following information is both informative and helpful. As described in more detail below, the Company has recently undergone a change in ownership and management, and the Company now desires to (i) disclose the chauge in ownership, (ii) disclose disciplinary actions and investigations that resulted from administrative oversights of the prior ownership, and (iii) take necessary actions to ensure that the Company remains in compliance with the laws and regulations of your state.

Change of Ownership and Management

On May 28, 2021, IV Solutions Holdings LLC, a Delaware limited liability company ("IV Solutions Holdings"), purchased all of the ownership interests of the Company from the Company's previous owner, Advanced Rx Pharmacy, Inc., as evidenced by the Assignment Separate from Certificate attached hereto as **Attachment A**. IV Care LLC ("Parent") is the sole member of IV Solutions Holdings, as evidenced by the Amended and Restated Limited Liability Company Agreement of IV Solutions Holdings attached hereto as **Attachment B**. At the time of IV Solutions Holdings' purchase of the Company, the Parent was owned 50% by Ron McFarlane and 50% by three entities associated with another individual, Zev Scherl. On August 17, 2021, Ron McFarlane purchased the other 50% of the membership interests of the Parent, as evidenced by the Assignment Separate from Certificate attached hereto as **Attachment C**. Now, Ron McFarlane is the sole member of the Parent, as evidenced by the Amended and Restated Limited Liability Company Agreement of the Parent attached hereto as **Attachment D**.

Ron McFarlane is the sole Manager of each of the Company, IV Solutions Holdings and Parent. Victoria Starr has been appointed as the Secretary of the Company.

The Company is a Florida limited liability company. The Company notified the Florida Board of Pharmacy (the "Florida Board") of the change of control described above shortly following closing of IV Solutions Holdings' purchase of the Company. On July 8, 2021, following an inspection, the Florida Board granted the Company a new license, which is number PH33457. The Company remains in good standing with the Florida Board while working with the Division of Medical Quality Assurance to address the administrative issues described below.

Ohio Administrative Oversight

In or around May 2017, while under prior ownership and management, the Company apparently changed locations without obtaining the approval of the State of Ohio Board of Pharmacy (the "Ohio Board"). In or around October 2017, again while under prior ownership and management, the Company apparently changed its name without obtaining the approval of the Ohio Board. This resulted in the Company, according to the Ohio Board, dispensing prescriptions of drugs in violation of Ohio law from the

period of May 2017 through January 2018. On February 5, 2021, the Ohio Board (i) disciplined the Company by written reprimand and (ii) imposed a monetary penalty on the Company in the amount of $4,500.

During its pre-purchase diligence review, IV Solutions Holdings identified the monetary penalty imposed by the Ohio Board as outstanding. IV Solutions Holdings required that the former owners immediately arrange for the Company to pay the fine. On May 26, 2021, the Company paid the fine. On May 28, 2021, IV Solutions Holdings bought the Company. On June 29, 2021, legal counsel for the Ohio Board confirmed to us that the matter was closed. On August 16, 2021, legal counsel for the Ohio Board notified the Company that the Ohio Board intends to issue a new license to the Company, such that the discipline imposed by the Ohio Board will not be associated with the Company's Ohio license under its new owner, IV Solutions Holdings.

If you have any questions for the Ohio Board regarding the Ohio matter, Karrie Southard, the Director of Licensing for the Ohio Board, confirmed to the Company that you may reach out to her directly by email at Karrie.Southard@pharmacy.ohio.gov or by telephone at 614-466-7617.

The Company would also like to note that the heart of the Ohio matter involved the dispensing of "dangerous drugs, including controllcd substances" without necessary approvals following the change in address aud name. The Company is no longer dispensing any controlled substances of any nature, and it presently does not intend to resume the distribution of any controlled substances in your state or otherwise.

Alaska Administrative Oversight

Between February 2018 and November 2020, while under prior ownership and management, the Company apparently changed its Pharmacist-in-Charge without providing the Alaska State Board of Pharmacy (the "Alaska Board") timely notice. On July 14, 2021, the Alaska Board determined that the Company committed "a technical violation" that was "not related to the delivery of patient care." Accordingly, an investigator for the Alaska Board determined that the appropriate disciplinary action would be the imposition of a civil fine without censure or reprimand, in the amount of $500. In August 2021, the Company admitted to the technical violation and agreed to pay the $500 fine pursuant to an Imposition of Civil Fine agreement. The Company is currently waiting for the Alaska Board to adopt the Imposition of Civil Fine at its next meeting. If the Alaska Board indeed adopts the Imposition of Civil Fine, the $500 fine will then become payable, and the Company will promptly pay it, at which time the Alaska matter will be considered "resolved" pursuant to a proposed Order attached to the Imposition of Civil Fine.

Resulting Investigations

The administrative errors in Ohio have led to additional investigations from pharmacy boards.

On July 21, 2021, the Pharmacy Quality Assurance Commission in the State of Washington notified the Company that it was opening an investigation pursuant to a "report of disciplinary action in another state." The Company submitted a written response to the Washington investigator by the required deadline, explaining the nature of the Ohio matter and how it had been resolved. In the written response, the Company clarified that it was not required to provide notice to Washington of the change in location and name because the Company applied for a Washington license only after such changes had occurred. The Company confirmed that it would cooperate with Washington's investigation in all respects.

In March 2021, the Alabama State Board of Pharmacy (the "Alabama Board") issued a Statement of Charges and Notice of Hearing that alleged that the Company violated Alabama law based upon the entry of the order by the Ohio Board. IV Solutions Holdings and the Company's new management only became aware of the matter with the Alabama Board when it received a Scheduling Order dated August 4, 2021. The Company is preparing to respond timely and appropriately to the Alabama Board.

Efforts of New Ownership and Management to Remedy Prior Errors

Since taking control of the Company, IV Solutions Holdings and the Company's new management have spent a substantial amount of time and effort attempting to identify and remedy any technical and administrative errors that may have occurred under the prior ownership, like those that occurred in Ohio and Alaska. It is the Company's intent to review its license in each of the states in which it is licensed, along with any applications and other materials submitted to such states, to ensure that its records are current and to endeavor to correct any previous administrative oversights to the extent possible. We are sending you this letter as part of such effort.

The Company takes its compliance obligations seriously. In this regard, the Company welcomes further conversations with you regarding the Company's license and authorization to conduct business in your state, and it looks forward to working with you in its efforts to eusure its compliance with all applicable laws and regulations.

To the extent that the Company has submitted any applications that contain information or representations inconsistent with the matters described above, we apologize for the oversight and desire to amend or withdraw such applications. To the extent the Company's prior ownership and management failed to make necessary disclosures to you relating to the change of location, name or Pharmacist-in-Charge, then we hope that this letter cures the prior non-disclosure, and the Company will submit any forms relating to the prior changes that you determine are appropriate. If you require any additional filings, disclosures or materials based upon these facts, please let us know, and we would be happy to provide the required information as promptly as possible.

If you would like to schedule a time to have a discussion regarding the Company's status, or if you would like to request any additional information, please email us at vstarr@ivsolutionsrx.com, with a copy to rmcfarlane@ivsolutionsrx.com.

Sincerely,
PSG of Sarasota, LLC d/b/a IV Solutions Rx

By: Ronald McFarlane
Name: Ron McFarlane
Its: Manager

ASSIGNMENT SEPARATE FROM CERTIFICATE

Pursuant to that certain Equity Purchase Agreement dated as of May 28, 2021 by and between IV Solutions Holdings LLC ("**Purchaser**") and Advanced Rx Pharmacy, Inc. ("**Seller**"), Seller hereby assigns and transfers unto Purchaser 100% of all membership interests of PSG of Sarasota, LLC, a Florida limited liability company.

Effective Date: May 28, 2021

IN WITNESS WHEREOF, the undersigned have executed this Assignment Separate from Certificate, effective as of the date immediately above.

SELLER:

ADVANCED RX PHARMACY, INC.

By: _____
Name: JEFFREY AZEVEDO
Title: CEO

AGREED AND ACCEPTED:

PURCHASER:

IV SOLUTIONS HOLDINGS LLC

By: _____
Name: Ron McFarlane
Title: Manager

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

OF

IV SOLUTIONS HOLDINGS LLC

August 17, 2021

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT OF IV SOLUTIONS HOLDINGS LLC

This AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT (this "Agreement") is made and entered into as of August 17, 2021 by IV Care LLC (the "Member"), a Delaware limited liability company and the sole member of IV Solutions Holdings LLC (the "Company"), a Delaware limited liability company, and the initial manager of the Company to set forth the terms and conditions on which the management, business and affairs of the Company shall be conducted.

SECTION 1
ORGANIZATIONAL MATTERS

1.01 Formation. The Company was formed effective April 29, 2021 as a Delaware limited liability company. The rights and obligations of the Member shall be as provided in the Act, except as otherwise expressly provided herein. In the event of any inconsistency between any provisions contained in this Agreement and any non-mandatory provisions of the Act, the provisions contained in this Agreement shall govern and in the event of any inconsistency between any provisions contained in this Agreement and any mandatory provisions of the Act, the mandatory provisions of the Act shall govern.

1.02 Name. The name of the Company is IV Solutions Holdings LLC.

1.03 Purpose. The primary purpose of the Company shall be to carry on any lawful business, purpose or activity permitted by the Act. The Company may engage in any and all other lawful activities as may be necessary, incidental or convenient to carrying out the business of the Company as contemplated by this Agreement.

1.04 Certificate of Formation; Filings. The Company executed a Certificate of Formation and filed it with the Delaware Secretary of State as required by the Act. The Member or its designee(s) may execute and file any amendments to the Certificate of Formation authorized by the Member from time to time in a form prescribed by the Act.

1.05 Fictitious Business Name Statements; Qualification in Other States. Fictitious or assumed business name statements and qualifications in various states may be filed and published as deemed necessary by the Member.

1.06 Registered Office and Registered Agent in Delaware. The Company shall continuously maintain a registered office and a designated and duly qualified agent for service of process on the Company in the State of Delaware. The registered office and registered agent may be changed from time to time by action of the Member or any manager.

1.07 Term. The Company shall have perpetual existence and shall continue until terminated pursuant to this Agreement.

SECTION 2
DEFINITIONS

The following terms used in this Agreement shall have the following meanings (unless otherwise expressly provided herein):

(a) "Act" shall mean the Delaware Limited Liability Company Act, as amended and in force from time to time.

(b) "Agreement" means this Amended and Restated Limited Liability Company Agreement, as amended from time to time. This Agreement amends and restates the Limited Liability Company Agreement of the Company dated May 24, 2021.

(c) "Certificate" shall mean the Certificate of Formation of the Company as filed with the Delaware Secretary of State from time to time.

(d) "Code" shall mean the Internal Revenue Code of 1986, as amended, or corresponding provisions of subsequent superseding federal revenue laws.

(e) "Person" shall mean any natural person or any corporation, limited liability company, partnership, association or trust, and the heirs, executors, administrators, legal representatives, successors and assigns of such Person where the context so permits.

SECTION 3
MANAGEMENT

3.01 By Manager(s). The management of the Company and its business is vested in the manager(s), who may, but need not, be members of the Company. The manager(s) shall be responsible for the management of the Company and shall have the right, power and authority to manage, direct and control all of the business and affairs of the Company, to transact business on its behalf, and to sign for it on its behalf and otherwise bind the Company.

3.02 Number and Qualification. Ron McFarlane shall be the sole initial manager of the Company. The Member may from time to time appoint additional managers by written consent. The manager(s) shall serve until removed by the Member or until his, her or its earlier resignation or death. Any manager may be removed at any time with or without cause by the Member. If any manager(s) is so removed, a new manager(s) may, but need not, be elected by the Member.

3.03 Officers and Agents. The Member and the manager(s) may appoint individuals with or without such titles as it or they may elect, including, without limitation, the titles of President, Vice President, Treasurer, and Secretary, to act on behalf of the Company with such power and authority as the Member or manager(s) may delegate in writing to any such persons.

3.04 Resignation and Removal of Officers and Agents. Any officer or agent of the Company may resign at any time by giving written notice to the Member and manager(s). Any such resignation shall take effect at the time specified therein, or, if the time is not specified therein, upon its acceptance by the Member or manager(s). Any officer or agent of the Company may be removed at any time, for any or no reason, by the Member or the manager(s).

3.05 Indemnification. To the fullest extent permitted by applicable law, the Member (irrespective of the capacity in which it acts) and each manager shall be entitled to indemnification from the Company for any loss, damage or claim incurred by the Member or manager by reason of any act or omission (whether or not constituting negligence or gross negligence) performed or omitted by the Member or manager in good faith on behalf of the Company, provided that any indemnity under this Section shall be provided out of and to the extent of Company assets only. To the fullest extent permitted by applicable law, expenses (including legal fees) incurred by the Member or manager in defending any claim, demand, action, suit or proceeding shall from time to time be advanced by the Company prior to the final disposition of such claim, demand, action suit or proceeding upon receipt by the Company of an undertaking by or on behalf of the Member or manager to repay such amount if it shall ultimately be determined that the Member or manager is not entitled to be indemnified.

3.06 Actions by the Manager(s). Any action required or permitted to be taken at a meeting of the manager(s) may be taken without a meeting and without notice if one or more written consents to such action are signed by all manager(s). Action taken under this Section is effective when all manager(s) then serving sign the consent or consents, unless the consent or consents specifies a different effective date.

SECTION 4
ACTION BY THE MEMBER

4.01 Meetings. Meetings of the Member, for any purpose or purposes, unless otherwise prescribed by statute, may be called by the Member at any time.

4.02 Action by Consent. Any action required or permitted to be taken at a meeting of the Member may be taken without a meeting and without notice if one or more written consents to such action are signed by the Member. Action taken under this Section is effective when the Member signs the consent or consents, unless the consent or consents specifies a different effective date.

SECTION 5
LOANS AND DISTRIBUTIONS

5.01 Loans.

(a) *Loans.* The Member or manager(s) may endeavor to obtain a loan or loans to the Company, from time to time, for necessary capital on reasonable terms, in order to finance the ownership and operation of the business of the Company.

(b) *Loans to Company by Member.* Nothing in this Agreement shall prevent the Member from making secured or unsecured loans to the Company by agreement with the Company in accordance with the terms of this Agreement.

5.02 Distributions. Distributions shall be made by the Company to the Member at such times and in such amounts as the Member shall determine in its sole discretion; provided, however, the Company's obligation, and the Member's authority, to make any distribution is subject to the restrictions governing distributions under the Act and such other pertinent governmental restrictions as are now and may hereafter become effective.

SECTION 6
TAX MATTERS

It is intended that the Company be treated as a single member entity within the meaning of Section 301.7701-2(c)(2) of the Treasury Regulations and, accordingly, disregarded as a separate entity for tax purposes.

SECTION 7
DISSOLUTION AND TERMINATION

7.01 Events of Dissolution. The Company shall be dissolved only upon the occurrence of one or more of the following events:

(a) The determination in writing of the Member;

(b) The adjudication of the Company as insolvent within the meaning of insolvency in either bankruptcy or equity proceedings, or the filing of an involuntary petition in bankruptcy against the Company (which is not dismissed within ninety (90) days), or the filing against the Company of a petition for reorganization under the federal bankruptcy code or any state statute (which is not dismissed within ninety (90) days), or a general assignment by the Company for the benefit of creditors, or the voluntary claim (by the Company) that it is insolvent under any provisions of the federal bankruptcy code (or any state insolvency statutes), or the appointment for the Company of a temporary or permanent receiver, trustee, custodian or sequestrator, and such receiver, trustee, custodian or sequestrator is not dismissed within ninety (90) days; or

(c) As otherwise required under mandatory provisions of the Act.

7.02 Liquidation. Upon the dissolution of the Company, it shall wind up its affairs by either or a combination of both of the following methods as the Member shall determine:

(a) Selling the Company's assets and, after paying the Company's liabilities or reserving sufficient funds for such liabilities, distributing the net proceeds to the Member in return of its contributions and in respect of its limited liability company interests in the Company; and/or,

(b) Distributing the Company's assets to the Member in kind with the Member accepting the Company's assets, subject to its liabilities, in return of its contributions and in respect of its limited liability company interests in the Company.

7.03 Orderly Liquidation. A reasonable time as determined by the Member not to exceed eighteen (18) months shall be allowed for the orderly liquidation of the assets of the Company and the discharge of liabilities to the creditors so as to minimize any losses attendant upon dissolution.

7.04 Distributions. Upon dissolution, the Company's assets (including any cash on hand) shall be distributed in the following order and in accordance with the following priorities:

(a) First, to the payment of the debts and liabilities of the Company (including but not limited to loans made by the Member) and the expenses of liquidation, including a sales commission to the selling agent, if any; then

(b) Second, to the setting up of any reserves which the Member shall deem reasonably necessary for any contingent or unforeseen liabilities or obligations of the Company. At the expiration of such period as the Member shall deem advisable, but in no event to exceed eighteen (18) months, the Member shall distribute the balance thereof in the manner provided in the following subparagraph; then

(c) Third, to the Member.

7.05 Certificate of Cancellation.

(a) Within a reasonable time following the completion of the liquidation of the Company, there shall be supplied to the Member a statement which shall set forth the assets and the liabilities of the Company as of the date of complete liquidation. Upon completion of the liquidation of the Company and the distribution of all the Company's assets, the Company shall terminate, and the Member shall execute and record a Certificate of Cancellation of the Company as provided in Section 18-203 of the Act as well as any and all other documents required to effectuate the dissolution and termination of the Company.

(b) Upon the issuance of the filing of the Certificate of Cancellation, the existence of the Company shall cease, except for the purpose of suits, other proceedings and appropriate action as provided in the Act. The Member shall thereafter have authority to distribute any Company property discovered after dissolution, convey property, if any, and take such other action as may be necessary on behalf of and in the name of the Company, subject to the requirements of the Act.

SECTION 8
MISCELLANEOUS PROVISIONS

8.01 Bank Accounts. The Company shall maintain such bank accounts as the Member or manager(s) may determine to be appropriate from time to time.

8.02 Books of Account and Records. Proper and complete records and books of account shall be kept or shall be caused to be kept by the Member and manager(s) in which shall be entered fully and accurately all transactions and other matters relating to the Company in such detail and completeness as is customary and usual for businesses of the type engaged in by the Company. The books and records shall at all times be maintained at the principal office of the Company and shall be open to inspection and examination of the Member or its duly authorized representatives during reasonable business hours.

8.03 Checks, Drafts, etc. All checks, drafts, notes, or other obligations for the payment of money shall be signed by the Member, a manager, or such officer or officers or agent or agents as the Member shall by general or special resolution direct. The Member may also in its discretion require, by general or special resolutions, that checks, drafts, notes, and other obligations for the payment of money shall be countersigned or registered as a condition to their validity by such manager, officer or officers or agent or agents as shall be directed in such resolution.

8.04 Application of Delaware Law. This Agreement and the interpretation hereof, shall be governed exclusively by its terms and by the laws of the State of Delaware, without reference to its choice of law provisions, and specifically the Act.

8.05 Amendments. This Agreement may be amended by the Member at any time.

8.06 Waivers. The failure of any party to seek redress for violation of or to insist upon the strict performance of any covenant or condition of this Agreement shall not prevent a subsequent act, which would have originally constituted a violation, from having the effect of an original violation.

8.07 Severability. If any provision of this Agreement or the application thereof to any person or circumstance shall be invalid, illegal or unenforceable to any extent, the remainder of this Agreement and the application thereof shall not be affected and shall be enforceable to the fullest extent permitted by law.

8.08 Heirs, Successors and Assigns. Each and all of the covenants, terms, provisions and agreements herein contained shall be binding upon and inure to the benefit of the parties hereto and, to the extent permitted by this Agreement, their respective heirs, legal representatives, successors and assigns.

8.09 Creditors. None of the provisions of this Agreement shall be for the benefit of or enforceable by any creditor of the Company. The specific intent of the undersigned is that there shall be no third-party beneficiaries of this Agreement.

8.10 Limitation on Liability. The Member shall not be liable for the debts, liabilities or obligations of the Company beyond its initial capital contribution and any additional capital contribution made by the Member. The Member shall not be required to contribute to the capital of, or to loan any funds to, the Company.

8.11 Entire Agreement. This Agreement sets forth all of the promises, agreements, conditions and understandings between the parties respecting the subject matter hereof and supersedes all negotiations, conversations, discussions, correspondence, memoranda and agreements between the parties concerning such subject matter.

[*Signature page follows*]

The undersigned sole Member and initial manager of the Company hereby agree, acknowledge and certify that the foregoing Amended and Restated Limited Liability Company Agreement constitutes the sole and entire limited liability company agreement (as defined in the Act) of IV Solutions Holdings LLC, a Delaware limited liability company, adopted as of the date first written above.

MEMBER:
IV Care LLC

By: Ron McFarlane
Name: Ron McFarlane
Title: Sole Member and Manager

MANAGER:

By: Ron McFarlane
Ron McFarlane

ASSIGNMENT SEPARATE FROM CERTIFICATE

Pursuant to that certain Unit Purchase Agreement dated as of August 17, 2021 by and among IV Care LLC ("**Purchaser**" or "**Company**"), Amplify Funds, LLC ("**Amplify**"), Seven Ten Holdings Trust ("**Seven Ten**"), One Twenty One Holdings Trust ("**One Twenty One**"), and Zev Scherl, (a) Amplify hereby assigns and transfers unto Purchaser 400,000 Series A Preferred Units standing in Amplify's name on the Company's books and records, which constitutes the entirety of Amplify's rights and interests in the Company; (b) Seven Ten hereby assigns and transfers unto Purchaser 200,000 Series A Preferred Units standing in Seven Ten's name on the Company's books and records, which constitutes the entirety of Seven Ten's rights and interests in the Company; and (c) One Twenty One hereby assigns and transfers unto Purchaser 200,000 Series A Preferred Units standing in One Twenty One's name on the Company's books and records, which constitutes the entirety of One Twenty One's rights and interests in the Company.

Capitalized terms used, but not otherwise defined, herein shall have the meanings ascribed to such terms in the Limited Liability Company Agreement of the Company dated as of May 24, 2021, as the same may be amended, modified or supplemented from time to time.

Dated: August 17, 2021

IN WITNESS WHEREOF, the undersigned have executed this Assignment Separate from Certificate, effective as of the date immediately above.

SELLERS:

AMPLIFY FUNDS, LLC

By: _____
Name: Zev Scherl
Title: Managing Member

SEVEN TEN HOLDINGS TRUST

By: _____
Name: Jenny Scherl
Title: Sole Trustee

ONE TWENTY ONE HOLDINGS TRUST

By: Samuel Scherl
Name: Sam Scherl
Title: Sole Trustee

AGREED AND ACCEPTED:

PURCHASER:

IV CARE LLC

By: Ron McFarlane
Name: Ron McFarlane
Title: Manager

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

OF

IV CARE LLC

August 17, 2021

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT OF IV CARE LLC

This AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT (this "Agreement") is made and entered into as of August 17, 2021 by Ron McFarlane (the "Member"), an individual resident of North Carolina and the sole member of IV Care LLC (the "Company"), a Delaware limited liability company, to set forth the terms and conditions on which the management, business and affairs of the Company shall be conducted.

SECTION 1
ORGANIZATIONAL MATTERS

1.01 Formation. The Company was formed effective April 30, 2021 as a Delaware limited liability company. The rights and obligations of the Member shall be as provided in the Act, except as otherwise expressly provided herein. In the event of any inconsistency between any provisions contained in this Agreement and any non-mandatory provisions of the Act, the provisions contained in this Agreement shall govern and in the event of any inconsistency between any provisions contained in this Agreement and any mandatory provisions of the Act, the mandatory provisions of the Act shall govern.

1.02 Name. The name of the Company is IV Care LLC.

1.03 Purpose. The primary purpose of the Company shall be to carry on any lawful business, purpose or activity permitted by the Act. The Company may engage in any and all other lawful activities as may be necessary, incidental or convenient to carrying out the business of the Company as contemplated by this Agreement.

1.04 Certificate of Formation; Filings. The Company executed a Certificate of Formation and filed it with the Delaware Secretary of State as required by the Act. The Member or its designee(s) may execute and file any amendments to the Certificate of Formation authorized by the Member from time to time in a form prescribed by the Act.

1.05 Fictitious Business Name Statements; Qualification in Other States. Fictitious or assumed business name statements and qualifications in various states may be filed and published as deemed necessary by the Member.

1.06 Registered Office and Registered Agent in Delaware. The Company shall continuously maintain a registered office and a designated and duly qualified agent for service of process on the Company in the State of Delaware. The registered office and registered agent may be changed from time to time by action of the Member or any manager.

1.07 Term. The Company shall have perpetual existence and shall continue until terminated pursuant to this Agreement.

SECTION 2
DEFINITIONS

The following terms used in this Agreement shall have the following meanings (unless otherwise expressly provided herein):

(a) "Act" shall mean the Delaware Limited Liability Company Act, as amended and in force from time to time.

(b) "Agreement" means this Amended and Restated Limited Liability Company Agreement, as amended from time to time. This Agreement amends and restates the Limited Liability Company Agreement of the Company dated May 24, 2021.

(c) "Certificate" shall mean the Certificate of Formation of the Company as filed with the Delaware Secretary of State from time to time.

(d) "Code" shall mean the Internal Revenue Code of 1986, as amended, or corresponding provisions of subsequent superseding federal revenue laws.

(e) "Person" shall mean any natural person or any corporation, limited liability company, partnership, association or trust, and the heirs, executors, administrators, legal representatives, successors and assigns of such Person where the context so permits.

SECTION 3
MANAGEMENT

3.01 By Manager(s). The management of the Company and its business is vested in the manager(s), who may, but need not, be members of the Company. The manager(s) shall be responsible for the management of the Company and shall have the right, power and authority to manage, direct and control all of the business and affairs of the Company, to transact business on its behalf, and to sign for it on its behalf and otherwise bind the Company.

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3.03 Officers and Agents. The Member and the manager(s) may appoint individuals with or without such titles as it or they may elect, including, without limitation, the titles of President, Vice President, Treasurer, and Secretary, to act on behalf of the Company with such power and authority as the Member or manager(s) may delegate in writing to any such persons.

3.04 Resignation and Removal of Officers and Agents. Any officer or agent of the Company may resign at any time by giving written notice to the Member and manager(s). Any such resignation shall take effect at the time specified therein, or, if the time is not specified therein, upon its acceptance by the Member or manager(s). Any officer or agent of the Company may be removed at any time, for any or no reason, by the Member or the manager(s).

3.05 Indemnification. To the fullest extent permitted by applicable law, the Member (irrespective of the capacity in which it acts) and each manager shall be entitled to indemnification from the Company for any loss, damage or claim incurred by the Member or manager by reason of any act or omission (whether or not constituting negligence or gross negligence) performed or omitted by the Member or manager in good faith on behalf of the Company, provided that any indemnity under this Section shall be provided out of and to the extent of Company assets only. To the fullest extent permitted by applicable law, expenses (including legal fees) incurred by the Member or manager in defending any claim, demand, action, suit or proceeding shall from time to time be advanced by the Company prior to the final disposition of such claim, demand, action suit or proceeding upon receipt by the Company of an undertaking by or on behalf of the Member or manager to repay such amount if it shall ultimately be determined that the Member or manager is not entitled to be indemnified.

3.06 Actions by the Manager(s). Any action required or permitted to be taken at a meeting of the manager(s) may be taken without a meeting and without notice if one or more written consents to such action are signed by all manager(s). Action taken under this Section is effective when all manager(s) then serving sign the consent or consents, unless the consent or consents specifies a different effective date.

SECTION 4
ACTION BY THE MEMBER

4.01 Meetings. Meetings of the Member, for any purpose or purposes, unless otherwise prescribed by statute, may be called by the Member at any time.

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LOANS AND DISTRIBUTIONS

5.01 Loans.

(a) *Loans.* The Member or manager(s) may endeavor to obtain a loan or loans to the Company, from time to time, for necessary capital on reasonable terms, in order to finance the ownership and operation of the business of the Company.

(b) *Loans to Company by Member.* Nothing in this Agreement shall prevent the Member from making secured or unsecured loans to the Company by agreement with the Company in accordance with the terms of this Agreement.

5.02 Distributions. Distributions shall be made by the Company to the Member at such times and in such amounts as the Member shall determine in its sole discretion; provided, however, the Company's obligation, and the Member's authority, to make any distribution is subject to the restrictions governing distributions under the Act and such other pertinent governmental restrictions as are now and may hereafter become effective.

SECTION 6
TAX MATTERS

It is intended that the Company be treated as a single member entity within the meaning of Section 301.7701-2(c)(2) of the Treasury Regulations and, accordingly, disregarded as a separate entity for tax purposes.

SECTION 7
DISSOLUTION AND TERMINATION

7.01 Events of Dissolution. The Company shall be dissolved only upon the occurrence of one or more of the following events:

(a) The determination in writing of the Member;

(b) The adjudication of the Company as insolvent within the meaning of insolvency in either bankruptcy or equity proceedings, or the filing of an involuntary petition in bankruptcy against the Company (which is not dismissed within ninety (90) days), or the filing against the Company of a petition for reorganization under the federal bankruptcy code or any state statute (which is not dismissed within ninety (90) days), or a general assignment by the Company for the benefit of creditors, or the voluntary claim (by the Company) that it is insolvent under any provisions of the federal bankruptcy code (or any state insolvency statutes), or the appointment for the Company of a temporary or permanent receiver, trustee, custodian or sequestrator, and such receiver, trustee, custodian or sequestrator is not dismissed within ninety (90) days; or

(c) As otherwise required under mandatory provisions of the Act.

7.02 Liquidation. Upon the dissolution of the Company, it shall wind up its affairs by either or a combination of both of the following methods as the Member shall determine:

(a) Selling the Company's assets and, after paying the Company's liabilities or reserving sufficient funds for such liabilities, distributing the net proceeds to the Member in return of its contributions and in respect of its limited liability company interests in the Company; and/or,

(b) Distributing the Company's assets to the Member in kind with the Member accepting the Company's assets, subject to its liabilities, in return of its contributions and in respect of its limited liability company interests in the Company.

7.03 Orderly Liquidation. A reasonable time as determined by the Member not to exceed eighteen (18) months shall be allowed for the orderly liquidation of the assets of the Company and the discharge of liabilities to the creditors so as to minimize any losses attendant upon dissolution.

7.04 Distributions. Upon dissolution, the Company's assets (including any cash on hand) shall be distributed in the following order and in accordance with the following priorities:

(a) First, to the payment of the debts and liabilities of the Company (including but not limited to loans made by the Member) and the expenses of liquidation, including a sales commission to the selling agent, if any; then

(b) Second, to the setting up of any reserves which the Member shall deem reasonably necessary for any contingent or unforeseen liabilities or obligations of the Company. At the expiration of such period as the Member shall deem advisable, but in no event to exceed eighteen (18) months, the Member shall distribute the balance thereof in the manner provided in the following subparagraph; then

(c) Third, to the Member.

7.05 Certificate of Cancellation.

(a) Within a reasonable time following the completion of the liquidation of the Company, there shall be supplied to the Member a statement which shall set forth the assets and the liabilities of the Company as of the date of complete liquidation. Upon completion of the liquidation of the Company and the distribution of all the Company's assets, the Company shall terminate, and the Member shall execute and record a Certificate of Cancellation of the Company as provided in Section 18-203 of the Act as well as any and all other documents required to effectuate the dissolution and termination of the Company.

(b) Upon the issuance of the filing of the Certificate of Cancellation, the existence of the Company shall cease, except for the purpose of suits, other proceedings and appropriate action as provided in the Act. The Member shall thereafter have authority to distribute any Company property discovered after dissolution, convey property, if any, and take such other action as may be necessary on behalf of and in the name of the Company, subject to the requirements of the Act.

SECTION 8
MISCELLANEOUS PROVISIONS

8.01 Bank Accounts. The Company shall maintain such bank accounts as the Member or manager(s) may determine to be appropriate from time to time.

8.02 Books of Account and Records. Proper and complete records and books of account shall be kept or shall be caused to be kept by the Member and manager(s) in which shall be entered fully and accurately all transactions and other matters relating to the Company in such detail and completeness as is customary and usual for businesses of the type engaged in by the Company. The books and records shall at all times be maintained at the principal office of the Company and shall be open to inspection and examination of the Member or its duly authorized representatives during reasonable business hours.

8.03 Checks, Drafts, etc. All checks, drafts, notes, or other obligations for the payment of money shall be signed by the Member, a manager, or such officer or officers or agent or agents as the Member shall by general or special resolution direct. The Member may also in its discretion require, by general or special resolutions, that checks, drafts, notes, and other obligations for the payment of money shall be countersigned or registered as a condition to their validity by such manager, officer or officers or agent or agents as shall be directed in such resolution.

8.04 Application of Delaware Law. This Agreement and the interpretation hereof, shall be governed exclusively by its terms and by the laws of the State of Delaware, without reference to its choice of law provisions, and specifically the Act.

8.05 Amendments. This Agreement may be amended by the Member at any time.

8.06 Waivers. The failure of any party to seek redress for violation of or to insist upon the strict performance of any covenant or condition of this Agreement shall not prevent a subsequent act, which would have originally constituted a violation, from having the effect of an original violation.

8.07 Severability. If any provision of this Agreement or the application thereof to any person or circumstance shall be invalid, illegal or unenforceable to any extent, the remainder of this Agreement and the application thereof shall not be affected and shall be enforceable to the fullest extent permitted by law.

8.08 Heirs, Successors and Assigns. Each and all of the covenants, terms, provisions and agreements herein contained shall be binding upon and inure to the benefit of the parties hereto and, to the extent permitted by this Agreement, their respective heirs, legal representatives, successors and assigns.

8.09 Creditors. None of the provisions of this Agreement shall be for the benefit of or enforceable by any creditor of the Company. The specific intent of the undersigned is that there shall be no third-party beneficiaries of this Agreement.

8.10 Limitation on Liability. The Member shall not be liable for the debts, liabilities or obligations of the Company beyond its initial capital contribution and any additional capital contribution made by the Member. The Member shall not be required to contribute to the capital of, or to loan any funds to, the Company.

8.11 Entire Agreement. This Agreement sets forth all of the promises, agreements, conditions and understandings between the parties respecting the subject matter hereof and supersedes all negotiations, conversations, discussions, correspondence, memoranda and agreements between the parties concerning such subject matter.

[*Signature page follows*]

The undersigned, being the sole Member and manager of the Company, hereby agrees, acknowledges and certifies that the foregoing Amended and Restated Limited Liability Company Agreement constitutes the sole and entire limited liability company agreement (as defined in the Act) of IV Care LLC, a Delaware limited liability company, adopted as of the date first written above.

SOLE MEMBER AND MANAGER:

By: Ron McFarlane
Ron McFarlane

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 (9/22/2021)

y

Where is the facility located?
☐ Nevada
■ Out-of-State

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New Pharmacy	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH PH04073	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: MedWiseRx

Physical Address: 1812 Centre Creek Drive Suite 115

City: Austin State: TX Zip: 78754

Mailing Address (if different from physical address): 228 Strawbridge Dr Suite 100

City: Moorestown State: NJ Zip: 08057

Telephone: 512-579-0026 Toll Free # (NAC 639.708, NRS 639.23286): 844-866-3730

Fax: 512-579-0008 Contact Email: mwr-aus@trhc.com

Website: www.sinfoniarx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Bisi Aiyelabowo

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21979 ✓ OK exp. 10/31/2023

Type of Pharmacy (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Retail/Community	☐ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
■ Other: Non-Dispensing	☐ Off-site Cognitive Services
	☐ Long Term Care
	☐ Hospital
	■ Other: Medication Therapy Management

Days of Operation

■ Monday ■ Tuesday ■ Wednesday ■ Thursday ■ Friday ■ Saturday ☐ Sunday

Section 2: List all Nevada Registered Pharmacist that will be Providing Pharmacy Services to/for Patients for this Pharmacy (NRS 639.070, NAC 639.650) (Use continuation sheet if necessary and check here [ ])

Name: Bisi Aiyelabowo	NV Pharmacist Registration #: 21979
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 Criminality	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: List any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physician, Podiatrist, Optometrist, Physician, Dentist, Dentist, Surgeon, Chiropodist, Podiatrist, etc.) that provide the oversight of the pharmacy (see Definitions and FAQ for more information). Write NA if not applicable. Use a continuation sheet if more than 4 additional owners provided.

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): Tabula Rasa HealthCare, Inc.

Corporation/Organization Name: Tabula Rasa HealthCare Group, Inc.

Mailing Address: 228 Strawbridge Drive Suite 100

City: Moorestown State: NJ Zip: 08057

Telephone: 866-648-2767 Email: mwr-aus@trhc.com

Contact Person Name: Richard Greene, VP Regulatory Affairs

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: _____

Statement of Responsibility

1. I am the Secretary (title) for Tabula Rasa HealthCare Group, 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).

Brian W. Adams

Print Name of Authorized Person

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

12/2/21

Date

[redacted]

Affidavit for Pharmacy License

I, Brian W. Adams 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 Secretary (title) for Tabula Rasa HealthCare Group, Inc. (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 16th day of December, 20 21

Notary Public

Courtenay L. Sellers
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50092284
MY COMMISSION EXPIRES October 16, 2023

COURTENAY L. SELLERS
NOTARY PUBLIC
NEW JERSEY

Managing Pharmacist Name: N/A - Out-of-State Pharmacy Pharmacist Registration #: _____

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

_____ 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.

_____ 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.

_____ 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.

_____ 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)).

_____ 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

[redacted]	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?		
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

[redacted]	State:	Date:	Case #:

[redacted]	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) Date

• **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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** N/A - non-dispensing pharmacy	✓	✓	✓	✓
• **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** N/A	✓	✓	✓	✓
• **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/ 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.

Brian W. Adams

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)

12/2/21

Date

Board Use Only	Date Received: _____	Amount: 500 check # 31861

MedWiseRx™

Tabula Rasa HealthCare Group, Inc. dba

MedWiseRx

Regulatory Action

Texas License (# 33191)
(Located at: 1812 Centre Creek Drive, Suite 115 Austin, TX 78754)

- October 19, 2020 – On 7/2/20, the **Kansas** Board of Pharmacy received an application from MedWiseRx (Austin, TX) for a change in name/ownership that had taken place on 1/1/20. The Board approved the application effective 8/13/2020. It was found that the pharmacy continued to operate in the state as a non-resident pharmacy after the 1/1/change, but prior to their July notification to and August approval by the Board. The Summary Order civil fine of $500 was paid and the issue was closed: 10-19-2020.

Tabula Rasa HealthCare Group, Inc dba MedWiseRx

Richard B. Greene

Richard B. Greene, PharmD, MBA, PRS, FASCP
VP Regulatory Affairs

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 30, 2020

MEDWISERX
1812 CENTRE CREEK DR, STE 115
AUSTIN, TX 78754

RE: Case No. 20-246

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $500. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

Filed By
OCT 1 2020
KANSAS STATE
BOARD OF PHARMACY

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 20-246
Tabula Rasa HealthCare Group, Inc. dba MedWiseRx	)	
	)	
Registration No. 22-112563	)	

SUMMARY ORDER

NOW, on this 1st day of October 2020, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of Tabula Rasa HealthCare Group, Inc. dba MedWiseRx ("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 Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board had previously issued Respondent Registration No. 22-111022 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas ("Respondent's Registration").

2. On January 1, 2020, name and ownership of Respondent's facility were changed from SinfoniaRx, Inc. to Tabula Rasa HealthCare Group, Inc. dba MedWiseRx.

3. On July 2, 2020, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application, notifying the Board of the changes in name and ownership.

4. On August 13, 2020, the Board approved Respondent's Non-Resident Pharmacy Registration Application, effective immediately.

5. With the August 13, 2020 approval, Respondent's previous registration number 22-111022 was cancelled and Respondent was issued new registration number 22-112563, under the new name and ownership.

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. 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.

3. Respondent's failure to submit the complete change of name and ownership application to the Board until July 12, 2020 – 188 days past the January 5, 2020 deadline – is a violation pursuant to K.S.A. 68-2-9.

4. Pursuant to K.S.A. 65-1657, no non-resident 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.

5. Respondent's application documents indicated Respondent had functioned as a non-resident in the state of Kansas after the name and ownership change which rendered Respondent's registration invalid, and prior to obtaining new registration as a non-resident pharmacy from the Board on August 13, 2020.

6. By operating as a non-resident pharmacy in the state of Kansas prior to its Non-Resident Pharmacy Registration Application approval by the Board, Respondent violated K.S.A. 65-1657.

ORDER

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 $500.00. Respondent has 30 days from the date of this order to pay the full $500.00.

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.

10/1/2020
Date

Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 1st day of October 2020, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

MEDWISERX
1812 CENTRE CREEK DR, STE 115
AUSTIN, TX 78754

Kansas Board of Pharmacy Staff

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 30, 2020

MEDWISERX
1812 CENTRE CREEK DR, STE 115
AUSTIN, TX 78754

RE: Case No. 20-246

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $500. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

Filed By
OCT 1 2020
KANSAS STATE
BOARD OF PHARMACY

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 20-246
Tabula Rasa HealthCare Group, Inc. dba MedWiseRx	)	
	)	
Registration No. 22-112563	)	

SUMMARY ORDER

NOW, on this 1st day of October 2020, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of Tabula Rasa HealthCare Group, Inc. dba MedWiseRx ("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 Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board had previously issued Respondent Registration No. 22-111022 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas ("Respondent's Registration").

2. On January 1, 2020, name and ownership of Respondent's facility were changed from SinfoniaRx, Inc. to Tabula Rasa HealthCare Group, Inc. dba MedWiseRx.

3. On July 2, 2020, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application, notifying the Board of the changes in name and ownership.

4. On August 13, 2020, the Board approved Respondent's Non-Resident Pharmacy Registration Application, effective immediately.

5. With the August 13, 2020 approval, Respondent's previous registration number 22-111022 was cancelled and Respondent was issued new registration number 22-112563, under the new name and ownership.

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. 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.

3. Respondent's failure to submit the complete change of name and ownership application to the Board until July 12, 2020 – 188 days past the January 5, 2020 deadline – is a violation pursuant to K.S.A. 68-2-9.

4. Pursuant to K.S.A. 65-1657, no non-resident 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.

5. Respondent's application documents indicated Respondent had functioned as a non-resident in the state of Kansas after the name and ownership change which rendered Respondent's registration invalid, and prior to obtaining new registration as a non-resident pharmacy from the Board on August 13, 2020.

6. By operating as a non-resident pharmacy in the state of Kansas prior to its Non-Resident Pharmacy Registration Application approval by the Board, Respondent violated K.S.A. 65-1657.

ORDER

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 $500.00. Respondent has 30 days from the date of this order to pay the full $500.00.

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.

10/1/2020
Date

Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 15th day of October 2020, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

MEDWISERX
1812 CENTRE CREEK DR, STE 115
AUSTIN, TX 78754

Kansas Board of Pharmacy Staff

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TABULA RASA HEALTHCARE GROUP, 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 NOVEMBER, A.D. 2021.

4674249 8300

SR# 20213910253

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

Authentication: 204818620

Date: 11-30-21

Service Request# **20213910253**

State of Delaware

SECRETARY OF STATE
DIVISION OF CORPORATIONS
P.O. BOX 898
DOVER, DELAWARE 19903

9668222
TABULA RASA HEALTHCARE, INC.
228 STRAWBRIDGE DRIVE, SUITE 100
MORRISTOWN, NJ 08057

11-30-2021

ATTN: RICHARD B GREENE

DESCRIPTION	AMOUNT
4674249 - TABULA RASA HEALTHCARE GROUP, INC.	
Entity Status - Short Form	
Certification Fee	*$50.00*
Expedite Fee, 24 Hour	*$40.00*
TOTAL CHARGES	*$90.00*
TOTAL PAYMENTS	*$90.00*
BALANCE	*$0.00*

CERTIFICATE
TEXAS STATE BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **33191**

Expiration Date: **3/31/2022**

Balances: **0**

MEDWISERX
1812 CENTER CREEK DR STE 115
AUSTIN TX 78754

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TabulaRasa
HealthCare Group, Inc.

MedWiseRx Ownership

Tabula Rasa HealthCare, Inc. – owns 100% of Tabula Rasa HealthCare Group, Inc.
228 Strawbridge Drive, Suite 100 (corporate address)
Moorestown, NJ 08057
EIN: 46-5726437
Incorporated in Delaware

Tabula Rasa HealthCare, Inc. is a public corporation. (NASDQ: TRHC)

Tabula Rasa HealthCare Group, Inc. – Owns 100% of the pharmacies **dba MedWiseRx**
228 Strawbridge Drive, Suite 100 (corporate address)
Moorestown, NJ 08057
EIN: 26-4642609
Incorporated in Delaware

Tabula Rasa HealthCare Group, Inc. is a private corporation 100% owned by Tabula Rasa HealthCare, Inc.

Corporate Officers

Orsula V. Knowlton, PharmD - President
Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057
[redacted]

Calvin H. Knowlton, BScPharm, MDiv, PhD - CEO
Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057
[redacted]

Brian W. Adams - Secretary
Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057
[redacted]

TabulaRasa
HealthCare Group, Inc.

Officers – Directors

President - Director
Orsula V. Knowlton
[redacted] Spyglass Circle
Fernandina Beach, FL 32034-6579

Chief Executive Officer – Chairperson, Director
Calvin H. Knowlton
[redacted] Spyglass Circle
Fernandina Beach, FL 32034-6579

Secretary
Brian W. Adams
[redacted] Station Avenue
Haddonfield, NJ 08033

Work Address for all three:

228 Strawbridge Drive, Suite 100
Moorestown, NJ 08057-4600

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 MedWiseRx

Physical Address 1812 Centre Creek Drive Suite 115

City Austin State TX Zip 78754

Mailing Address (if different from physical address) 228 Strawbridge Drive Suite 100

City Moorestown State NJ Zip 08057

Telephone 512-579-0026 Website www.sinfoniarx.com

Licensing Company Email mwr-aus@trhc.com

Section 2: Personal Information

First BISI Middle _____ Last AIYELABOWO

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

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

Mailing Address [redacted] Tristan Way

City Cedar Park State TX Zip 78613

Telephone [redacted] Email [redacted]@trhc.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?		X

Applicant's initials BA

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 at Buffalo		08/12 - 05/17	
Address	City	State	Zip
1160 Hayes Rd	Buffalo	NY	14215
Diploma/Degree obtained, if any			
Doctor of Pharmacy (Pharm.D)			
School Name		From - To (MM/YY – MM/YY)	
University at Buffalo		08/15 - 05/17	
Address	City	State	Zip
160 Hayes Rd	Buffalo	NY	14215
Diploma/Degree obtained, if any			
Master of Business Administration (MBA)			
School Name		From - To (MM/YY – MM/YY)	
Hunter College		08/2007 - 12/2011	
Address	City	State	Zip
695 Park Ave	New York	NY	10065
Diploma/Degree obtained, if any			
Bachelor of Arts			
School Name		From - To (MM/YY – MM/YY)	
Newtown High School		09/2003 - 05/2007	
Address	City	State	Zip
48-01 90th Street	Queens	NY	11373
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
06/2021 - Current	[redacted] Tristan way	Cedar Park	Tx	78613
05/2020 - 06/2021	[redacted] S Mopac Expy	Austin	Tx	78746
09/2016 - 05/2020	[redacted] 187 Place	Jamaica	NY	11423
08/2012 - 09/16	[redacted] Peach Tree Rd	Cheektowaga	NY	14225
01/1996 - 08/2012	[redacted] 187 Place	Jamaica	NY	11423
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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: Medwise Rx			From - To (MM/YY – MM/YY): 09/2021 - Current	
Business Address: 1812 Centre Creek Suite 115		City: Austin	State: Tx	Zip: 78754
Phone: 512-296-1016	Title: Pharmacist		Number of Employed Hours: 40 hours / week	
Description of Duties: Provides patient-centered MTM services for the purpose of optimizing medication theraphy to improve clinical, economical and humanistic outcome				

Business Name: Walgreens			From - To (MM/YY – MM/YY): 08/2020 - 09/2021	
Business Address: 12550 Metric Blvd		City: Austin	State: TX	Zip: 78727
Phone: 512-835-4963	Title: Pharmacy manager		Number of Employed Hours: 42 hours / week	
Description of Duties: Responsible for overseeing the daily business operations of the pharmacy, including immunizations, dispensing prescription medication and consultations				

Business Name: Walgreens			From - To (MM/YY – MM/YY): 06/2020 - 08/2020	
Business Address: 1900 W. Braker Ln		City: Austin	State: Tx	Zip: 78758
Phone: 512-831-0819	Title: Pharmacist		Number of Employed Hours: 40 hours / week	
Description of Duties: Dispensed prescription medications to patients. Administered immunizations. Provided consultation for over the counter and prescription drugs				

Business Name: Duane Reade by Walgreens			From - To (MM/YY – MM/YY): 12/2017 - 05/2020	
Business Address: 2409 Broadway		City: New York	State: NY	Zip: 10024
Phone: 212-874-0238	Title: Pharmacist		Number of Employed Hours: 40 hours / week	
Description of Duties: Dispensed prescription medications to patients. Administered immunizations. Provided consultation for over the counter and prescription drugs				

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:

B Ayelala
Original Signature (electronic, copies or stamps not accepted)

12-07-2021
Date

Applicant's initials BA

I, Bisi Aiyelabowo, **certify that as the designated representative for**

MedWise Rx,

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

Bisi Aiyelabowo

Print Name (First, Last)

B Aiyelabowo

Original Signature (electronic, copies or stamps not accepted)

12-07-2021

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.

BISI AIYELABOWO
Print Name (First, Last)

B Ayelabo
Original Signature (electronic, copies or stamps not accepted)

12-07-2021
Date

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

State of Texas, ss. County of Travis

I, BISI AIYELABOWO, 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.

B Ayelabo
Original Signature

12-07-2021
Date

Subscribed and Sworn to before me this 7 day of December, 2021

Notary Public Signature

ASA CHRISTENSEN
Notary Public, State of Texas
Comm. Expires 03-04-2025
Notary ID 129331301

(Seal)

Applicant's initials BA

TEXAS STATE BOARD OF PHARMACY

Re:	Med Wise Rx
Address:	1812 Center Creek Drive, Suite 115 Austin, Texas 78754
License No.:	33191
Date Issued:	March 17, 2020
Licensure Status:	Active
Expiration Date:	March 31, 2022
Type of Pharmacy:	Central Processing Pharmacy – Class G
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Med Wise Rx (Texas Pharmacy License #33191) 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 25, 2021
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.

Richard Greene, PharmD, MBA

From: compounding@nabp.pharmacy
Sent: Thursday, December 2, 2021 10:28 AM
To: mwr-mor
Subject: RE: NABP Compounding Pharmacy Accreditation - Notice of Eligibility - CareKinesis Inc, Moorestown, NJ

[EXTERNAL EMAIL] This email originated from outside TRHC. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Dr Greene,

Thank you for your interest in the NABP Compounding Pharmacy Accreditation program. This is a courtesy reminder that the Compounding Pharmacy Accreditation application for **CareKinesis Inc**, in **Moorestown, NJ,** is due to be submitted ***on or before December 30, 2021.***

Please contact me if there are any questions or concerns.

Cordially,

Compounding Pharmacy Accreditation Team
847/391-4539

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | compounding@nabp.pharmacy

From: compounding@nabp.pharmacy <compounding@nabp.pharmacy>
Sent: Friday, October 1, 2021 4:23 PM
To: mwr-mor@trhc.com
Subject: NABP Compounding Pharmacy Accreditation - Notice of Eligibility - CareKinesis Inc, Moorestown, NJ

Hello Dr Greene,

Thank you for your interest in the Compounding Pharmacy Accreditation. This is to confirm that the National Association of Boards of Pharmacy® (NABP®) has reviewed and scored the pharmacy's VPP Inspection Report in an effort to determine the pharmacy's eligibility to continue with the Compounding Pharmacy Accreditation program.

Congratulations! Your pharmacy is eligible to proceed with NABP's Compounding Pharmacy Accreditation. Now that the pharmacy has been deemed eligible to advance through the accreditation process, a full application and payment of the accreditation fees is required. In order to submit the online application and payment, please visit the NABP e-Profile Login.

Please note that a completed application and payment must be submitted **within three (3) months of the date of this eligibility letter** to advance through the accreditation process. Should a completed application not be submitted in this time frame, the pharmacy's eligibility will expire and a new VPP Inspection would be required in order to reevaluate the pharmacy's eligibility for Compounding Pharmacy Accreditation. After your application has been received, the pharmacy will receive a Post-Survey Letter that outlines the pharmacy's post-survey action items and additional information on how to proceed.

The NABP Compounding Pharmacy Accreditation fees cover a 3-year accreditation and are as follows:

- First year total due at time of application: $3000 application fee + $250 annual participation fee
- Second year total due at 1st year anniversary: $250 Annual Participation Fee
- Third year total due at 2nd year anniversary $250 Annual Participation Fee

Please see the attached eligibility letter, which details the results of your pharmacy's VPP Inspection. For reference, the NABP Compounding Pharmacy Accreditation Standards and P&P Assessment documents are also attached. If you have additional questions, please email compounding@nabp.pharmacy or call (847) 391-4587.

We look forward to a continued successful partnership.

Cordially,

Compounding Pharmacy Accreditation Team
847/391-4539

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | compounding@nabp.pharmacy

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 33191

MEDWISERX

License Information

License Status Active
License # 33191
Expiration Date 03/31/2022
Date License Issued 03/17/2020

Address

1812 CENTER CREEK DR STE 115
AUSTIN, TX 78754
County TRAVIS
Phone (512) 579-0026

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 Central Processing Pharmacy
Type of Ownership Corporation
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
STONECIPHER, CHAD EDWIN

Pharmacy Profile ¥

Accessible to disabled persons? Yes

Participates in the Texas Medicaid program? No

Translating services (Listed Below If Available)

Other

¥ 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

- 1090989 33191 MEDWISERX 2020-12 12-2025.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	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patisnt Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	Yes

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
AIYELABOWO, BISI	66013	10/24/2019	05/31/2023	Staff	Active
BIENVENU, RICHARD	53697	08/08/2013	06/30/2023	Staff	Active
CHOI, KWANG SOO	44520	08/11/2006	10/31/2022	Staff	Active
FARDO, EMILY ANNA	66526	04/30/2020	06/30/2022	Relief	Active
HO, SAMUEL	56975	08/06/2015	09/30/2023	Staff	Active
MASON, CRISTA MICHELLE	55088	07/31/2014	05/31/2022	Staff	Active
OGUNMAKIN, TAIYE O.	58865	07/28/2016	02/28/2022	Relief	Active
QAISI, SHROUQ	60258	03/09/2017	04/30/2023	Staff	Active
SADRUDDIN, NEELA	61531	09/07/2017	01/31/2022	Staff	Active
SAMUELSON, STEPHANIE MARIE	64189	01/31/2019	05/31/2023	Staff	Active
SHAMSIE, STEPHANIE GALINDO	35724	10/23/1995	03/31/2022	Relief	Active
STONECIPHER, CHAD EDWIN	48046	09/29/2009	11/30/2023	PIC	Active

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Texas Registered Technicians, Trainees Pharmaceutical Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
BUSTAMANTE, VANESSA	115251	06/07/2004	02/28/2023	Staff	Active
BUTLER, LAUREN	230220	05/05/2014	12/31/2022	Staff	Active
DANG, TRAMANH PHAM	238392	12/19/2014	10/31/2022	Staff	Active
DAVIDSON, RACHEL ANNE	323454	06/24/2021	06/30/2023	Staff	Active
FALTAS, MANAL SHOKRY NASHED	249833	11/19/2015	05/31/2022	Staff	Active
HAYES , EBONI	323539	06/25/2021	06/30/2023	Staff	Active
JUAREZ, CHANCE WAYLEN	148861	03/26/2008	03/31/2022	Staff	Active
MINGO, KUMORA	213276	10/18/2012	10/31/2022	Staff	Active
MUHIMBARE, RAISSA	299387	08/16/2019	08/31/2023	Staff	Active
VAZQUEZ, VIVIAN	256202	05/31/2016	03/31/2023	Staff	Active

Page 1 of 1 20 View 1 - 10 of 10

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
TABULA RASA HEALTHCARE GROUP, INC	OWNER	228 STARWBRIDGE DRIVE	MOORESTOWN	NJ	08057
KNOWLTON, ORSULA V	OFFICER				
KNOWLTON, CALVIN H	OFFICER				
ADAMS, BRIAN W	OFFICER				

Page 1 of 1 20 View 1 - 4 of 4

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.

TEXAS STATE BOARD OF PHARMACY

Pharmacist-in-Charge Attestation:

I hereby attest the following statements are true and accurate (*initial each statement below*):

CM I am the Pharmacist-in-Charge (PIC) of Medwise Rx (*Name of Pharmacy*), pharmacy license number 33191 (*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 12/21/2020 (*Date of Inspection*);

CM I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector;

CM I reviewed the document titled *Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF* (on the reverse side of this attestation);

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;

CM 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: Crista Mason (*Signature of PIC*) **Date:** 12/21/2020

Printed Name: CRISTA MASON **License No.:** 55088

Phcy Lic # 33191

Expiration Date: 3/31/22

NOTICE OF INSPECTION
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, Texas 78701-3942
(512) 305-8000

✓ Compliance

Investigation

Name of Individual	Title	R.Ph. Lic. #	Expires
Crista Michelle Mason	PIC	555088	5/31/22

Name of Facility	Class of Pharmacy License
Medwise Rx	G

Address	
1812 Center Creek Dr. Ste 115	

City/State	Zip	Phone #
Austin, TX	78754	(512) 579-0026

DEA Registration #	Expiration Date
—	—

Date	Time of Entry
12/21/2020	9:30 am

PURPOSE OF INSPECTION

___ Routine	___ Pre-Inspection	___ Rank Change
___ New Pharmacy	___ Change of Ownership	___ Reverse Rank Change
___ Complaint	___ Follow-up to Complaint	✓ Licensee Request
___ Follow-up to Warning Notice	___ Follow-up to Theft/Loss Report	___ Sterile Compounding (High Risk)
___ Follow-up to Disciplinary Order	___ Other_____	

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent Felicia Carrasco 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 am the PIC for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Signature

Witnesses:

Felicia Carrasco
Signature

Signature

05/17

TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A A-S B C C-S (BEDS ____) D Other 51

Name of Pharmacy Medwise Rx

Pharmacist in Charge Crista Michelle Mason

Personnel

(see attached)

TSBP License # 22191

Lic [illegible] Exp 5/31/22

Lic ____ Exp ____

Lic ____ Exp ____

Lic ____ Exp ____

Lic ____ Exp ____

KEY: Circled items need improvement, x items in Column One Refer to Legal Division (R/L) for review and possible discipline. x items in Column Two receive a Warning Notice (W/N)

For an explanation of specific violations noted, refer to remarks section of inspection report

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4		Balance Failed
	5		Equipment Inspection
	6		Inadequate Library
	7		Improper security
	8		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	47		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	61		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	76		No PIC
	34		Notification Violation
	79		Nametags
	60		Improper documentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory
	15		No PIC inventory
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	17		Incomplete inventory
	18		Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24		Theft/Loss ~~not~~ reported no drugs
	30		Invoices not dated/initialed
	86		Absence of RPh pick up records
	19		Rx lacks proper information
	25		No documentation of refill authorization
	32		Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80		No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21		Computer records incomplete
	22		Computer system noncompliance
	82		PMR Incomplete
	83		PMR Absent
	84		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	71		Incomplete P&P manual
	72		Improper procedures for IV preparation
	81		Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87		Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	63		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Advised To :

Action Taken

(1) ___✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Julian Carrano
Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

12/21/2020
Date

10:00 am
Time of Exit

CRISTA MAYON Pharmacist in Charge
Printed Name and Title of Authorized Individual

4TT

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)

Y

Where is the facility located?
☐ Nevada
☒ Out-of-State

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New Pharmacy	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Location Change *	PH 03575	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Optime Care Inc

Physical Address: 4060 Wedgeway Ct

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 314-731-6900 Toll Free # (NAC 639.708, NRS 639.23286): 888-287-2017

Fax: 888-868-3147 Contact Email: cindy.hohn@optimecare.com

Website: www.optimecare.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Brandon L. Salke

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21131 ok exp. 10/31/2023

Type of Pharmacy (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Retail/Community	■ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
☐ Other: _____	☐ 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: Brandon L. Salke	NV Pharmacist Registration #: 21131
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.

N/A

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): AscellaHealth, LLC

Corporation/Organization Name: Optime Care Inc

Mailing Address: 4060 Wedgeway Ct

City: Earth City State: MO Zip: 63045

Telephone: 314-731-6900 Email: donovan.quill@optimecare.com

Contact Person Name: Donovan J. Quill

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

N/A

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

N/A

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 President (title) for Optime Care 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).

Donovan J. Quill

Print Name of Authorized Person

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

11/15/2021

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Donovan J. Quill 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 Optime Care Inc (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 15 day of November, 2021

Notary Public

CINDY L. HOHN
Notary Public - Notary Seal
State of Missouri
Commissioned for Lincoln County
My Commission Expires: July 22, 2025
Commission Number: 13423262

N/A

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: N/A Pharmacist Registration #: _____

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

_____ 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.

_____ 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.

_____ 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.

_____ 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)).

_____ 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.

N/A _____ _____

Original signature of Managing Pharmacist (copies or stamps not accepted) 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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** 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** 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: a. An applicant or a licensee that is a publicly traded corporation; 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 c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded -** The top 4 shareholder/stockholders. **b. For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.		✓	✓	✓
• **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 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)	✓	✓	✓	✓
• **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.

Donovan J. Quill, 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)

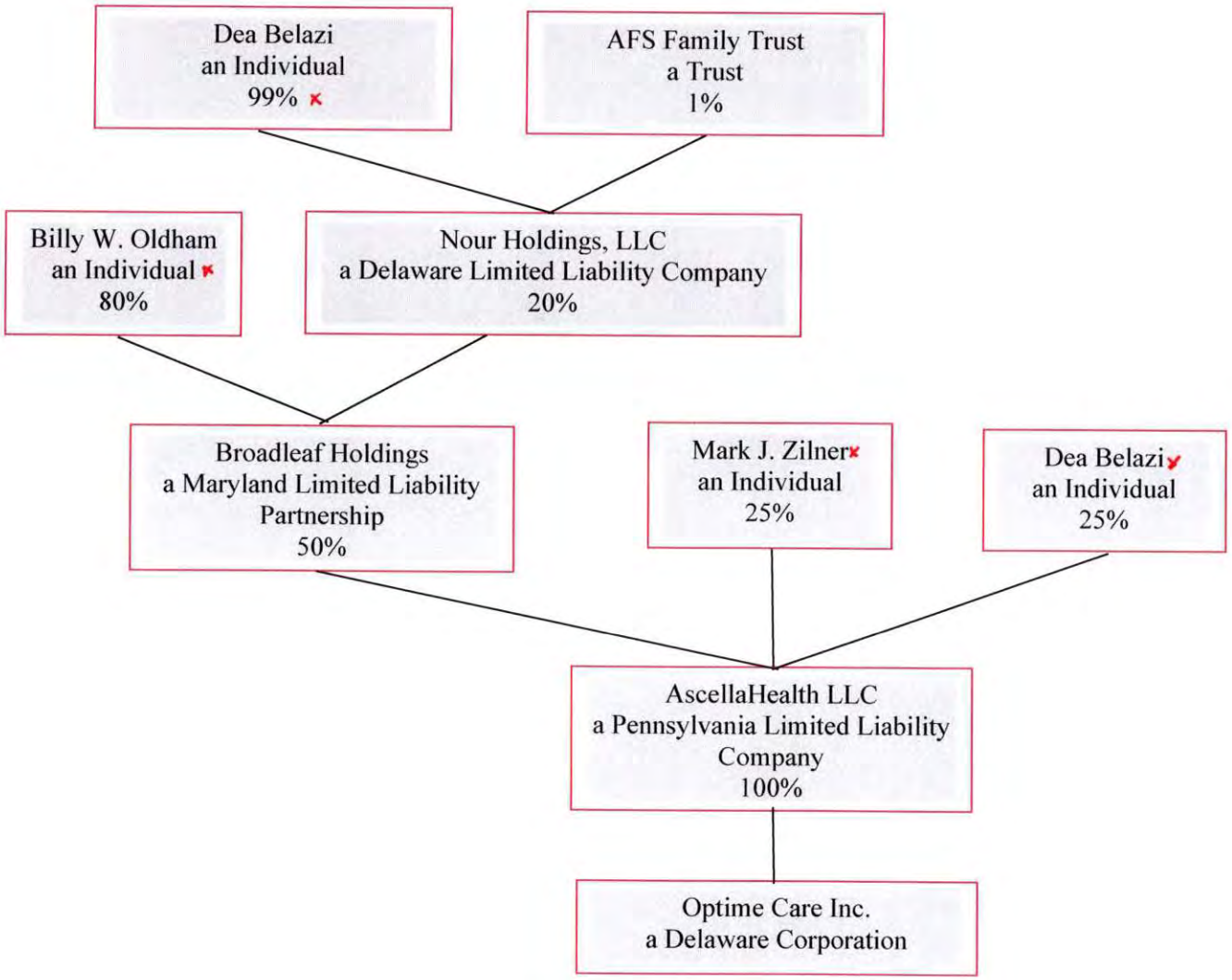
11/15/2021
Date

Board Use Only	Date Received: _____	Amount: 500 CHECK # 11728

EXHIBIT A

OPTIME CARE INC
A Delaware Corporation

Ownership Structure



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: Optime Care Inc

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): 4060 Wedgeway Ct

City: Earth City State: MO Zip: 63045

Telephone: 314-731-6900 Website: www.optimecare.com

Licensing Company Email: cindy.hohn@optimecare.com

Section 2: Personal Information

First: Dea Middle: Taher Last: Belazi

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

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

Mailing Address: [redacted] Westlakes Dr., [redacted]

City: Berwyn State: PA Zip: 19312

Telephone: [redacted] Email: dbelazi@ascellahealth.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: n/a 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: DB

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)	
Southkingstown High School		09/91 - 06/95	
Address	**City**	**State**	**Zip**
215 Columbia St.	Wakefield	RI	02879
Diploma/Degree obtained, if any			
Highschool Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Rhode Island College of Pharmacy		09/95 - 05/01	
Address	**City**	**State**	**Zip**
7 Greenhouse Road	Kingston	RI	02881
Diploma/Degree obtained, if any			
PharmD.			

School Name		From - To (MM/YY – MM/YY)	
Johns Hopkins School of Public Health		09/02 - 05/04	
Address	**City**	**State**	**Zip**
615 N. Wolfe Street	Baltimore	MD	21205
Diploma/Degree obtained, if any			
Masters of Public Health (MPH)			

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
07/17 - present	[redacted] High Grove Ln.	Malvern	PA	19355
10/10 - 08/17	678 Knox Road	Wayne	PA	19087

Applicant's initials DB

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)
AscellaHealth, LLC			09/13 - present
Business Address	**City**	**State**	**Zip**
1055 Westlakes Dr., #175	Berwyn	PA	19312
Phone	**Title**		
877-389-9039	President & Managing Member		
Description of Duties			
Oversee and manage all operations of the company			

Business Name			From - To (MM/YY – MM/YY)
Woltersklower Health			07/08 - 02/13
Business Address	**City**	**State**	**Zip**
2394 E. Camelback Road	Phoenix	AZ	85016
Phone	**Title**		
602-381-9500	Vice President of Payor Solutions		
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:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/23/2

Date

Applicant's initials DB

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.

Dea Belazi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/23/21

Date

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

State of PA, ss. County of Chester

I, Dea Belazi, 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

12/23/21

Date

Subscribed and Sworn to before me this 23 day of December

Notary Public Signature

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Lauren Matter, NOTARY PUBLIC
Chester County
My Commission Expires 06/14/2025
Commission Number 1306694

(Seal)

Applicant's initials DB

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: Optime Care Inc.

Physical Address: 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 314-731-6900 Website: www.optimecare.com

Licensing Company Email: cindy.hohn@optimecare.com

Section 2: Personal Information

First: Billy Middle: Wayne Last: Oldham

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

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

Mailing Address: [redacted] Westlakes Dr., [redacted]

City: Berwyn State: PA Zip: 19312

Telephone: [redacted] Email: boldham@ascellahealth.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 _____

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)	
MANCHESTER BUSINESS SCHOOL			09/92 - 08/94	
Address		City	State	Zip
BOOTH ST WEST		MANCHESTER, UK		
Diploma/Degree obtained, if any				
MBA				

School Name			From - To (MM/YY – MM/YY)	
HARDING UNIVERSITY			08/88 - 05/92	
Address		City	State	Zip
CENTER ST.		SEARCY	AR	72143
Diploma/Degree obtained, if any				
BBA - ECONOMICS				

School Name			From - To (MM/YY – MM/YY)	
HARDING ACADEMY			08/79 - 05/88	
Address		City	State	Zip
PARK ST		SEARCY	AR	72143
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
05/2012 - present	[redacted] Whirlaway Ct.	Leesburg	VA	20176
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)	
AscellaHealth LLC			08/2013 - present	
Business Address		**City**	**State**	**Zip**
1055 Westlakes Dr., Suite 175		Berwyn	PA	19312
Phone	**Title**			
703-777-5978	Treasurer and Chairman of the Board			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
EVOLVENT TECHNOLOGIES			09/01 – 08/13	
Business Address		**City**	**State**	**Zip**
13755 SUNRISE VALLEY DR.		HERNDON	VA	20164
Phone	**Title**			
703 824 6000	COO - 2001-2004; CEO - 2004 - 13			
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?		✓

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 # 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)

12/16/21
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.

Billy W. Oldham

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/16/21

Date

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

State of Virginia, ss. County of Loudoun

I, Jeffrey Carter, 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

12/16/21

Date

Subscribed and Sworn to before me this 16 day of December., 2021

Notary Public Signature

Jeffrey Wayne Carter
Commonwealth of Virginia
Notary Public
Commission No: 7942421
My Commission Expires: June/30/2025

(Seal)

Applicant's initials

Y

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 Optime Care Inc

Physical Address 4064 Wedgeway Ct.

City Earth City State MO Zip 63045

Mailing Address (if different from physical address) 4060 Wedgeway Ct.

City Earth City State MO Zip 63045

Telephone 314-731-6900 Website optimecare.com

Licensing Company Email cindy.hohn@optimecare.com

Section 2: Personal Information

First Mark Middle Joseph Last Zilner

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

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

Mailing Address [redacted] Edgewood Avenue

City Indiana State PA Zip 15701

Telephone [redacted] Email MZILNER@diamondpharmacy.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 MZ

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)	
INDIANA AREA SENIOR HIGH SCHOOL		9/82 – 5/85	
Address	**City**	**State**	**Zip**
450 N 5TH ST.	INDIANA	PA	15701
Diploma/Degree obtained, if any			
HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
DUQUESNE UNIVERSITY		9-85 – 5/87	
Address	**City**	**State**	**Zip**
600 FORBES AVE	PITTSBURGH	PA	15282
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
NORTHEASTERN UNIVERSITY		9/87 – 5-91	
Address	**City**	**State**	**Zip**
360 HUNTINGTON AVE	BOSTON	MA	02115
Diploma/Degree obtained, if any			
BS 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			

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
6/06 – CURRENT	[redacted] EDGEWOOD AVE	INDIANA	PA	15701
From - To (MM/YY – MM/YY)	Address	City	State	Zip
	330 Eighmy RD	Pittsburgh		
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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: DIAMOND PHARMACY SERVICES			From - To (MM/YY – MM/YY): 6/91 – CURRENT
Business Address: 645 KOPPER DRIVE	City: INDIANA	State: PA	Zip: 15701
Phone: 724-349-1111	Title: PRESIDENT + CEO		
Description of Duties: OVERALL MANAGEMENT			

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.

Applicant's initials: MPB

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 _____ 4

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 # 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 Explanation

Original Signature (electronic, copies or stamps not accepted)

12/15/21

Date

Applicant's initials

This response is intended to supplement Mark Zilner's positive responses to Section 8, Question 5 and 6. As noted in Section 7 of the Application, Mark Zilner is an owner, officer, and employee of Diamond Drugs, Inc. d/b/a Diamond Pharmacy Services (hereinafter "Diamond"). Diamond is licensed in as a non-resident pharmacy in nearly every state. Its 50-year history, and under Mr. Zilner's tenue, Diamond has not had any violations beyond minor administrative errors. The information contained below outlines the administrative actions taken against.

In December of 2015, Diamond was disciplined by the Oklahoma Board of Pharmacy for an administrative error in our license renewal. Due to changes in Oklahoma Pharmacy Regulations, effective for 2015 license renewals, out of state pharmacy licensees that compounded pharmaceuticals were required to have an Oklahoma-licensed Pharmacist in Charge ("PIC") present at their dispensing location in the Pharmacy's state of domicile, the PIC we were using resided in Oklahoma. The Complaint was filed in December of 2015, and was resolved in January of 2016. Per the Consent Order agreed to by the parties, Diamond immediately paid a fine, designated an Indiana, PA based Pharmacist as the Pharmacist in Charge, and agreed to be placed on probation in Oklahoma until December of 2020. Diamond was not then, or at any time, restricted from dispensing in Oklahoma.

Diamond is licensed or authorized to dispense prescription in Every State except for Alaska. Nearly every state requires a licensee to report any and all discipline imposed by any outside jurisdiction/state. Any state that receives such a report of discipline may review and impose "sister-state" discipline even without wrongdoing within their state. Diamond reported the Oklahoma discipline to all states where licensed. Most states declined to pursue such sister-state discipline. Of the relatively few that did, nearly all of them issued a letter of admonition and/or imposed a small fine. The exceptions were Alabama, Michigan and Illinois.

Alabama placed Diamond on probation, which will expire in September of 2022 and does not prohibit Diamond from dispensing. Michigan issued an Order in 2017 imposing a fine, and placing Diamond's license in "Limited Disciplinary" status, restricting Diamond from dispensing in Michigan until we provided Michigan with evidence that we complied with the Oklahoma Order, and that such status would be automatically lifted. We immediately sent Michigan evidence that we amended our Oklahoma registration, that we paid the Oklahoma fine, and that we were not restricted from dispensing into Oklahoma. We were then issued a Michigan license renewal and continued to dispense in Michigan at that time.

In 2019, Michigan filed a Complaint against Diamond's license alleging that by dispensing into Michigan prior to the expiration of the Oklahoma probation, we were in violation of the Michigan license limitation imposed by their 2017 Order. Diamond has maintained its position that the 2017 Order is not legally or procedurally sufficient to restrict us from dispensing in Michigan. We have resolved this matter by agreeing to pay a $1,000.00 fine, and to adhere to the Board's interpretation of the 2017 Order.

On June 17, 2020, Diamond appeared before the Oklahoma State Board of Pharmacy on a Petition to Modify their 2015 Order at Case No. 1368. We asked the Board to lift our probation that was scheduled to run until December 3, 2020. The Board (by 4-1 vote) granted our petition, and our probation has been lifted. Once we received the official, executed Order from Oklahoma, we provided it to Michigan, and it lifted our "Limited" status on or about July 10, 2020

Illinois filed a complaint on December 19, 2019 at Case No. 2019-01490. The Complaint made no allegations of specific violations that occurred in Illinois or were related to Diamond dispensing or distributing any drugs into Illinois. Rather, the allegations were solely based on "sister-state" discipline arising from the actions listed above. We reached a settlement agreement, which was finalized on April 24, 2010, where Diamond agreed to pay a fine of $10,000.00 and is in probation in Illinois for three years. This Order does not in any way restrict Diamond's practice of Pharmacy in Illinois or in any other jurisdiction.

Although there are a number of regulatory actions that have occurred since 2015, Diamond's is able to dispense in all jurisdictions. Furthermore, it is important to note that none of the conduct that was the subject of these actions implicated patient health or safety. Diamond has implemented several internal changes both in process and structurally to ensure that these administrative issues will not arise again.

Diamond's distribution division was disciplined by DEA for the Northern District of Ohio. The alleged violation was for record-keeping issues from 2013-2014, regarding controlled substances in emergency drug kits. There was no implication of patient health and safety or diversion of drugs. This action did not impact Diamond's ability to handle or dispense controlled substances anywhere in the United States.

Please let us know if you need any further clarification to the items listed in this section.

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, J, M

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2016011308
Brandon L Salke - 2012027495

OPTIME CARE INC
OPTIME CARE INC
BRANDON L SALKE, PIC
4060 WEDGEWAY CT
EARTH CITY MO 63045
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

1675

The Division of Professional Registration and its boards are open during the regular business hours of 8:00a.m. to 5:00p.m. Monday through Friday, excluding state holidays.

Did you know that there is a drop box located in the front of the Professional Registration building? Individuals may leave items for the division and its boards any time. We do ask that all items be placed in a sealed envelope labeled with the board name or name of the individual if not located in a board.

Board of Pharmacy

PR Home (https://pr.mo.gov/) » Pharmacy Home (https://pr.mo.gov/pharmacists.asp) » Pharmacy Licensee Search (https://pr.mo.gov/pharmacy-licensee-search.asp)

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Optime Care Inc
Profession Name:	Pharmacy
Licensee Number:	2016011308
Expiration Date:	10/31/2023
Original Issue Date:	4/8/2016
Address:	Brandon L Salke, PIC
Address Con't:	4060 Wedgeway Ct
City, State Zip:	Earth City, MO 63045
County:	St. Louis County
Practitioner DBA Name:	Optime Care Inc
Classification:	Class A, J, M

Current Discipline Status:	None

Board of Pharmacy (https://pr.mo.gov/pharmacists)
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone

573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov (mailto:MissouriBOP@pr.mo.gov)
https://pr.mo.gov/pharmacists (https://pr.mo.gov/pharmacists)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTIME CARE 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 NINTH DAY OF NOVEMBER, A.D. 2021.

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

5800132 8300

SR# 20213741509

Authentication: 204636820

Date: 11-09-21

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

Optime Care Inc
Nevada Pharmacy Application
Change of Ownership

Section 12

Officer / Director / Owner Information

Officers

Name	Title	Date of Birth	Business Address
Donovan J. Quill	President	[redacted]	4060 Wedgeway Ct. Earth City, MO 63045
Billy W. Oldham	CFO, Secretary	[redacted]	1055 Westlakes Dr., #175 Berwyn, PA 19312

Directors

Name	Title	Date of Birth	Business Address
Billy W. Oldham	Chairman	[redacted]	1055 Westlakes Dr., #175 Berwyn, PA 19312
Dea Belazi	Director	[redacted]	1055 Westlakes Dr., #175 Berwyn, PA 19312

Stockholder/s

Name	Title	FEIN	Business Address
AscellaHealth, LLC	Sole Stockholder	90-1012556	1055 Westlakes Dr., #175 Berwyn, PA 19312

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 Optime Care Inc

Physical Address 4060 Wedgeway Ct

City Earth City State MO Zip 63045

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 314-731-6900 Website www.optimecare.com

Licensing Company Email cindy.hohn@optimecare.com

Section 2: Personal Information

First Brandon Middle Lee Last Salke

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

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

Mailing Address 4060 Wedgeway Ct

City Earth City State MO Zip 63045

Telephone [redacted] Email brandon.salke@optimecare.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 BS

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. Louis College of Pharmacy		08/06 - 05/12	
Address: 1 Pharmacy Place	City: Saint Louis	State: MO	Zip: 63110
Diploma/Degree obtained, if any: Pharm D.			

School Name		From - To (MM/YY – MM/YY)	
Jefferson City Highschool		08/02 - 05/06	
Address: 609 Union St	City: Jefferson City	State: MO	Zip: 65101
Diploma/Degree obtained, if any: Highschool 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
04/14-present	[redacted]N WEston Ct	Saint Charles	MO	63303
06/12 - 04/14	1388 Whispering Pines Dr	Saint Louis	MO	63146
08/10 - 06/12	5529 Gravois walk	Saint Louis	MO	63123

Applicant's initials _____

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: Optime Care Inc			From - To (MM/YY – MM/YY): 02/17 - present	
Business Address: 4060 Wedgeway Ct		City: Earth City	State: MO	Zip: 63045
Phone: 314-731-6900	Title: Pharmacist-in-Charge		Number of Employed Hours: 9,760	
Description of Duties: oversee pharmacy operations including Inventory, Dispensing, Record keeping, staff management and Regulatory oversight				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description 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.

N/A **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

Applicant's initials _____

I, Brandon Salke, **certify that as the designated representative for**

Optime Care 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

Brandon Salke

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/2021

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.

Brandon Salke

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/2021

Date

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

State of Missouri, ss. County of Lincoln

I, Brandon Salke, 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

11/15/2021

Date

Subscribed and Sworn to before me this 15 day of November.

Notary Public Signature

CINDY L. HOHN
Notary Public - Notary Seal
State of Missouri
Commissioned for Lincoln County
My Commission Expires: July 22, 2025
Commission Number: 13423262

(Seal)

Applicant's initials

Optime Care Inc
Nevada Pharmacy Application
Change of Ownership

Section 3. Item #3

Michigan Consent Order

On February 13, 2019 a Consent Order was executed by and between Optime Care Inc ("Optime Care"), located at 4060 Wedgeway Ct, Earth City, MO 63045, and the Michigan Department of Licensing and Regulatory Affairs ("Michigan LARA"). In conjunction with the Consent Order, Optime Care was assessed a fine in the amount of $5,000.

Optime Care unintentionally dispensed prescription drugs into the State of Michigan prior to obtaining a Michigan Pharmacy License. Once Optime Care became aware that a Michigan Pharmacy License was required to ship medications to residents of Michigan, Michigan LARA was notified by Optime Care and Optime Care was subsequently instructed to submit the requisite application for licensure. The application was submitted and a Michigan Pharmacy License was issued to Optime Care on May 17, 2018.

Inasmuch as Optime Care violated the Michigan Public Health Code, MDL 333.17748(1), the parties agreed to a Consent Order and assessment of a fine in the amount of $5,000. In an email dated December 5, 2018 from Mr. Lorne L. Carignan representing the Michigan LARA, it is noted that there was "no evidence that Optime Care acted intentionally to circumvent the law; that the drugs were defective in any way; or that, except for the licensure issued, the drugs were improperly distributed". In addition, Mr. Lorne recommended to the pharmacy board to "obviate the need for a formal complaint and close this case."

Optime Care has complied with the terms and conditions of the Consent Order, the fine was paid, the matter was closed and there has been no further action taken against Optime Care's Michigan Pharmacy License.

Supporting documentation is enclosed.

Brandon Salke

From: Donovan Quill
Sent: Monday, October 11, 2021 10:09 AM
To: Brandon Salke; Cindy Hohn
Subject: FW: Signed Consent Order Received [IWOV-iDocs.FID2611453]

Please see email below from MI department of licensing also please attach this to the file that Cindy has.

Donovan J. Quill
President and CEO
Office: 888-287-2017
Cell: (610)597-4221
Fax: 888-868-3147

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From: Carignan, Lorne (LARA) [mailto:CarignanL@michigan.gov]
Sent: Wednesday, December 05, 2018 7:24 AM
To: Steven Pozaric
Subject: Signed Consent Order Received

We are in receipt of the signed Consent Order.

Michigan LARA-BPL will be recommending acceptance of the Order at the next Pharmacy Board Meeting, and execution of the Consent Order by the Board will obviate the need for the issuance of a formal complaint and will close this case. By signing the Consent Order and paying the fine (which is not yet due), Optime Care will have fulfilled its obligations to the State of Michigan in this matter.

As stated in the Order, Optime Care is properly licensed and Michigan LARA has no evidence that Optime Care acted intentionally to circumvent the law; that the drugs were defective in any way; or that, except for the licensure issue, the drugs were improperly distributed.

Thank you.

Mr. Lorne L. Carignan

Bureau of Professional Licensing
Department of Licensing and Regulatory Affairs
Phone: (517) 241-4156 Fax: (517) 241-7535
carignanl@michigan.gov

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

OPTIME CARE INC.
License No. 53-01-011393,
Respondent.

File No. 53-18-152029

ERRATA

On February 13, 2019, the Disciplinary Subcommittee of the Michigan Board of Pharmacy accepted and executed a Consent Order and Stipulation, which was previously agreed to and signed by Respondent in the above-captioned matter.

The Order incorrectly listed Respondent's manufacturer-wholesaler license number instead of Respondent's pharmacy license number. Therefore,

IT IS ORDERED that the license number in the Order shall be corrected from 53-06-004958 to 53-01-011393.

IS FURTHER ORDERED that the remainder of the Order dated February 13, 2019, shall remain as drafted. A copy of the Order is attached.

IT IS FURTHER ORDERED that this Errata shall be effective on the date signed, as set forth below.

Dated: 2/27/19

Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

Attachment
llc

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

OPTIME CARE INC.
License Number: 53-06-004958,

Respondent.

File No. 53-18-152029

CONSENT ORDER

The Department of Licensing and Regulatory Affairs received evidence and information that Respondent Pharmacy violated the Public Health Code, MCL 333.1101 *et seq.* Specifically, Respondent Pharmacy distributed drugs in Michigan before obtaining a license to do so, in violation of MCL 333.17748(1).

MCL 333.17768(1) authorizes the Board's disciplinary subcommittee to take disciplinary action against a licensee who violates the Public Health Code. MCL 333.16231(5) authorizes the Department to submit a stipulation and final order to a disciplinary subcommittee for approval if an agreement is reached resolving alleged violations of the Public Health Code before the issuance of a complaint.

Respondent Pharmacy has admitted violating MCL 333.17748(1) and has agreed by the attached Stipulation that the Disciplinary Subcommittee may execute this Consent Order without detailing the facts and evidence substantiating the alleged violation(s) in a formal complaint.

The Disciplinary Subcommittee has reviewed this Order and agrees that the public interest is best served by resolution of this matter without further administrative process.

Therefore, IT IS FOUND that Respondent Pharmacy violated MCL 333.17748(1).

Accordingly, IT IS ORDERED that for the cited violation(s) of the Public Health Code, Respondent Pharmacy is FINED $5,000.00 payable 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 file number 53-18-152029.

IT IS FURTHER ORDERED that if Respondent Pharmacy fails to comply with the terms and conditions of this Order, Respondent Pharmacy's license shall be automatically SUSPENDED for a minimum of one day. If Respondent Pharmacy complies with this Order within six months of the suspension, the license shall be automatically reinstated. If Respondent Pharmacy's license remains suspended for more than six months, Respondent Pharmacy must apply for reinstatement of the license in accordance with MCL 333.16245 and 333.16247.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

Dated: 2/13/19

STIPULATION

1. Respondent Pharmacy admits violating MCL 333.17748(1) and acknowledges that the Department could prove the violation(s) with facts and evidence at an administrative hearing. Respondent agrees to resolve this matter by this Stipulation and Order without having the facts and evidence of the violation detailed in a formal complaint.

2. Respondent Pharmacy has had the opportunity to consult with an attorney and agrees to these terms voluntarily without duress of any kind.

3. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right provided by the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq.*, to require the Department to prove the violation(s) of the Public Health Code by presentation of evidence and legal authority, and Respondent Pharmacy is

waiving the right to appear with an attorney and witnesses to present a defense to the allegations.

4. This Order resolves all pending issues in this matter and closes this case. No further action will be taken against Respondent Pharmacy based on the facts alleged herein, provided Respondent Pharmacy complies with all the terms of this Order.

5. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq.*, and this action will be reported to the National Practitioner's Data Bank, and any other entity as required by state or federal law.

6. Factors taken into consideration in the formulation of this Order include the following:

> Respondent Pharmacy, based in Missouri, is a nationwide pharmacy licensed in all 50 states and is a wholesale distributor of a single drug, Korlym (mifepristone), used to treat patients with Cushing's syndrome. Due to an accidental oversight, Respondent Pharmacy inadvertently failed to obtain a Michigan license before distributing approximately 200 prescriptions of Korlym in Michigan from August 2017 to April 2018.
>
> Upon discovering the error during a quality assurance audit, Respondent Pharmacy immediately notified the Department and took steps to obtain the appropriate licenses. Respondent Pharmacy is now properly licensed to operate in Michigan. The Department has no evidence that Respondent Pharmacy acted intentionally to circumvent the law, that the drugs were defective in any way, or that, except for the lack of licensure, the drugs were improperly distributed.

7. This 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 matter.

8. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent Pharmacy and the Department expressly reserve the right to further proceedings without prejudice should this Order be rejected.

AGREED TO BY:

Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 12-10-18

AGREED TO BY:

Donovan Quill, President and CEO,
Optime Care Inc.,
Respondent Pharmacy

Dated: 12/3/2018

STATE OF MISSOURI
BOARD OF PHARMACY

PHARMACY INSPECTION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY	LICENSE NUMBER	CLASS	INSPECTION DATE
Optime Care Inc 4060 Wedgeway Court Earth City MO 63045	2016011308	A,J, M	5/5/2020

PHARMACIST-IN-CHARGE	PIC LICENSE NO
Brandon Salke	2012027495

LAST CONTROLLED SUBSTANCES INVENTORY	ADMINISTRATIONS
	☐ Yes ☑ No

PHONE	Fax	Email	STERILE COMPOUNDING
3147316900	3147316901	Brandon.Salke@OptimeCare.com	☐ Yes ☑ No

Inspection Type: Routine ***Inspection Result:*** Compliance Notice ***Inspector:*** Bennie Dean

Start Time: 11:00 AM ***End Time:*** 2:45 PM ***Acknowledged By:*** Brandon Salke

This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities. Licensees should review Missouri law to ensure compliance

LICENSES/REGISTRATION

	Y	N	N/A
Pharmacy permit is current and posted [20 CSR 2220-2.020(5)]	☑	☐	☐
Permit has correct class(es) [20 CSR 2220-2.020(10)]	☑	☐	☐
All licenses/registrations current and posted [§ 338.013.3]	☑	☐	☐
Technician list maintained [20 CSR 2220-2.090(2)(BB)]	☑	☐	☐
BOP offsite storage notifications submitted [20 CSR 2220-2.010(1)(I), (J)]	☐	☐	☑
BOP remodel notifications submitted [20 CSR 2220-2.020(4)]	☐	☑	☐

Observations

-Remodeling requires 30-day advanced approval (compliance notice)

PHARMACY OPERATIONS

	Y	N	N/A
Pharmacy is clean/sanitary [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Proper sanitation used in dispensing process [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Adequate security maintained to deter drug theft [20 CSR 2220-2.010(H)]	☑	☐	☐
Hot/cold water sewage disposal available and functioning [20 CSR 2220-2.090(2)(V)]	☑	☐	☐
Required drug reference(s) available [20 CSR 2220-2.010(2)(C)]	☑	☐	☐
Dispensing equipment clean/working condition [20 CSR 2220-2.010(2)(C)]	☑	☐	☐
Vacuum-tube delivery system working properly [20 CSR 2220-2.800]	☐	☐	☑
Automated dispensing/storage system meets requirements [20 CSR 2220-2.900]	☐	☐	☑
Automated filling system meets requirements [20 CSR 2220-2.950]	☐	☐	☑

Observations

PHARMACIST SUPERVISION	Y	N	N/A
Pharmacist on duty or signs posted [20 CSR 2220-2.010(1)(A)]	☑	☐	☐
Technicians supervised, work verified by a pharmacist [20 CSR 2220-2.700(1); 2.010 (1)(B)]	☑	☐	☐

Observations

POLICIES AND PROCEDURES	Y	N	N/A
Policies and procedures available and followed	☑	☐	☐
Policies and procedures cover required topics	☑	☐	☐

Observations

DRUG INVENTORY/STORAGE	Y	N	N/A
Drug storage temperature in required range [20 CSR 2220-2.010(2)(G)]	☑	☐	☐
Thermometer/temp measuring device present and functioning [20 CSR 2220-2.010(2)(F)]	☑	☐	☐
Drugs/devices properly separated from food/beverages [20 CSR 2220-2.010(1)(G)]	☑	☐	☐
Expired/misbranded/adulterated drugs separate from active inventory [20 CSR 2220-2.010(6)]	☑	☐	☐
Return to stock prescriptions in original container/properly labeled [20 CSR 2220-3.040(3)]	☐	☐	☑

Observations

RECEIPT/DISTRIBUTION OF DRUGS	Y	N	N/A
Records maintained for receipt of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐
Receiving legend drugs from licensed entities [§ 338.315]	☑	☐	☐
Records maintained for distribution of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐

Observations

REPACKAGING/PREPACKAGING	Y	N	N/A
Appropriate containers/packaging used [20 CSR 2220-2.130(1)(B)]	☐	☐	☑
Label contains required elements [20 CSR 2220-2.130(1)(D)]	☐	☐	☑
Expiration date complies with 20 CSR 2220-2.130(1)(D)	☐	☐	☑

Observations

DISPENSING RECORDS	Y	N	N/A
Prescription files or images properly maintained [20 CSR 2220-2.010(4), 2.083]	☑	☐	☐
Manual prescription records comply with 20 CSR 2220-2.017	☐	☐	☑
Electronic prescription records comply with 20 CSR 2220-2.080	☑	☐	☐

Observations

DISPENSING/LABELING	Y	N	N/A
Sampled prescriptions in required two-line format [§ 338.056]	☐	☐	☑
Sampled prescriptions contain all required information	☑	☐	☐
Sampled prescriptions dispensed as prescribed	☑	☐	☐
Sampled prescriptions comply with other applicable dispensing laws	☑	☐	☐
Generic substitutions comply with 338.056	☑	☐	☐
Prescription labels contain required information [§ 338.059]	☑	☐	☐
Child resistant packaging present [16 CFR 1700.14]	☑	☐	☐
Return to stock items properly reversed in computer system [20 CSR 2220-3.040(3)]	☐	☐	☑
Prescription transfers properly documented [20 CSR 2220-2.120(1)(a)]	☐	☐	☑
Verbal offer to counsel made to each patient [20 CSR 2220-2.190(1)]	☑	☐	☐
Written offer to counsel provided when required [20 CSR 2220-2.190(1)]	☑	☐	☐
Automated Filling System properly checked by pharmacist [20 CSR 2220-2.950(4)]	☐	☐	☑

Observations

LONG-TERM CARE DISPENSING	Y	N	N/A
Packaging complies with 20 CSR 2220-2.140	☐	☐	☑
Sampled labels complete [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Proper return and reuse of medication [20 CSR 2220-3.030(1)(2)]	☐	☐	☑
Proper label changes for previously dispensed prescriptions [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

MULTI-MED DISPENSING	Y	N	N/A
Packaging and containers comply with 20 CSR 2220-2.145(2)(C), (D)	☐	☐	☑
Med paks properly labeled [20 CSR 2220-2.145(2)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Return/reuse complies with 20 CSR 2220-2.145(2)(H)	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.145(2)(F); 20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES

	Y	N	N/A
BNDD/DEA registrations current/active [§ 195.030.2; 21 CFR 1301.11]	☑	☐	☐
Sampled prescriptions comply with CS dispensing laws/rules	☐	☐	☑
CS prescriptions manually signed or valid electronic prescription [21 CFR § 1306.8]	☐	☐	☑
Medical reason for dispensing more than a 30-day supply of a C-II documented [§ 195.080.2]	☐	☐	☑
CS prescription quantity limits and partial fill requirements followed [195.080, 19 CSR 30-1.064]	☐	☐	☑
C-II drugs under lock/secure cabinet (19 CSR 30-1.034]	☐	☐	☑
C-III to IV dispersed in inventory or under lock/secure cabinet [19 CSR 30-1.034(1)]	☐	☐	☑
C-III to C-V invoices dated when received [19 CSR 30-1.048(4)]	☐	☐	☑
Loss reports properly filed [19 CSR 30-1.034(2)(B); 21 CFR 1301.76(b)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES INVENTORY

	Y	N	N/A
CS inventory available and taken annually and when required [19 CSR 30-1.042]	☑	☐	☐
CS inventory contains date and time taken [19 CSR 30-1.042(1)(D)]	☑	☐	☐
CS inventory includes C-V pseudoephedrine products [19 CSR 30-1.042]	☐	☐	☑
Pharmacist-in-charge change inventory taken [20 CSR 2220-2.090(2)(T)]	☐	☐	☑

Observations

C-II Ordering

	Y	N	N/A
Sampled CSOS or 222 forms, accessible, executed and complete [21 CFR § 1305.13, .22]	☐	☐	☑
CSOS usernames/passwords not shared [21 CFR §1305.21]	☐	☐	☑

Observations

OTC/PSEUDOEPHEDRINE SALES

	Y	N	N/A
Schedule V OTC PSE products behind counter or under lock [19 CSR 30-1.034]	☐	☐	☑
Combat Meth Act self-certification current [21 CFR 1306.8]	☐	☐	☑
Pseudoephedrine sales properly entered into database and accessible [19 CSR 30-1.074]	☐	☐	☑

Observations

ADMINISTRATION BY PROTOCOL

	Y	N	N/A
Protocol complete, current, signed/dated, and followed [20 CSR 2220-6.050(5)(B)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.050(6)]	☐	☐	☑
Vaccines are authorized by and age limits followed [§338.010]	☐	☐	☑

Observations

ADMINISTRATION BY PRESCRIPTION ORDER

	Y	N	N/A
Prescription requirements met [20 CSR 2220-6.040(5)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.040(6)]	☐	☐	☑

Observations

NON-STERILE COMPOUNDING

	Y	N	N/A
Compounding equipment functioning/maintained [20 CSR 2220-2.400(5)©]	☐	☐	☑
Active/therapeutic ingredients on prescription container [20 CSR 2220-2.400(7)(F)]	☐	☐	☑
Compound log accurately maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Other compounding records properly maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Bulk active ingredients meet compendial standards or certificate of analysis maintained [20 CSR 2220-2.400(8)(A)2]	☐	☐	☑
Return to stock items handled as batched with lot # and BUD on container label and documented in compound log [20 CSR 2220-2.400(7)(A), (D)]	☐	☐	☑
Batch/bulk compounds stored and labeled with lot # and BUD [20 CSR 2220-2.400(7)(A)6.]	☐	☐	☑
Adverse effects/complaints documented and investigated [20 CSR 2220-2.400(8)(B)]	☐	☐	☑
Recalls and prescriber/patient notifications conducted when required [20 CSR 2220-2.400(8)(C)]	☐	☐	☑

Observations

Additional Observations:

Additional Comments:

- No Controlled Substances stocked in pharmacy

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* □ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8* ☐ *Partnership - Pages 1,2,6,8*

■ *Non Publicly Traded Corporation – Pages 1,2,4,8* ☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: PREMISE HEALTH WELLNESS CENTER

Physical Address: 510 Maryland Way, Suite 100RX, Brentwood, TN 37027

Mailing Address: P.O. Box 901

City: Deerfield State: IL Zip Code: 60015

Telephone: (615) 238-0335 Fax: (615) 238-0336

✓ Toll Free Number: 877-703-4430 (Required per NAC 639.708)

E-mail: licenseadministration@walgreens.com Website: www.walgreens.com

Managing Pharmacist: Benjamin Rapp License Number: 22245

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☒	☐ Community	☐	☒ Long Term Care
☐	☒ Other: _____	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
All boxes must be checked		☐	☒ Mail Service Sterile Compounding **
For the application to be complete		☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Susan Halliday

Original Signature of Person Authorized to Submit Application, no copies or stamps

Susan Halliday, Assistant Treasurer

Print Name of Authorized Person

4/9/2021

Date

Board Use Only Date Processed:_____ Amount: ~~$500~~ NT30-00118489770

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: IL

Parent Company if any: Walgreen Co.

Mailing Address: P.O. Box 901

City: Deerfield State: IL Zip: 60015

Telephone: 847-527-4768 Fax: _____

Contact Person: Karina Lipnickas

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Walgreens Boots Alliance Inc. 108 Wilmot Road, Deerfield, IL 60015
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

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:00 am 5:00 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Susan Halliday

Responsible Person of Walgreen Co.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Susan Hall

Original Signature of Person Authorized to Submit Application, no copies or stamps

Susan Halliday
Print Name of Authorized Person

4/9/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF IL)
) ss.
LAKE COUNTY)

I, Benjamin Rapp, 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 for Premise Health Wellness Center (the 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 sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product 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 AFFIANT SAYETH NOT.

I, Benjamin Rapp, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
7th day of April, 2021

NOTARY PUBLIC

OFFICIAL SEAL
DILYAN TSANEV
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires 10/01/2024

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Benjamin H. Rapp

Date: 01/05/2022
Amount:
License #: 22245

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:10/31/2023

Benjamin H. Rapp

License #
22245
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 #: 22245

Expires: 10/31/2023
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Benjamin H. Rapp

NONTRANSFERABLE
POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

52606

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000006784
EXPIRATION DATE: 09/30/2023

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
PHARMACY
PREMISE HEALTH WELLNESS CENTER

COMMISSIONER OF HEALTH

WALGREENS #21278
P O BOX 901
DEERFIELD IL 60015-0901

12716411
52606

State of Tennessee
Department of Health

BOARD OF PHARMACY
PHARMACY
PREMISE HEALTH WELLNESS CENTER
5410 MARYLAND WAY STE. 100RX
BRENTWOOD TN 37027

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006784
EXPIRATION DATE: 09/30/2023

CONTROLLED SUBSTANCE REGISTRATION

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER

DCF171

File Number 1084-348-1

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 I am the keeper of the records of the Department of Business Services. I certify that

WALGREEN CO., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON FEBRUARY 15, 1909, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 9TH *day of* NOVEMBER ***A.D.*** 2021 .

Authentication #: 2131302368 verifiable until 11/09/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW8792889	05-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3 3N,4,5	CHAIN PHARMACY	09-30-2019

WALGREEN CO.
DBA PREMISE HEALTH WELLNESS CENTER
5410 MARYLAND WAY STE 100RX
BRENTWOOD, TN 37027 5064

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
FW8792889	05-31-2022	$731

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2,2N,3 3N,4,5	CHAIN PHARMACY	09-30-2019

WALGREEN CO.
DBA PREMISE HEALTH WELLNESS CENTER
5410 MARYLAND WAY STE 100RX
BRENTWOOD, TN 37027 5064

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)

Walgreen Co. ("Walgreens") has operated retail drug stores since 1901. Walgreens and its wholly owned subsidiaries currently own and operate over 9,200 stores in the United States and Puerto Rico.

In the normal course of its business operations, Walgreens' pharmacies are periodically subject to inspection and, on occasion, administrative action by state agencies that regulate the practice of pharmacy. Typically, the pharmacy is given an opportunity to correct the deficiency within a specified period of time and, if it does so, the matter is closed without disciplinary or adverse licensure action. In the course of the last reporting period, one or more pharmacies owned directly or indirectly by Walgreen Co. have been disciplined and/or required as part of a corrective action plan, to pay an administrative fine to a state regulatory agency. We can confirm, however, that none of the pharmacies subject to these actions had their retail pharmacy license in any way suspended, restricted, or denied as a result.

.

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: Premise Health Wellness Center	
STREET: 5410 Maryland Way, Ste 100RX	
CITY: Brentwood	ZIP: 37027
DATE OPENED: —	TELEPHONE NO.: (615) 238-0335
LICENSE NO.: 6784	EXPIRY DATE: 9/30/21
DEA NO.: FW8792889	EXPIRY DATE: 5/31/22
PHARMACIST IN CHARGE/Duty: Benjamin Rapp	LIC NO.: 23937 / EXPIRY DATE: 6/30/21

Inspected by: Rita Golden — Date: 4/8/21

This Inspection — Satisfactory: Yes ☑ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
NA		2. D. Ph./Tech ration — NO techs
✓		3. Personnel/apparel clean
NA		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
NA		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

✓	19. RXs numerically filed
	☐ All C's together ☑ C-11's separate ☐ Multiple file method
✓	20. Patients identifiable
✓	21. Prescribers identifiable
✓	22. New verbal RXs initialed by appropriate personnel
✓	23. Date of original dispensing
✓	24. Initials of dispensing D.Ph.
✓	25. Quantity dispensed indicated
NA	26. Appropriate Emergency C-11 RXs
✓	27. Computer labels applied appropriately to RXs
✓	28. Pharmacist Signature Log
NA	29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
✓		36. Readily retrievable
✓		37. All C-11 records separate
✓		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
NA		40. Record of drug transfers
✓		41. NA ☐ Schedule V sales record book — Rx only ☑ Methamphetamine Sales Log
✓		42. Last DEA Inventory (date) 6-9-2020
✓		42. Last Theft/loss report (date) NONE
✓		43. Access to Control Substance Monitoring Database

Pharmacy Hours: M-F 8-5 / Closed Sa/Su

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☑

Immediately							
Needs Improvement							
Within 30 Days							

Remarks or Recommendations: _____

I Benjamin Rapp hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18 RDA SW-30

Last Updated: 4/9/2021

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy
County = All
Results = 1

Click here to return to the search page

1

Premise Health Wellness Center 5410 Maryland Way Ste. 100RX
Brentwood, TN 37027

Qualifications
Controlled Subs

Rank: Pharmacy
Pharmacist: RAPP, BENJAMIN HUGH

Facility License Number: 00006784
Status: Licensed
Date of Original Licensure: 09/25/2019
Date of Expiration: 09/30/2021
No Disciplinary Actions

File Number 1084-348-1

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 I am the keeper of the records of the Department of Business Services. I certify that

WALGREEN CO., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON FEBRUARY 15, 1909, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 28TH *day of* JANUARY *A.D.* 2021 .

Authentication #: 2102800296 verifiable until 01/28/2022

Authenticate at: http://www.cyberdriveillinois.com

Jesse White

SECRETARY OF STATE

WALGREEN CO.
OFFICERS AND DIRECTORS

TITLE	NAME	CORPORATE ADDRESS	OWNERSHIP
President & Director	John T Standley	108 Wilmot Road Deerfield, IL 60015	0%
Senior Vice President, Chief Financial Officer, Retail Pharmacy USA, and Treasurer, Director	Alan Nielsen	108 Wilmot Road Deerfield, IL 60015	0%
Senior Vice President, Pharmacy and Retail Operations	Lisa Badgley	108 Wilmot Road Deerfield, IL 60015	0%
Secretary	Joseph B. Amsbary, Jr.	108 Wilmot Road Deerfield, IL 60015	0%
Assistant Treasurer	Susan Halliday	108 Wilmot Road Deerfield, IL 60015	0%
Director	Alexander W. Gourlay	108 Wilmot Road Deerfield, IL 60015	0%

OBJECTIVES OF THE COMPANY - The purpose or purposes for which the corporation is organized are: To manufacture, compound, buy, sell, and generally deal in drugs, medicines, chemicals and druggists' sundries of all kinds at wholesale and retail together with all goods, wares and merchandise.

Walgreen Co.
Corporate Offices
300 Wilmot Rd. MS#3215
Deerfield, IL 60015
www.walgreens.com

April 9, 2021

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

Re: Application for Non-Resident Pharmacy Permit

Dear Sir or Madam:

Enclosed please find new Application for Non-Resident Pharmacy Permit for Premise Health Wellness Center located in Brentwood, TN. Please mail the new license to my attention at the mailing address on the application. If you have any questions, please feel free to call me at 847-527-4768 or e-mail me at karina.lipnickas@walgreens.com.

Sincerely,

Karina Lipnickas
License Specialist

Enclosure

Tennessee

License No. 0000006784

Board of Pharmacy

This is to Certify that

PREMISE HEALTH WELLNESS CENTER

having qualified as required by law, has become duly recorded and is hereby licensed as a

PHARMACY

In testimony whereof we hereunto affix the signature of the secretary and the seal of the Tennessee Board of Pharmacy.

Debra M. Wilson
President

Rissa H. Pryor
Vice President

Melissa McCall

Lisa D. Tittle

Katy H. Wright

James Adam Rodgers

R Michael Dickens

Reginald Dilliard
Executive Director, Board of Pharmacy

John W Tidwell
Director, Health Related Boards

Lisa Piercey
Commissioner, Department of Health

DCF182

49184

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000006784
EXPIRATION DATE: 09/30/2021

This is to certify that all requirements of the State of Tennessee have been met:

PHARMACY BOARD
PHARMACY
PREMISE HEALTH WELLNESS CENTER

COMMISSIONER OF HEALTH

WALGREEN CO
P O BOX 901
DEERFIELD IL 60015-0901

11827069
49184

State of Tennessee
Department of Health

TENNESSEE BOARD OF PHARMACY
PHARMACY
PREMISE HEALTH WELLNESS CENTER
5410 MARYLAND WAY STE. 100RX
BRENTWOOD TN 37027

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006784
EXPIRATION DATE: 09/30/2021

CONTROLLED SUBSTANCE REGISTRATION

DIRECTOR, HEALTH-RELATED BOARDS

COMMISSIONER

DCF171

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* ☒ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** 60006426A

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8* ☐ *Partnership - Pages 1,2,6,8*

☒ *Non Publicly Traded Corporation – Pages 1,2,4,8* ☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Simple Meds, LLC

Physical Address: 6862 Hillsdale Court, Indianapolis, IN 46250-2001

Mailing Address: 6862 Hillsdale Court, Indianapolis, IN 46250-2001

City: Indianapolis State: Indiana Zip Code: 46250-2001

Telephone: 317-913-1300 Fax: 317-913-0930

Toll Free Number: 844-275-6377 (Required per NAC 639.708)

E-mail: kyle.decker@simplemeds.com Website: simplemeds.com

Managing Pharmacist: Madeline Highsmith License Number: 21617 NV Temp.

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☐	☐ Other: _____	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Kyle Decker
Print Name of Authorized Person

8/23/2021
Date

Board Use Only Date Processed:_____ Amount: 500 check # 501071897

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

State of Incorporation: Pennsylvania

Parent Company if any: SelectQuote, Inc.

Corporation Name: Express Med Pharmaceuticals, Inc.

Mailing Address: 3950 Brodhead Rd., Suite 100

City: Monaca State: PA Zip: 15061

Telephone: 855-398-6471 Fax: 724-775-6495

Contact Person: Jeffrey J. Liberati

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 08/18/1999

Registration number issued: 0001794783

Stock Exchange: New York Stock Exchange

Hours of Operation for the pharmacy:

Monday thru Friday 8:00 am 7:00 pm Saturday 10:00 am 1:00 pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Must be included with the application for a 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.

See Attachment B

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Jeffrey J. Liberati

Responsible Person of Express Med Pharmaceuticals, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jeffrey J. Liberati
Print Name of Authorized Person

2/23/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF INDIANA)
) ss.
MARION COUNTY)

I, Madeline Highsmith, 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 for Simple Meds, LLC. (the 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 sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product 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 AFFIANT SAYETH NOT.

I, Madeline Highsmith do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Madeline E. Highsmith
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
1st day of October, 2021.

NOTARY PUBLIC

ASHLEY JEAN LATHROP
Notary Public - Seal
Hendricks County - State of Indiana
Commission Number 711157
My Commission Expires Mar 6, 2026

Managing Pharmacist

Pharmacist Name: Madeline Highsmith License #: Pending for Nevada

Pharmacy Name: Simple Meds, LLC

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

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 the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

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.

	Yes	No
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?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Madeline E. Hughsmith — Signature

9/27/2021 — Date

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Madeline E. Highsmith

Date: 10/06/2021
Amount:
License #: 21617

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:04/06/2022

Madeline E. Highsmith

License #
21617
Temporary

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

Expires: 04/06/2022
STATUS: Temporary

License Type: Pharmacist
License #: 21617

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Madeline E. Highsmith

NONTRANSFERABLE
POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

CORPORATE OFFICER AND EXECUTIVE MANAGEMENT LISTING

Express Med Pharmaceuticals, Inc.	**Owner (100% stock)**			
dba, SelectRx	**SelectQuote Ventures, Inc.**			
3950 Brodhead Rd. Suite 100	**6800 W. 115th St. Suite 2511**			
Monaca, PA 15061	**Overland Park, KS 66211**			
	P: 913-599-9225			
Phone: 855-398-6471	**Tax ID: 86-2734618**			
Fax: 724-775-6495	**Sale Date: 04-30-2021**			
Tax ID: 23-2949842				
PP415385L - PA				
DEA: BE5796656				
NPI: 1114017019				
NABP: 3974145				
Board of Directors				
Robert Clay Grant				
Timothy Danker				
Raffaele Sadun				
Corporate Officer Listing				
Name	**Title**	**Address (Business)**	**DOB**	**% Stock**
Robert Clay Grant (Bob)	Director / President	6800 W. 115th St. Suite 2511 Overland Park, KS 66211	8/8/1984	0
Raffaele Sadun	Director/ Treasurer	6800 W. 115th St. Suite 2511 Overland Park, KS 66211	4/3/1976	0
Daniel A. Boulware (Al)	Secretary	6800 W. 115th St. Suite 2511 Overland Park, KS 66211	11/8/1975	0

STATE OF NEBRASKA

United States of America, } ss.
State of Nebraska }

Secretary of State
State Capitol
Lincoln, Nebraska

I, Robert B. Evnen, Secretary of State of the State of Nebraska, do hereby certify that

SIMPLE MEDS, LLC

was duly formed under the laws of Nebraska on September 10, 2014;

all fees, taxes, and penalties due under the Nebraska Uniform Limited Liability Company Act or other law to the Secretary of State have been paid;

the Company's most recent biennial report required by section 21-125 has been filed by the Secretary of State;

the Secretary of State has not administratively dissolved the company;

the Company has not delivered to the Secretary of State for filing a Statement of Dissolution;

a Statement of Termination has not been filed by the Secretary of State.

This certificate is not to be construed as an endorsement, recommendation, or notice of approval of the entity's financial condition or business activities and practices.

In Testimony Whereof,

I have hereunto set my hand and affixed the Great Seal of the State of Nebraska on this date of

September 27, 2021

Secretary of State

Verification ID d1e4010 has been assigned to this document. Go to ne.gov/go/validate to validate authenticity for up to 12 months.

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

07/20/2021

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT,

EXPRESS MED PHARMACEUTICALS, INC.

is duly registered as a Pennsylvania Business Corporation under the laws of the Commonwealth of Pennsylvania and remains subsisting so far as the records of this office show, as of the date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Veronica W. Degraffenreid

Acting Secretary of the Commonwealth

Certification Number: TSC210720070133-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information	
Facility Name:	Simple Meds, LLC
Address:	6862 Hillsdale Ct Indianapolis, IN 46250
Owner Name:	KYLE DECKER 26023016A

License Information	
Number Issued:	60006821B
License Type:	CSR-Pharmacy
Status:	Active
Issue date:	11/18/2021
Expiration Date:	12/31/2023
Obtained By:	Application

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at www.in.gov/pla/3119.htm. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at http://www.in.gov/pla/boards.htm.

Digitally Certified on: Wed Nov 24 09:47:09 AM EST 2021

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Digitally Certified Proof of Licensure

RE: Simple Meds, LLC

I, Deborah J. Frye, Executive Director of the Indiana Professional Licensing Agency and custodian of the records therein, hereby certify that the attached is the digitally certified proof of licensure, as requested, and as it appears in the files of the Indiana Professional Licensing Agency on the date/time certified.

This digital certification follows the requirements of Indiana's Electronic Digital Signature Act (Indiana Code 5-24-1-1 et seq.) and rules developed by the Indiana State Board of Accounts, 20 IAC 3-1 et seq. to establish a valid digital electronic signature.

To verify the authenticity of the digital certification as of the date and time stamp below, go to
https://secure.in.gov/apps/pla/search/verify/
and use our free web service. Simply browse to the location you saved the secure PDF document sent to you and upload to validate. You may also verify the authenticity in Adobe by ensuring the 'Certified by State of Indiana' blue ribbon displays at the top of the PDF.

Deborah J. Frye

Deborah J. Frye, Executive Director
Wed Nov 24 09:41:28 AM EST 2021

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information	
Facility Name:	[redacted]
Address:	[redacted]
Owner Name:	[redacted]

License Information	
Number Issued:	[redacted]
License Type:	[redacted]
Status:	[redacted]
Issue date:	[redacted]
Expiration Date:	[redacted]
Obtained By:	[redacted]

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at www.in.gov/pla/3119.htm. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at http://www.in.gov/pla/boards.htm.

Digitally Certified on: Wed Nov 24 09:41:28 AM EST 2021

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and use our free web service. Simply browse to the location you saved the secure PDF document sent to you and upload to validate. You may also verify the authenticity in Adobe by ensuring the 'Certified by State of Indiana' blue ribbon displays at the top of the PDF.

Deborah J. Frye

Deborah J. Frye, Executive Director
Wed Nov 24 09:47:09 AM EST 2021

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
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and use our free web service. Simply browse to the location you saved the secure PDF document sent to you and upload to validate. You may also verify the authenticity in Adobe by ensuring the 'Certified by State of Indiana' blue ribbon displays at the top of the PDF.

Deborah J. Frye

Deborah J. Frye, Executive Director
Thu Aug 19 10:24:14 AM EST 2021

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: Simple Meds, LLC

Physical Address: 6862 Hillsdale Court

City: Indianapolis State: IN Zip: 46250

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 317-913-1300 Website: simplemeds.com

Licensing Company Email: kyle.decker@selectrx.com

Section 2: Personal Information

First: Madeline Middle: Elizabeth Last: Highsmith

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

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

Mailing Address: [redacted] Driftwood Dr.

City: Carmel State: IN Zip: 46033

Telephone: [redacted] Email: [redacted]@selectrx.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: MEH

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 University College of Pharmacy			08/2010-05/2018	
Address		City	State	Zip
4600 Sunset Ave.		Indianapolis	IN	46208
Diploma/Degree obtained, if any				
Doctorate of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Noblesville High School			08/2006-06/2010	
Address		City	State	Zip
18111 Cumberland Rd.		Noblesville	IN	46060
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
10/2019 - Current	[redacted] Driftwood Dr.	Carmel	IN	46033
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2011-10/2019	[redacted] Wesley Circle	Noblesville	IN	46062
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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)	
Simple Meds, LLC			04/2018-Current	
Business Address		**City**	**State**	**Zip**
6862 Hillsdale Court		Indianapolis	IN	46250
Phone	**Title**		**Number of Employed Hours**	
317-913-1300	Staff Pharmacist		7,000	
Description of Duties				
Verifying prescriptions for accuracy and counseling patients on medication questions.				

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

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

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

Madeline E. Hughsmith
Original Signature (electronic, copies or stamps not accepted)

9/27/2021
Date

Applicant's initials MEH

I, Madeline Highsmith, **certify that as the designated representative for** Simple Meds, 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

Madeline Highsmith
Print Name (First, Last)

Madeline E. Highsmith
Original Signature (electronic, copies or stamps not accepted)

9/27/2021
Date

Applicant's initials MEH

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.

Madeline Highsmith
Print Name (First, Last)

Madeline E. Highsmith
Original Signature (electronic, copies or stamps not accepted)

9/27/2021
Date

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

State of Indiana, ss. County of Marion

I, Madeline Highsmith, 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.

Madeline Highsmith
Original Signature

9/27/2021
Date

Subscribed and Sworn to before me this 27th day of September.

Amy Durice Yeskie
Notary Public Signature

AMY DURICE YESKIE
NOTARY PUBLIC
SEAL
STATE OF INDIANA
Commission Number 661476
My Commission Expires 12/11/2022

(Seal)

Applicant's initials MEH

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
Simple Meds, LLC
6862 Hillsdale Court
Indianapolis IN 46250
Phone: 8442756337
Owner: Kyle Decker, VP
Ownership Type:

LICENSE
License No: 60006426A
Profession: Pharmacy
License Type: Pharmacy
6862 Hillsdale Court
Indianapolis IN 46250
Phone: 8442756337

Inspection Type:	Pharmacy Inspection
Inspection Date:	1/13/2021
Result:	Pass

Remarks: No non-sterile or sterile compounding on site. Sections of this inspection document will be left blank because they do not apply to this business model. This inspection was conducted by Diversion/Compliance Officer Timeothy Thomas. 317-753-4000 tithomas@pla.in.gov

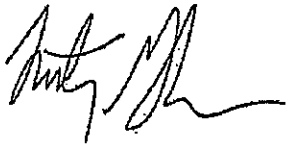
Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding
Remote Locations (Type II only)

Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

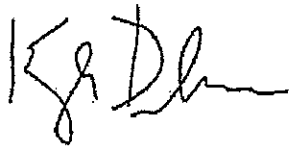
As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.



1/13/2021 12:20:55 PM



Signature of Inspector	Date/Time	Signature of Owner/Representative

1:4
638/656

SIMPLE MEDS, LLC
6862 HILLSDALE CT
INDIANAPOLIS, IN 46250-2001

10007698 .3/001969-1/1-0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS5024637	02-29-2024	$888
SCHEDULES	**BUSINESS ACTIVITY**	**ISSUE DATE**
2,2N, 3,3N,4,5	RETAIL PHARMACY	01-15-2021

SIMPLE MEDS, LLC
6862 HILLSDALE CT
INDIANAPOLIS, IN 46250-2001

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
FS5024637	02-29-2024	$888
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2,2N, 3,3N,4,5	RETAIL PHARMACY	01-15-2021

SIMPLE MEDS, LLC
6862 HILLSDALE CT
INDIANAPOLIS, IN 46250-2001

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Form DEA-223 (9/2016)

5

MATRIX GUIDELINE FOR DISCIPLINARY ACTIONS

	1st Action	2nd Action	3rd Action
Non ingested error	Letter	Letter	Hearing
No counseling	$750.00	Counseling CE + $1000.00	Hearing
Attorney Fees and Costs	Actual	Actual	Actual
Ingested no potential harm	$500.00	$1000.00	Hearing
Ingested with potential harm or adverse outcomes	$1000.00	Hearing	Hearing
Ingested with negative outcome or patient discomfort. No institution intervention	Hearing	Hearing	Hearing
Ingested with significant negative health circumstance. With institution admit	Hearing	Hearing	Hearing
Ingested with death related to inappropriate drug therapy	Hearing	Hearing	Hearing

The investigative committee will review each case individually and may recommend a board hearing, particularly with mitigating circumstances such as inappropriate technician involvement or pharmacist malfeasance.

In certain cases with ingested errors and significant negative health circumstances requiring institutional care, the investigative committee recommendation will be a board hearing.

In all death cases resulting from inappropriate drug therapy a board hearing will occur.

Attorney fees and costs may be added in contested disciplinary actions requiring extensive attorney preparation and presentation and are not described in the above matrix.

The board has directed that ownership may be charged in disciplinary cases. In non-ingested errors copies of admonition letters will be sent to management. Accumulative actions for ownership monitoring will be based upon a 3 year period. All actions including non-ingested errors will be given a case number and monitored.

The Board has the authority to fine from $0.00 to $10,000 for each Cause of Action.

Updated May 2019

ANNUAL DISCIPLINE CASES Reporting Period: January 2022 – January 2022			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
SS: Failure to meet controlled substance reporting requirements; failure to maintain adequate or accurate controlled substance records; inappropriate or unauthorized dispensing of medication; inappropriate acquisition or diversion of controlled substances/dangerous drugs. Practicing as a wholesaler without a license.	N/A	Respondent voluntarily surrendered his Pharmacist Certificate of Registration on August 2, 2021. Respondent may not apply for reinstatement of his pharmacist registration for a period of two (2) years. Respondent fined $5,000 and $595 in attorney's fees and costs.	PR: $10,000 fine; $1,785.77 in attorney's fees and costs.

5A

FILED
JUL 23 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. KINEX MEDICAL COMPANY, LLC, License No. MP00623, Respondent.	CASE NO. 21-039-MP-S 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 Kinex Medical Company, LLC, License No. MP00623, was a medical products provider based in Waukesha, Wisconsin licensed by the Board.

FACTUAL ALLEGATIONS

2. On or about March 4, 2021, Respondent's authorized representatives appeared before the Board on its application for a second medical products provider license to operate from 5985 Hauck Street #107 in Las Vegas. Respondent's license application was tabled.

3. On or about March 8, 2021, Respondent was served with a cease and desist with a citation and fine pursuant to NRS 639.2895 for Respondent and/or Respondent's employees engaging in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 without a license.

4. Respondent's authorized representatives subsequently represented to Board staff in the course of investigation that Respondent had ceased operations at 5985 Hauck Street #107 on March 30, 2021.

5. On or about March 30, 2021, Respondent and/or Respondent's employees began engaging in the business of furnishing medical devices in Nevada from 6075 W. Wigwam Avenue, Unit A089 in Las Vegas without a license.

6. On or about April 15, 2021, Respondent's authorized representatives appeared before the Board on its application for license to operate from 5985 Hauck Street #107 and, while under oath, represented to the Board in pertinent part that Respondent and/or Respondent's employees had ceased operations at 5985 Hauck Street #107 on March 30, 2021. Respondent's licensed application was conditionally approved pending inspection.

7. On or about May 4, 2021, Board staff conducted a pre-inspection visit and obtained evidence that Respondent and/or Respondent's employees had engaged in the business of furnishing medical devices in Nevada from 6075 W. Wigwam Avenue, Unit A089 from March 30 until at least April 16, 2021.

8. On or about May 11, 2021, Respondent, by and through counsel, admitted that Respondent and/or Respondent's employees had engaged in the business of furnishing medical devices in Nevada from 6075 W. Wigwam Avenue, Unit A089 from March 30 until at least April 16, 2021.

9. On or about June 15, 2021, Respondent was served with a second cease and desist with a citation and fine for Respondent and/or Respondent's employees continuing to engage in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 without a license. On the same date, Respondent was served with a separate cease and desist with a citation and fine for Respondent and/or Respondent's employees engaging in the business of furnishing medical devices in Nevada from 6075 W. Wigwam Avenue, Unit A089 without a license.

10. On or about June 29, 2021, Respondent, by and through counsel, withdrew its application for a second medical products provider license to operate from 5985 Hauck Street #107 in Las Vegas.

APPLICABLE LAW

11. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing 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 shall obtain a license pursuant to the provisions of this chapter. NRS 639.233(1).

12. It is unlawful for any wholesaler or manufacturer to furnish, sell, offer for sale, or deliver any medical devices, other than those referred to in NRS 639.270, to any person not authorized by the laws of this state to handle, sell, possess or deal in such devices. NRS 639.288.

13. If a medical products provider sells, leases or otherwise provides medical products at more than one location, it must obtain a license for each location where medical products are sold, leased or otherwise provided. NAC 639.6942(2).

14. Any person who is located outside of this State and who intends to sell medical products to any consumer or medical products provider in this State on a regular basis must apply for an appropriate license pursuant to the provisions of NAC 639.693 to 639.6958, *inclusive*. Any medical products provider or medical products wholesaler that is located outside of this State must comply with the provisions of NAC 639.693 to 639.6958, *inclusive*, for any sale, lease or other disposition of medical products to any person in this State other than a medical products wholesaler or manufacturer that is licensed by the Board. NAC 639.6944(1).

15. Performing any duties as the owner of a business or an entity licensed by the Board or as the employee of any such business 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 issued by the Board. NRS 639.210(4).

16. Aiding or abetting a person not licensed in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j)

and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

17. Performing any act, task or operation for which licensure is required without the required license constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

18. Violating any law or regulation relating to the practices of a medical products provider constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.6941(1)(a) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

19. Willfully making a materially false statement in the course of a Board investigation is a criminal offense and grounds for suspension or revocation of any license issued by the Board. NRS 197.190; NRS 639.210(9).

20. The Board may suspend or revoke a license if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any provision of Chapter 639 of the Nevada Revised Statutes. NRS 639.210(12).

21. The owner of a medical products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2); NAC 639.945(2).

FIRST CAUSE OF ACTION
Violations of State Law

22. By engaging in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 and 6075 W. Wigwam Avenue, Unit A089 as alleged herein, Respondent and/or Respondent's employees violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.233(1), NRS 639.288, NAC 639.6942(2) and/or NAC 639.6944(1), and Respondent is therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(2) and NRS 639.210(12).

SECOND CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

23. By engaging in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 and 6075 W. Wigwam Avenue, Unit A089 as alleged herein, Respondent and/or Respondent's employees performed the duties of a licensed medical products provider in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.6941(1)(a) and NAC 639.945(1)(i), and Respondent is therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(2) and NRS 639.210(4).

THIRD CAUSE OF ACTION

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

24. By engaging in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 and 6075 W. Wigwam Avenue, Unit A089 as alleged herein, Respondent and/or Respondent's employees aided and abetted unlicensed activity and engaged in unprofessional conduct as defined in NAC 639.6941(1)(a) and NAC 639.945(1) (j), and Respondent is therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(2) and NRS 639.210(4).

FOURTH CAUSE OF ACTION

Unprofessional Conduct –
Operating as Medical Products Provider Without the Required License

25. By engaging in the business of furnishing medical devices in Nevada from 5985 Hauck Street #107 and 6075 W. Wigwam Avenue, Unit A089 as alleged herein, Respondent and/or Respondent's employees performed acts, tasks and/or operations for which licensure is required without the required license and engaged in unprofessional conduct as defined in NAC 639.6941(1)(a) and/or NAC 639.945(1)(k), and Respondent is therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(2) and NRS 639.210(4).

FIFTH CAUSE OF ACTION

False Statements in Course of Investigation

26. By willfully making false statements in the course of the Board's investigation, as alleged herein, that are material to the administration and enforcement of law, Respondent and/or

Respondent's authorized representatives and employees violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 197.190, and Respondent is therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(2) and NRS 639.210(9).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to license of this Respondent.

Signed this 27th day of July, 2021.

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, Petitioner, v. KINEX MEDICAL COMPANY, LLC, License No. MP00623, Respondent.	CASE NO. 21-039-MP-S 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 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 1, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency

Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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 23 day of July, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KINEX MEDICAL COMPANY, LLC,** **License No. MP00623,** **Respondent.**	**CASE NO. 21-039-MP-S** **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 _____, 2021.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR KINEX MEDICAL COMPANY, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of July, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Michael Buckholdt
Saundra Sorenson
Kinex Medical Company
5985 Hauck Street, #107
Las Vegas, NV 89118

Kinex Medical Company
1801 Airport Road, Suite D
Waukesha, WI 53188

Lyn Beggs, Esq.
316 California Ave. #863
Reno, NV 89509

SHIRLEY HUNTING

FILED
AUG 20 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **vs.** **KINEX MEDICAL COMPANY, LLC** **License No. MP00623,** **Respondent.**	**Case No.: 21-039-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent Kinex Medical Company, LLC ("Kinex"), hereby files with the Nevada State Board of Pharmacy ("Board"), its Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 23, 2021.

ANSWER TO ACCUSATION

Jurisdiction

Kinex agrees that the Board has jurisdiction in this matter as set forth in Paragraph 1. Kinex further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 2-10

Paragraph 2: Kinex agrees and acknowledges the factual assertions set forth in Paragraph 2.

Paragraph 3: Kinex admits that it was served with a cease and desist notice which was dated March 8, 2021 but it was received approximately one week later. Kinex denies that its employees were engaging in the business of furnishing medical devises from 5985 Hauck Street, #107 without a license.

Paragraph 4: Kinex denies the allegations set forth in Paragraph 4.

Paragraph 5: Kinex denies the allegations set forth in Paragraph 5.

Paragraph 6: Kinex agrees and acknowledges that its authorized representatives appeared at a Board meeting on April 15, 2021. Kinex denies that its authorized representatives represented that it had ceased operations at 5985 Hauck Street, #107 as of March 30, 2021.

Paragraph 7: Kinex is without sufficient knowledge to respond to the allegations set forth in Paragraph 7.

Paragraph 8: Kinex is without sufficient knowledge to respond to the allegations set forth in Paragraph 8 but notes that its counsel referenced in Paragraph 8 is not subject to the jurisdiction of the Board.

Paragraph 9: Kinex agrees and acknowledges that it was served with two cease and desist notices on June 15, 2021, but denies the allegations contained within the notices.

Paragraph 10: Kinex agrees and acknowledges that it withdrew its pending application on June 29. 2021.

Applicable Law: Paragraphs 11 through 21

Kinex agrees that Paragraphs 11 through 21 of the Accusation accurately reflect current Nevada law however, Kinex denies that it has violated any of the statues or regulations cited therein.

Causes of Action: Paragraphs 22 through 26

First cause of action (paragraph 22): Kinex denies the allegations set forth therein.

Second cause of action (paragraph 23): Kinex denies the allegations set forth therein.

Third cause of action (paragraph 24): Kinex denies the allegations set forth therein.

Fourth cause of action (paragraph 25): Kinex denies the allegations set forth therein.

Fifth cause of action (paragraph 26): Kinex denies the allegations set forth therein.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Affirmative Defenses

First Affirmative Defense: Petitioner has failed to state a claim upon which a professional sanction or discipline can be based.

Second Affirmative Defense: Kinex has not violated any of the statutes or regulations referenced in Petitioner's Accusation.

Mitigating Information

Kinex, after more than twenty years of doing business in the state of Nevada under its current license and providing orthopedic medical equipment to Nevada patients, has ceased doing all business in Nevada. No medical devices of any nature are being shipped to Nevada patients and Kinex has no intention of returning to Nevada to engage in business as a medical product provider. Kinex reserves the right to present additional information in mitigation at the time of the hearing scheduled in this matter.

Respectfully submitted this 20th of August, 2021.

Lyn E. Beggs, Esq.
Attorney for Respondent Kinex Medical Company, LLC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway – Suite 206 • Reno, NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
• Web Page: bop.nv.gov

March 8, 2021

VIA CERTIFIED MAIL

Michael Buckholdt
Saundra Sorenson
Kinex Medical Company
5985 Hauck Street # 107
Las Vegas, NV 89118

Kinex Medical Company
1801 Airport Road, Suite D
Waukesha, WI 53188

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada

Dear Mr. Buckholdt and Ms. Sorenson:

The Nevada State Board of Pharmacy ("Board") has determined, based upon your admissions and/or documents submitted at a Board meeting, that Kinex Medical Company ("Kinex") has engaged in the business of furnishing medical devices in this State without a license. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS,639.233, NRS 639.288, NRS 639.310 and NAC 639.6944.

Kinex is hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST from engaging in the business of furnishing medical devices in this State. This letter shall serve as a CITATION pursuant to NRS 639.2895(2), for unlicensed operation of activity. The Board has assessed an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

Kinex 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.

Kinex has 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 letter. *See* NRS 639.2895(2).

Please be aware that the foregoing does not preclude a formal investigation or filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or c.lee@pharmacy.nv.gov.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

9171 9690 0935 0252 5975 46

9171 9690 0935 0252 5975 60

KINEX

NV Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, NV 89521

3/15/2021

Re: Addendum to MDEG Administrator Form

Dear Board Members,

This letter is to outline the discrepancies that were submitted on the MDEG administrator forms dated January 29th 2021 and March 4th 2021. Both of these reflected incorrect work history for Saundra Sorenson. I would like to provide explanation as to how this information was believed to be accurate by Ms. Sorenson.

Prior to February 2019 Kinex Medical Company and Gabel Distributors entered into a 1099 relationship in which Kinex equipment was dispensed to patients by Gabel Distributors. February 2019 Kinex and Gabel Distributors termed this 1099 relationship and at that time Kinex took over the lease to the Hauck street location as well as transitioned several of Gabel Distributors employees to become Kinex W2 employees.

In June 2019 Saundra Sorenson relocated from the Kinex location in Colorado to the location at Hauck Street in Las Vegas. During this time the transition from Gabel Distributors to Kinex Medical Company at the Hauck Street location was still in progress. Kinex has always referred to that location as the Gabel office. When Ms. Sorenson came to that location the terminology was skewed due to the transition and the former owner of Gabel Distributor being on-site very routinely.

There was no ill-intent to the information that Ms. Sorenson provided to the board as she believed the information to be accurate.

The work history in the MDEG administrator form dated March 15th 2021 is accurate and complete per the knowledge of Kinex Medical Company and Saundra Sorenson.

Regards,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC

Snell & Wilmer
3883 HOWARD HUGHES PARKWAY
SUITE 1100
LAS VEGAS, NV 89169
702.784.5200 P
702.784.5252 F

Kelly H. Dove
(702) 784-5286
kdove@swlaw.com

April 13, 2021

VIA U.S. MAIL AND EMAIL

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Suite 206
Reno, NV 89521

Re: Kinex Medical Company ("Kinex")

Dear Ms. Lee and Members of the Board:

Enclosed please find a copy of the certified check in satisfaction of the Citation dated March 8, 2021 (attached as **Exhibit 1**), which was scheduled for delivery to the Board's Reno address Friday, April 9, 2021. Kinex paid this fine in full with the hope and intention that it may move forward by expeditiously resolving any pending licensing issues and resume providing important products and services to patients in Nevada. In addition to making the payment, we also wanted to provide context that we believe will be helpful to the Board in understanding Kinex's strong history as a good corporate citizen, Kinex's recent licensing issues, and why it is appropriate to approve Kinex's application.

About Kinex

Kinex is an orthopedic specialty medical equipment company facilitating the delivery and billing of durable medical equipment and orthotics for acute, post-acute and in-home rehabilitation following injury or surgery. It is a national Medicare provider that holds more than 300 insurance contracts nationwide. For more than thirty years, Kinex has operated out of Wisconsin and distributes medical equipment to thirty-five states. For more than twenty years, Kinex has had a Nevada Medical Device Equipment and Gasses ("MDEG" or "DME") license tied to its home state location and has supplied medical equipment to Nevada through a Nevada-licensed distributor, Gabel Distributors, LLC ("Gabel"). Kinex also has a Nevada Business License and a Clark County Business License. Kinex had an unblemished record in Nevada during its long history of doing business here.

The Hauck Street Location[1]

Kinex Attempts to Secure a License for the Hauck Street Location

In February 2019, Kinex and Gabel agreed that they would substantially part ways. The plan was for Gabel to relocate and for Kinex to assume the distribution of its medical devices in Nevada from the same location Gabel had used. Gabel's principal, Andy Gabel, agreed to continue working with Kinex as a consultant. As noted above, Kinex already had a DME license tied to its home-state Wisconsin location, but in light of its intention to start operations at the Hauck Street location independent from Gabel, Kinex began communicating with the Board regarding licensing requirements.

Kinex's compliance manager, Leann Wilhelm, contacted the Board in April 2019 to request information on the process for obtaining an MDEG license in its own name for the Hauck Street location as it transitioned from working with Gabel. She was informed that two providers could not be simultaneously licensed at the same location, so if Kinex were to apply for a license before Gabel's license was transferred to its new location, Kinex's application would be denied on that basis. Further, Gabel's new location would require inspection before Gabel's license could be transferred. As such, Kinex believed that it could not obtain a Nevada license until Gabel's Hauck Street license was transferred to Gabel's new location.

Kinex took over the Hauck Street lease around May 2019 but Gabel's relocation was delayed and Gabel did not move from the Hauck Street location until approximately January 2020. During the period when Kinex and Gabel co-occupied the Hauck Street location, they continued to work together on some of the contracts but Andy Gabel was then working as a consultant and several formerly Gabel employees became Kinex employees.

Gabel's new location was inspected on or about February 20, 2020. Following that inspection, anticipating the transfer of Gabel's license, Kinex again contacted the Board via telephone about completing an application for the Hauck Street location.

During this period, the Governor declared a state of emergency in Nevada based on the pandemic, resulting in rapid and drastic changes and disruptions to the functioning of government entities and businesses. When Kinex next attempted to contact the Board with clarificatory questions about its application by phone, an automated message indicated that that the phones would be unstaffed indefinitely and that all communications should be by email. Kinex sent several emails to the Board from May 20, 2020 to June 25, 2020, including several follow-up emails and received a response on June 25, 2020. **Exhibit 2**, Emails dated May 20 and May 22, 2020; **Exhibit 3**, Emails dated May 29, June 1, June 8, June 16, and June 25, 2020.

[1] Both Mr. Buckholdt and Ms. Wilhelm will be available at the Board meeting to answer questions regarding or provide testimony as to this information.

After the response on June 25, 2020, there were several more exchanges of inquiries and responses between Kinex and the Board. **Exhibit 3,** Emails dated June 26, June 30, and July 23, 2020. Kinex ultimately submitted its application on August 20, 2020. However, the Board website still showed that Gabel maintained a license at the Hauck Street location. As such, this submission appeared to be prior to the expiration of Gabel's license for the physical location of the warehouse. Kinex also followed up with Gabel about the status of its license and was later informed that Gabel's new license had been issued on August 31, 2020 and that Gabel's application had been delayed because of interruptions caused by the pandemic.

On October 26, 2020, Kinex received a phone call from the Board, informing Kinex that the Board had the completed application but because of the pandemic circumstances, they would not be conducting the next board meeting as originally scheduled. The Board indicated that the meeting would be rescheduled for December and Kinex would be on that agenda. Consistent with that communication, on October 29, 2020, the Board notified Kinex by letter that it was in receipt of its application of a license and that Kinex must personally appear before the Board at the December 2, 2020 meeting. **Exhibit 4**, Letter dated Oct. 29, 2020. On November 5, 2020, email correspondence from the Board to Kinex's compliance manager confirmed that Kinex was indeed on the December agenda. **Exhibit 5**, Email dated Nov. 5, 2020.

Kinex appeared at the December 2, 2020 meeting, but when it attended, it turned out that its application had not been placed on the agenda and its application would not be considered at that time. After that Board meeting, Kinex followed up several times concerning the status of its application. **Exhibit 5**, Emails dated Jan. 15 and Jan. 19, 2021. Kinex was informed on January 20, 2021, that it could apply for a temporary license via email and placed that request immediately, on January 20, 2021. **Exhibit 6**, Email dated Jan. 20, 2021. Kinex followed up about the status of its request for a temporary license on January 28, February 4, February 23, and February 25. **Exhibit 6**, Emails dated Jan. 28, Feb. 4, Feb. 23 and Feb. 25, 2021. Kinex did not receive a response to any of its inquiries and was unsure of the status of its request for a temporary license.

Kinex's application was then rescheduled for the March 4, 2021, Board meeting, and Kinex appeared through Ms. Wilhelm, its compliance manager,[2] and Saundra Sorenson, its proposed MDEG administrator. Both representatives answered questions from the Board with candor and honesty. Ms. Sorenson's work history was discussed because her years of experience had been combined as one entry on the application, rather than separated by different periods. Further, there was some initial confusion about whether Ms. Sorenson had worked for Gabel or Kinex. While Ms. Sorenson's history was clarified by the discussion at the meeting, the Board requested that Kinex provide an amended MDEG Administrator application that corrected the inadvertent discrepancies and conformed with the testimony and correct information. Kinex promptly

[2] At the Board's request, Kinex provided a letter of authorization for Ms. Wilhelm's appearance on March 5, 2021, the same day as the Board meeting.

provided an amended application and explanatory letter on March 15, 2021. **Exhibit 7**, Correspondence dated March 15, 2021.

Cease and Desist, Citation

On March 8, 2021, the Board issued a Cease and Desist/Citation letter, which Kinex received on March 16, 2021, indicating that based on documents and admissions provided at the Board meeting, Kinex had engaged in the business of furnishing medical devices in Nevada without a license. As noted above, Kinex timely paid the Citation in efforts to resolve its outstanding Hauck Street licensing issue expeditiously and become compliant.

Kinex Seeks to Cure any Remaining Issues and Secure Proper Licensing so that It May Properly Continue Doing Business in Nevada.

Clarification of Ms. Sorenson's Work History

Kinex submitted to the Board an amended MDEG Administrator application with an explanatory letter. The amended application accurately portrays Ms. Sorenson's work history by separating each of the three locations at which Ms. Sorenson has worked for more than the last ten years. The initial response was intended to demonstrate Ms. Sorenson's years of experience relating to the products involved, and not to cause confusion or mislead in any way. Specifically, Ms. Sorenson began working with Total Orthopedics, Inc. in February 2011. She became employed by Kinex in August 2017, when Kinex acquired Total Orthopedics. Finally, Ms. Sorenson continued her employment with Kinex when she moved from Colorado to Las Vegas. In other words, Ms. Sorenson never changed jobs, but her employment changed first by virtue of the acquisition of Total Orthopedics by Kinex, and then by her move to Nevada.

It is our understanding that based on the clarifying discussion at the March Board meeting, combined with the submission of an amended application, this issue is resolved. Notably, even if Ms. Sorenson's hours at the Hauck Street location are not included in the evaluation of her qualifications to serve as an MDEG Administrator, she still satisfies all of the necessary qualifications for the application by virtue of her prior experience. Kinex will of course be happy to answer any additional questions the Board may have.

Pending License Application

Kinex is now scheduled to appear before the Board on April 15, 2021 to address any outstanding issues relating to its pending application, and, if the Board wishes, to address the Citation. Kinex appreciates that it made some mistakes in the process, particularly that it did not fully appreciate the limitations of its current licensure while it transitioned and sought a license for the new location. In hindsight, and following retention of counsel, Kinex understands that the transition could have been differently structured to avoid the gap period that resulted, and which

Snell & Wilmer

was exacerbated by circumstances caused by the pandemic. Kinex respectfully requests the Board to consider its frequent and candid contact with the Board as evidence of its good faith efforts to comply with the applicable regulations and law. Kinex at no time concealed its status or its pursuit of a license. Further, Kinex's products – knee braces, splints, etc. – are federally approved and its services in Nevada were being provided by the same people Kinex worked with when the Hauck Street location was run by Gabel. Kinex understands its errors to date, but despite its mistakes is an established, reputable company that seeks to be fully compliant.

Kinex respectfully submits this information and looks forward to speaking with the Board on April 15.

Very truly yours,

Snell & Wilmer

/s/ Kelly H. Dove
Kelly H. Dove
Counsel for Kinex Medical Company

KHD:mw

Enclosures

4844-6489-2644

EXHIBIT 1

EXHIBIT 1

BR918 NEW 3/19 M 62389-A

HOLD DOCUMENT UP TO THE LIGHT TO VIEW TRUE WATERMARK

CASHIER'S CHECK

HOLD DOCUMENT UP TO THE LIGHT TO VIEW TRUE WATERMARK

1774

66152138

2-28/710

BMO Harris Bank

PAY **Five Thousand and 00/100*****************

TO THE ORDER OF	DATE	AMOUNT
STATE OF NEVADA **OFFICE OF THE TREASURER**	04/08/2021	$5,000.00

Security Features Details on Back.

REMITTER **KINEX MEDICAL**

MEMO **COMPANY, LLC**

Authorized Signature

Drawer: **BMO Harris Bank N.A. 29(09325)**

BMO Harris Bank N.A., Chicago, IL

⑈66152138⑈ ⑆071000288⑆ 288 791 7⑈

BMO Harris Bank

PURCHASER'S RECEIPT - RETAIN FOR YOUR RECORDS

N O T N E G O T I A B L E 66152138

PAY **Five Thousand and 00/100*****************

TO THE ORDER OF	DATE	AMOUNT
STATE OF NEVADA **OFFICE OF THE TREASURER**	04/08/2021	$5,000.00

REMITTER

KINEX MEDICAL

NOTICE TO CUSTOMERS

The purchase of an indemnity Bond will be required before an Official Check of this bank will be replaced or refunded in the event it is lost, misplaced or stolen.

OFFICIAL BANK CHECK

MEMO **COMPANY, LLC**

EXHIBIT 2

EXHIBIT 2

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Friday, May 22, 2020 8:43 AM
To: 'pharmacy@pharmacy.nv.gov'
Subject: RE: Personal History Form Assistance
Attachments: ALL_Personal_HistoryRecordApp rev.2.pdf

Importance: High

Hello,

Can someone please advise on my questions below.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Leann Wilhelm, CHC
Sent: Wednesday, May 20, 2020 10:35 AM
To: 'pharmacy@pharmacy.nv.gov'
Subject: Personal History Form Assistance
Importance: High

Hello,

We are in the process of completing a new application as a durable medical equipment supplier in the state of Nevada. As I move through the application I see the personal history form that each owner of the company must complete. My question is do all the fields need to be completed? There is some very personal and in-depth questions on here as it relates to family, lockboxes and places they've lived in the last 25 years! Of all the applications we process for licensing I've never seen anything even close to this as far as request for personal information. Most of the owners are not comfortable in providing this information and we are looking to either have an exemption from this or a reduction in the information requested. They are all very comfortable in providing you their personal information such as name, date of birth, SSN, address, etc as well as attesting to not having any crimes or licensure suspensions but beyond that disclosing the very personal information about the owners and their families seems intrusive.

Please advise.

Leann Wilhelm, CHC
Compliance Officer

Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

EXHIBIT 3

EXHIBIT 3

KINEX

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Mark I. Sedar
Sent: Thursday, July 23, 2020 10:36 AM
To: Leann Wilhelm, CHC
Subject: RE: Personal History Form Email

[External Email - Use Caution]
Good morning Leann,

The picture is required for verification purposes during a board meeting if an appearance is mandatory.

Mark Sedar

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Thursday, July 23, 2020 8:26 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: Personal History Form Email

Hello Mark,

Do the applicants have to include a picture on their applications?

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (262) 521-7338
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Leann Wilhelm, CHC
Sent: Wednesday, July 1, 2020 9:04 AM
To: 'Mark I. Sedar' <msedar@pharmacy.nv.gov>
Subject: RE: Personal History Form Email

Thank you Mark, this is much appreciated.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (262) 521-7338
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Tuesday, June 30, 2020 5:37 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Personal History Form Email

[External Email - Use Caution]
Hello Leann,

Thank you for sharing with me the questions and concerns. Please see my comments below in red.

Mark Sedar

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Friday, June 26, 2020 6:30 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: Personal History Form Email

Good Morning Mark,

I greatly appreciate you getting back to me. As per my last email we are more than happy to comply with providing information which allows you to perform a background check and attest to not having any criminal history against them but some of the other information seems extreme in order to issue a license. I've been working with our company in processing licenses all across the country for 11 years now and I have never encountered anything this in depth in any state.

Here are the questions that our owners have concern with answering;

- Spouses information including SSN and employer information (no need for SSN)
- Previous marriage history (required)
- Children's information as they are minors (not required)
- Information on parents, brothers, and sisters (not required)
- Listing residencies for the last 25 years. Some are having issue in remembering the address back that far. They can easily provide the last 10 but cannot attest to the dates and specific addresses beyond that. (the past 10 years is adequate)
- Employment – Most of our owners are at retirement age or even beyond. They cannot remember employment history since they were 18 let alone dates and supervisors. These can be provided for the past 10 years but beyond that the cannot accurately attest to this information (The past 10 years is adequate)
- References – They can provide a name, phone and years known but providing their home address, employer and their address seems intrusive for someone just providing a reference (Reference names, city, state, and phone numbers only)
- Safe Deposit Box – This is very personal information and should not have to be shared (Not required)

Again, willing to comply however we feel these are outside of the scope of questions that would require obtaining a license. Please advise.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (262) 521-7338
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, June 25, 2020 5:20 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Personal History Form Email

[External Email - Use Caution]
Hello Leann,

My apologies for the lack of response to your original emails. In regards, to your questions, please list the questions that the owners are asking not to provide answers and I will review.

Thank you,

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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From: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Sent: Thursday, June 25, 2020 3:10 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: Fw: Personal History Form Email
Importance: High

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Thursday, June 25, 2020 11:58 AM
To: Candy Nally; Pharmacy Board
Subject: RE: Personal History Form Email

Hello,

It has been another 10 days since my last attempt to get in contact with someone. Is there anyone that can review my attached question?

I've been emailing (as your phone lines are off) since 5/20/20 and still NO ONE has gotten back to me.

Kindly advise.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (262) 521-7338
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026

www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Leann Wilhelm, CHC
Sent: Tuesday, June 16, 2020 10:56 AM
To: 'cnally@pharmacy.nv.gov' <cnally@pharmacy.nv.gov>
Subject: RE: Personal History Form Email
Importance: High

Hello,

I'm following up again on this as it's been another week and I still have not received a response on the attached question.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (262) 521-7338
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

From: Leann Wilhelm, CHC
Sent: Monday, June 8, 2020 2:41 PM
To: 'cnally@pharmacy.nv.gov' <cnally@pharmacy.nv.gov>
Subject: Personal History Form Email

Hello,

I have been trying to reach out to your organization for 3 weeks now and I finally was able to see that my question was assigned to you. I'm wondering if you could please review the attached email and advise.

Regards,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: (414) 930-4484
Toll Free: (800) 845-6364 ext. 7338
Fax: (866) 588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

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EXHIBIT 4

EXHIBIT 4

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
• Web Page: bop.nv.gov

October 29, 2020
Kinex Medical Company
1801 Airport Rd, Ste D
Waukesha, WI 53188

Dear Kinex Medical Company:

We are in receipt of your application for a license/registration from the Nevada State Board of Pharmacy.

After reviewing the application, you are required to personally appear before the Board at a regularly-scheduled meeting for their consideration of approval.

Your appearance has been scheduled for:

Wednesday, December 2, 2020
1:30 PM 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

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. During the hearing, you will be asked to waive your right to the required 21-day notice.

Your appearance is required at the meeting. If you do not appear at the meeting and have not contacted the Board prior to the meeting, the Board may take action on the application in your absence.

If you have any questions, please feel free to contact us.

Sincerely,

Mark Sedar
Chief Operating Officer

EXHIBIT 5

EXHIBIT 5

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Friday, January 15, 2021 5:11 PM
To: 'cnally@pharmacy.nv.gov'
Subject: FW: Liability Insurance

Importance: High

Hello Candy,

Can you please let me know why our company was not on the agenda for the most recent meeting? You had previously informed me that we were on the agenda for December. I attended the meeting this week and we were not on the agenda.

Please let me know how this can be addressed.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
https://protect-us.mimecast.com/s/vCcYCNkGgZCEmQL9Cm6riJ?domain=kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Wednesday, January 13, 2021 11:01 AM
To: 'cnally@pharmacy.nv.gov' <cnally@pharmacy.nv.gov>
Subject: RE: Liability Insurance
Importance: High

Hello Candy,

I looked at today's agenda for the board meeting and our name is not on there. Can you please confirm we are on the agenda and our license will be processed.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
https://protect-us.mimecast.com/s/vCcYCNkGgZCEmQL9Cm6riJ?domain=kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Friday, November 6, 2020 8:14 AM
To: 'Candy Nally' <cnally@pharmacy.nv.gov>
Cc: Kristopher Mangosing <kmangosing@pharmacy.nv.gov>
Subject: RE: Liability Insurance

Good Morning Candy,

I did send the insurance but here it is again. Please let me know if you have any questions.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
https://protect-us.mimecast.com/s/vCcYCNkGgZCEmQL9Cm6riJ?domain=kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Candy Nally <cnally@pharmacy.nv.gov>
Sent: Thursday, November 5, 2020 6:12 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Cc: Kristopher Mangosing <kmangosing@pharmacy.nv.gov>
Subject: FW: Liability Insurance

[External Email - Use Caution]

We still have you on the agenda for December. Please provide us with a copy of the insurance. I don't work on Fridays in case you have any questions.

Hope everything is okay with your family.

Thanks,

Candy M. Nally
Licensing Specialist
Nevada State Board of Pharmacy

cnally@pharmacy.nv.gov

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-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Friday, October 30, 2020 6:00 AM
To: Candy Nally <cnally@pharmacy.nv.gov>
Subject: Liability Insurance

Hello,

I got your voicemail yesterday and I'm so sorry for the delay in response. I had a family emergency which resulted in a trip to the ER.

I hope that there is a way to still accept this COI. Please let me know.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
https://protect-us.mimecast.com/s/vCcYCNkGgZCEmQL9Cm6riJ?domain=kinexmedical.com

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800-845-6364 ext. 7370
techsupport@kinexmedical.com <mailto:%20techsupport@kinexmedical.com>

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EXHIBIT 6

EXHIBIT 6

From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Thursday, February 25, 2021 9:38 AM
To: 'Mark I. Sedar'
Subject: RE: Liability Insurance
Attachments: 2021.1.29 - ALL_MDEG_AdministratorForm rev.2.pdf

Importance: High

Hello Mark,

I'm following up again on my request for a temporary license.

Also, I looked at the agenda for next month's meeting and we are listed on there as possible action. Can you please explain to me what that means?

12. Application for Nevada Medical, Devices, Equipment and Gases License – Appearance (**FOR POSSIBLE ACTION**)

A. Aircare Medical Inc. – Henderson, NV
B. Barber DME Supply Group – Nellis AFB, NV
C. Kinex Medical Company – Las Vegas, NV
D. Patients Choice LLC – North Las Vegas, NV
E. VieMed – Reno, NV

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Tuesday, February 23, 2021 11:57 AM
To: Mark I. Sedar
Subject: FW: Liability Insurance
Importance: High

Hello Mark,

I'm follow up again on this. Can you please let me know what you need in order to issue us a temporary license.

Thank you,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Wednesday, February 17, 2021 4:50 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: FW: Liability Insurance
Importance: High

Hello Mark,

I'm following up again regarding the issuance of the temporary license. Please provide a status update.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Friday, January 29, 2021 2:29 PM
To: 'Mark I. Sedar' <msedar@pharmacy.nv.gov>
Subject: RE: Liability Insurance
Importance: High

Good Afternoon Mark,

Attached is the MDEG administrator form filled out for Saundra Sorenson.

Please let me know if there is anything else needed in order to obtain our temporary license.

Thank you,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, January 28, 2021 11:19 AM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Liability Insurance

[External Email - Use Caution]

Please see the regulation below.

NAC 639.694 Administrator required. (NRS 639.070)

1. Except as otherwise provided in subsection 4, 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:

(1) At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or

(2) 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.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R033-09, 10-15-2010)

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

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-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Thursday, January 28, 2021 8:56 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: Liability Insurance

Hello Mark,

Is that the person who is physically managing this site or can that be a manager out of state?

Leann Wilhelm, CHC

Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, January 28, 2021 10:53 AM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Liability Insurance

[External Email - Use Caution]

Hello Leann,

Can you please confirm who is the MDEG Administrator for the facility? I do not see the MDEG Administrator form as part of your application.

Thank you,

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

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-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Thursday, January 28, 2021 6:56 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: FW: Liability Insurance

Importance: High

Hello Mark,

I have not heard back from you regarding our temporary license. Can you please let me know what other information you need from me or when we can expect this license.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Wednesday, January 20, 2021 4:50 PM
To: 'Mark I. Sedar' <msedar@pharmacy.nv.gov>
Subject: RE: Liability Insurance

Hello Mark,

I appreciate you letting me know about the process, I was unaware.

Yes, I would like to request a temporary license. If this works I would like to let this email serve as my request for a temporary license at;

5985 Hauck Street, Unit 107
Las Vegas, NV 89118

If there is anything else you need to process this request, please let me know.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Wednesday, January 20, 2021 3:42 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Liability Insurance

[External Email - Use Caution]

Leann,

I completely understand your situation, and please note that Candy has no authority over the board agenda schedule. Notification to appear before our board is mailed out 21 days before the scheduled meeting date. Applications are assigned to board agendas based on the earliest applications first with precedence to NV locations.

You are welcome to send in a request for a temporary license via email.

Thank you,

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

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-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Wednesday, January 20, 2021 1:01 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: Liability Insurance
Importance: High

Mark,

We submitted this application back in August and have been waiting since then. I was assured by Candy in November that this was on the agenda. I cannot wait until March to obtain an application.

I understand that there have been cuts to staff and agenda due to COVID, but when I was told this would be on the agenda and I get on a virtual meeting for a board meeting and sit through it only to find out we aren't on the agenda is very upsetting.

We as a business have been licensed for years in the state of NV and now trying to work out of a location closer to the physicians who are needing these products for their patients is proving to be unobtainable.

What can be done to expedite the issuance of this license?

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Wednesday, January 20, 2021 1:45 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Subject: RE: Liability Insurance

[External Email - Use Caution]

Good morning Leann,

Concerning your email to Candy Nally below, please note that due COVID restrictions, our board meetings were reduced in 2020 by 6 days. The lost days have impacted the number of appearances that we can assign to our board meetings. We are currently creating our agenda for the March Board Meeting, and I will consider your application.

Thank you,

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

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-----Original Message-----
From: Candy Nally <cnally@pharmacy.nv.gov>
Sent: Wednesday, January 20, 2021 10:19 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: FW: Liability Insurance
Importance: High

-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Tuesday, January 19, 2021 2:32 PM
To: Candy Nally <cnally@pharmacy.nv.gov>
Subject: FW: Liability Insurance
Importance: High

Hello Candy,

I still do not believe I have received a response from you. If there's someone else I should contact regarding our license, please let me know.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Friday, January 15, 2021 7:11 PM
To: 'cnally@pharmacy.nv.gov' <cnally@pharmacy.nv.gov>
Subject: FW: Liability Insurance
Importance: High

Hello Candy,

Can you please let me know why our company was not on the agenda for the most recent meeting? You had previously informed me that we were on the agenda for December. I attended the meeting this week and we were not on the agenda.

Please let me know how this can be addressed.

Leann Wilhelm, CHC
Compliance Officer
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Direct: 262-521-7338
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For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Wednesday, January 13, 2021 11:01 AM
To: 'cnally@pharmacy.nv.gov' <cnally@pharmacy.nv.gov>
Subject: RE: Liability Insurance
Importance: High

Hello Candy,

I looked at today's agenda for the board meeting and our name is not on there. Can you please confirm we are on the agenda and our license will be processed.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
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For Technical Support please call or email:
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techsupport@kinexmedical.com

-----Original Message-----
From: Leann Wilhelm, CHC
Sent: Friday, November 6, 2020 8:14 AM
To: 'Candy Nally' <cnally@pharmacy.nv.gov>
Cc: Kristopher Mangosing <kmangosing@pharmacy.nv.gov>

Subject: RE: Liability Insurance

Good Morning Candy,

I did send the insurance but here it is again. Please let me know if you have any questions.

Leann Wilhelm, CHC
Compliance Officer
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techsupport@kinexmedical.com

-----Original Message-----
From: Candy Nally <cnally@pharmacy.nv.gov>
Sent: Thursday, November 5, 2020 6:12 PM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Cc: Kristopher Mangosing <kmangosing@pharmacy.nv.gov>
Subject: FW: Liability Insurance

[External Email - Use Caution]

We still have you on the agenda for December. Please provide us with a copy of the insurance. I don't work on Fridays in case you have any questions.

Hope everything is okay with your family.

Thanks,

Candy M. Nally
Licensing Specialist
Nevada State Board of Pharmacy
cnally@pharmacy.nv.gov

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-----Original Message-----
From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Friday, October 30, 2020 6:00 AM
To: Candy Nally <cnally@pharmacy.nv.gov>

Subject: Liability Insurance

Hello,

I got your voicemail yesterday and I'm so sorry for the delay in response. I had a family emergency which resulted in a trip to the ER.

I hope that there is a way to still accept this COI. Please let me know.

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
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techsupport@kinexmedical.com <mailto:%20techsupport@kinexmedical.com>

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EXHIBIT 7

EXHIBIT 7

NV Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, NV 89521

3/15/2021

Re: Addendum to MDEG Administrator Form

Dear Board Members,

This letter is to outline the discrepancies that were submitted on the MDEG administrator forms dated January 29th 2021 and March 4th 2021. Both of these reflected incorrect work history for Saundra Sorenson. I would like to provide explanation as to how this information was believed to be accurate by Ms. Sorenson.

Prior to February 2019 Kinex Medical Company and Gabel Distributors entered into a 1099 relationship in which Kinex equipment was dispensed to patients by Gabel Distributors. February 2019 Kinex and Gabel Distributors termed this 1099 relationship and at that time Kinex took over the lease to the Hauck street location as well as transitioned several of Gabel Distributors employees to become Kinex W2 employees.

In June 2019 Saundra Sorenson relocated from the Kinex location in Colorado to the location at Hauck Street in Las Vegas. During this time the transition from Gabel Distributors to Kinex Medical Company at the Hauck Street location was still in progress. Kinex has always referred to that location as the Gabel office. When Ms. Sorenson came to that location the terminology was skewed due to the transition and the former owner of Gabel Distributor being on-site very routinely.

There was no ill-intent to the information that Ms. Sorenson provided to the board as she believed the information to be accurate.

The work history in the MDEG administrator form dated March 15th 2021 is accurate and complete per the knowledge of Kinex Medical Company and Saundra Sorenson.

Regards,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 3/12/2021

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be 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.
4. Be employed be 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
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

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 dates after the beginning of the employment.

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.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Durable medical equipment supplier

Nature of MDEG

Kinex Medical Company, 5985 Hauck Street, Unit 107, Las Vegas, NV 89118

Name and Address of Business for Which MDEG Administrator Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Sorenson	Saundra	Lynn
Last Name	First Name	Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted]Crested Moss Ave	North Las Vegas	NV 89081
Present Residence Address-Street or RFD	City	State/Zip

5985 Hauck St, Unit 107	Dates	Las Vegas	NV 89118
Present Business Address		City	State/Zip

Office Manager	Dates	02/2020 - Present
Present Position with the MDEG		

Phone: [redacted] Fax:

Email address: saundra_sorenson@kinexmedical.com

[redacted]	Denver, CO		
Date of Birth	Place of Birth (City, County, State)		
53	[redacted]		Female
Age	Social Security Number or ITIN		Sex

Green	Brown	165	5'4"
Color of Eyes	Color of Hair	Weight	Height

Scars, tattoos or distinguishing marks and/or characteristics No

Are you a citizen of the United States? (Yes) No

If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

March 11, 2020

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

02/2011 Total Orthopedics, Inc - 4700 S. Wadsworth Blvd, Littleton, CO 80123 FT (2,000/yr)

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Office Manager	Coordination of orders with service reps	Jim Martin
Title	Description of Duties	Name of Supervisor

08/2017 Kinex Medical Company - 4700 S. Wadsworth Blvd, Littleton, CO 80123 FT (2,000/yr)

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Office Manager	Coordination of orders with service reps	Lynn Michalski
Title	Description of Duties	Name of Supervisor

06/2019 Kinex Medical Company - 5985 Hauck St, Unit 107, Las Vegas, NV 89118 FT (2,000/yr)

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Office Manager	Coordination of orders with service reps	Lynn Michalski
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

I have ☚ I have not ☚ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☚ I have not ☚ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ☚ I have not ☚ been the subject of an administrative action whether completed or pending.
3. I have ☚ I have not ☚ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

a) Board Administrative Action: State:_____

b)

Date: _____

Case Number: _____

c) Criminal Action: State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG? Yes ☚ No ☚

5 .Will you be employed fulltime with the MDEG? Yes ☚ No ☚

6 .Will you be present at the site of the MDEG during its normal operating hours? Yes ☚ No ☚

If you answer No to questions 4, 5 or 6 please provide a written letter of explanation.

ATTA H

TAK

30

Date of photograph 3/4/2021

I, Saundra Sorenson, 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 case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant “Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent,” and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

Saundra Sorenson

.....

Original Signature of Applicant

TRANSCRIPT OF AUDIO-RECORDED

MEETING OF THE

KINEX MEDICAL COMPANY PHARMACY BOARD

APRIL 2021

Litigation Services Job Number: 825894

MALE 1: Kinex, hopefully.

MS. PARK: Okay. We'll go back to Kinex.

MS. JACOBO: Um, [inaudible].

MALE 2: What number were they?

MALE 1: 15.

MALE 2: 15. [inaudible].

MS. JACOBO: Okay. She just called in. Perfect. Let me unmute her phone. We'll just give her a few seconds.

MS. PARK: Sure.

MS. SORENSON: Can you hear me?

GROUP: Yes.

MS. PARK: We can hear you.

MS. SORENSON: Okay. I'm so sorry.

MS. JACOBO: All right. So I think the -- the question we have for you before we, um, moved on to the, uh, last agenda item was, uh, for Ms. Sorenson [ph].

Uh, Ms. Sorenson, there was a list of MDEG products that, uh, Kinex will be providing to patients, and as the MDEG administrator, what kind of experience do you have with those products?

MS. SORENSON: Um, I've cleaned them. I know the gist of [inaudible] and what they're for. And that they're prescribed after, like, [inaudible].

Prescribed after a total [inaudible] pain management.

MS. JACOBO: Okay. Um, so, in your application, you mentioned you're doing orthotics, as well. And I don't know if, uh, Mr. Buckholdt -- if you mentioned that. Uh, do you have experience with orthotics?

MR. BUCKHOLDT: Off-the-shelf orthotics. These are not custom-fabricated products.

MS. JACOBO: Okay.

MS. SORENSON: [inaudible] prescribed them.

MALE 1: Okay. Got anything else to add?

MS. JACOBO: I do not have anything else.

MALE 1: All right.

MS. PARK: Okay. So I think where we're at, um, or -- in terms of the services that you offer, certainly we see value in those services for the patients here in Nevada. You can imagine our concerns are more so along the lines of, um, following our -- our laws, our licensing, and -- and so forth.

So I think, um, and I look towards the other members of the Board to kind of get a sense of what they may be thinking. Um, maybe it's something we can consider, um, with additional conditions, potentially with licensing if you were to pull their licensing. I don't -- I don't know where we're at and so, just [inaudible] --

MALE 2: Madam President, ma- -- may I -- may I speak?

MS. PARK: Absolutely.

MALE 2: Uh, if they're not licensed, this board has no jurisdiction over them to discipline them for not ceasing and desisting. Am I right about -- for discipline, I'm saying, uh, fines or anything like that. But -- but -- but --

MALE 1: But -- Okay.

MALE 2: -- wait a minute, let -- hear me out. But -- so, if we had -- had no jurisdiction over them because they're not licensed, is there -- before this even -- if it gets to motion, before even possibly gets there -- is there anything that could be -- once you give them the license, now you -- we've licensed them.

Now they can -- now we can discipline in the same breath. Is -- I mean, it's never happened before, but I'm just curious.

MALE 1: No, it's happened before. No, you have it right. So you're disciplining them for unlicensed practice, which you have jurisdiction over. But you wouldn't then rediscipline them, though.

But I think what Helen was talking about, which is not discipline, is we have the outstanding issue of

the relationship. Maybe some additional inspections to make sure they're following other laws would be some of the conditions you could put on it.

MALE 2: I see. Okay.

MS. SORENSON: [inaudible] I think this is probably clear to the Board. But they -- Kinex does have a DME license issued by your Board tied to its Wisconsin location.

MALE 1: Correct.

MS. SORENSON: So.

MR. MITCHELL: I've got a -- I've got a question and I'd like to share my thoughts. Uh, I haven't said anything either last meeting or this meeting as Wayne mentioned for the record.

Mr. Buckholdt, when you were describing, uh, services provided, uh, you indicated that, uh, DVT prevention was going to be involved.

MR. BUCKHOLDT: Yes.

MR. MITCHELL: Can you, uh, expound on that a little bit for me?

MR. BUCKHOLDT: Sure. So it's not uncommon for some doctors to get surgeons [ph] to prescribe portable DVT prophylaxis. So there's a project called VenaPro, for example, which is mechanical compression battery operated through a calf muscle pump.

Um, usually within the first 14 days following lower extremity surgery when people are more at risk for DVT. So pro- -- products like that.

MR. MITCHELL: Okay.

MR. BUCKHOLDT: Mechanical compression DVT.

MR. MITCHELL: Is it like a -- it's like a portable SeQual machine or something, or --?

MR. BUCKHOLDT: So it's, you know, this one is a -- is a small calf pump, you know?

MR. MITCHELL: Okay.

MR. BUCKHOLDT: You know, so, there's a pad that wraps around the calf. You know, it compresses the gastroc muscle, you know, in order to push the blood through the Saphenous vein back up toward the heart to prevent any clotting or anything like that.

So when physicians aren't using chemo, um, phylaxis, you know, or are treating through blood thinners -- and who prefer to use compression through DVT -- it's not uncommon for them to order products like that, you know, through us to be delivered, you know, to a home in conjunction with other products.

MR. MITCHELL: Okay. Thank you. Yeah, I just -- I was, you know, I know CPMOs, older technology, so, this is good information. I really appreciate that.

MR. BUCKHOLDT: You're welcome.

MR. MITCHELL: Okay. So let me think out loud a little bit. Trying to absorb a lot of the things that were going on here with Kinex. Uh, I'm concerned about a lot of inconsistencies. That's my biggest thing.

And so the inconsistencies, I hate to say this, and I probably shouldn't, but I'm willing to, uh, will translate into some trust issues. Uh, the start of the last meeting when we had the MDEG administrator who didn't remember who she worked for when. Uh, that apparently has been clarified to a limited extent.

But I don't think that that still absolves that whole question. It was one of the fellow Board members, actually, asked that question at the last meeting. Who is writing your paychecks? I think it's a legitimate question. And so we're getting all that.

And then, I'm looking at this letter, uh, dated from Leanna [ph] on 3/15. And it goes back and it -- and we've got this crazy relationship -- we have an unusual relationship. A 1099 between Gable [ph] and Kinex.

And, clearly, in this letter, it says in February of 2019, uh, that relationship was dissolved. Then we hear that they're doing billing from both sides. If their relationship is dissolved, what is that all about?

In their defense, Kinex says, well, COVID hit. COVID hit February 2020, not 2019. Um, so, there's just -- there's a lot of things that bother me about this. And I don't know if my fellow Board members have any input on that or not.

MS. PARK: I think you summed it up very nicely.

MALE 1: Yes.

MR. MITCHELL: Yeah, this is what I'm thinking. It's like, what's really going on here?

And I understand trying to take care of the patients, um, I'm a big advocate of that and that you have to say, okay, look, we're going to take care of our patients, we're going to call the Board staff and say, look, we got this thing messed up. We want to take care of our patients.

And the Board staff is not -- is going to make a temporary license arrangement or something else. They're also, uh, clinical professionals. They're not going to shut anybody down over that. But none of this is -- there's just too many inconsistencies. That's what I'm having a problem with. So that's my two cents. Thank you.

MS. PARK: Thank you.

MALE 3: I share the same sentiment. And I'm also a big advocate of taking care of the -- you know,

taking care of the patient. Um, I share, uh, the same sentiment. Doesn't mean that I am not willing to give them a license, uh, with, um, restrictions, um, that is my -- that's my three cents.

[all laughing]

MS. PARK: Okay.

MS. JACOBO: So my whole question is the whole -- they acknowledged that, you know, their relationship was dissolved in 2019 --

MR. MITCHELL: Correct.

MS. JACOBO: -- and they continued to practice and didn't request a temporary license until January.

MR. MITCHELL: Right.

MS. JACOBO: That's like a whole nine months. So acknowledging that you were performing an activity, or unlicensed activity.

MR. MITCHELL: Right. And now we got that whole thing about -- well, some insurances are with Gable -- were invoicing on Gable, uh, letterhead.

And we know that you can't have, uh, two companies both licensed in the same location, so, we know that. That's -- that almost sounds like that's going on here, too.

MS. JACOBO: I think the line of demarcation is very, very fuzzy.

MR. MITCHELL: Mm-hmm.

MS. JACOBO: With these companies, especially with the third parties, the -- I don't think they can tell, like, that these are two separate entities.

MR. MITCHELL: Right. I don’t know.

MS. PARK: Did Gable move to another location here in Nevada?

MALE 1: Yes.

MS. PARK: So it's not like they couldn't just probably distribute out of that location. It doesn't necessarily have to be at their old Hauck Street is my --

MALE 1: Yeah. Well, I mean, I don't --

MS. PARK: Yeah.

MALE 1: I -- I think that subcontracting is -- is -- for tons of different things -- is a common occurrence.

MR. MITCHELL: Yes.

MALE 1: We all do that. But I guess we would have to be in there to really look at it. I -- I do think that we would be able to have a sense of it, um, if we went and looked at it.

MALE 2: Gable is currently licensed with us as an MDEG at a separate location.

MR. MITCHELL: Okay. So that leaves the question:

are they providing services out of Kinex location on Hauck Street and billing out of the Gable location?

MALE 2: We don't know the answer to that, again, they're saying that they subcontracted out and that that was Gable's responsibility if we move forward with looking at that --

MR. MITCHELL: Okay.

MALE 2: We'll be talking to Gable, too.

MR. MITCHELL: All right.

MS. JACOBO: So yes. We see that as a separate issue. But I do like, um, President Park's idea about, um, like, in general --

MS. PARK: Restrictions?

MS. JACOBO: Well, restrictions and perhaps inspections just to make sure that we're following up on other --

MS. PARK: I think what -- the sense I get, at least, from Mr. Buckholdt, is that he recognizes that there's been a series of collapses in terms of just all of these -- these things that Mr. Mitchell just highlighted. Every single one is problematic.

And I get the sense that he understands why it's problematic and that there is a number of issues that certainly need to be addressed, um, and what, um, what I think is just giving -- trying to think of a path

forward. Right?

So knowing that these things have occurred, and we have acknowledgement from Kinex through Mr. Buck- -- uh, Buckholdt that these are problematic and that those will be addressed. And so you know, and I'm thinking about the patients, too, that are out there.

And, um, if we are to consider moving forward, then we would have to look very closely at Kinex, which I think is understandable based on, you know, our interactions to date. To make sure that they are, you know, operating within the law.

That they're doing what they're supposed to be doing. And I think that's, um, that's an -- an option for the Board to consider, you know, in terms of moving forward.

MR. TOMASSO: I understand what you're saying, that you're saying don't do it again. That's what you're doing. When you're com- -- somebody say, okay, we're going to give you a license, but don't do it again.

I think that this Board's going to vote that they're going to give them the license. That this board has to make them pay the penalty for what they did do. I think that was egregious, what they did in our state.

[talking over each other]

MALE 2: They did. They'll pay -- they paid a fine back to the state that doesn't come to us. $5,000, Brett or Courtney [ph]?

MS. LEE: Yes.

MALE 2: They paid [inaudible] --

MR. TOMASSO: And how about probation, too, or something like that? It's got to be -- you got to put something [inaudible] -- you got to -- there has to be something other than $5,000.

MS. LEE: [inaudible].

MALE 3: We will, we just have to, you know, and that's what I was going to ask next. [inaudible] and if you don't want it or if you want it to be more restrictive, you know, plea- -- you know, please. Yeah.

MALE 2: [inaudible] going down a path of additional inspections at the cost of the licensee and then they will open their doors to us and we will, uh, take a very hard look at their model. Beyond the issues that were here during this inspection process.

MR. TOMASSO: Okay. I said all I'm going to say.

MS. PARK: Yeah. I -- it's -- I -- I hear what you're saying, Mr. Tomasso.

MALE 2: [inaudible].

MR. TOMASSO: No, that was it.

[all laughing, talking over each other]

MS. PARK: All right. I think this is -- I appreciate the, uh, the feedback from Board members. This is a very difficult and unusual, um, situation.

MR. ZAKARIASSEN: And I'll just throw my feelings in there, too. I think that, uh, Mr. Buckholdt took the onus to correct things.

Um, it seemed to me that, uh, you know, his strong wording is, you know, this will never happen again, we are going to do this. So he's taking some definitive, positive steps to do this.

I don't know if the additional inspection process will get a feel for that, but, uh, you know, I feel that -- that, uh, you know, somebody just took ahold of this by the reins and said, you know, I'm -- I'm -- I'm going to make sure that this doesn't happen again, but yeah. I think there was some positive leadership there with him. And, um, that's, uh, that's my opinion.

MS. PARK: Thank you, Mr. Zakariassen. And I think, um, if the Board should move forward with, uh, granting the, um, the license with restrictions, it's going to be, you know -- just the expectation will be that, you know, we're not going to be in this

situation once again.

And the standards, they are -- are going to be, uh, closely watched, uh, and monitored. I guess I'd ask Board staff what types of, um, in terms of restrictions or how we can keep a closer look on Kinex should the Board decide to approve a license.

[talking over each other]

MALE 2: Well, uh, to answer Dick's [ph] concern, I -- I think we can put the -- the license could be on probation. I mean, you can give a -- a probationary license. Right? So we can address Dick's thing.

You can -- and then, the conditions of that probation would be, uh, something like quarterly inspections for a year at the cost of them. And then, if something -- if something comes out, we would go the show-cause route.

Um, I think that -- I'll -- I'll leave it to Brett or Courtney that you could -- being under probationary status, we still would just do the show-cause or we would just revoke the license or if we find something in the inspections that doesn't need to [inaudible] --

MALE 1: We'd have to -- well, I think we'd have to bring charges.

MALE 2: Okay. So yeah. Sometimes, we can say --

we do this kind of with the temporary license. We're going to give you the license, but if the board says no, then it dissipates immediately.

So I think I would -- we would properly would go through the show-cause and we'll bring back what we find during the inspection and say this isn't a safe practice for Nevada. It isn't following Nevada law. So I think you can get to where Dick was with the probation.

MR. MITCHELL: I'm still troubled by -- going back to February 2019. And then we send a cease and desist which they don't do. Tho- -- I find -- that's what I'm saying. There's, like, a number of moving parts here that I'm still worried about and it paints a big picture.

MS. JACOBO: Can I just confirm that they continued to operate after they paid the fine?

MALE 2: Uh, yes, but to their point, it was just, you know, it was one visit by us after that which may actually be --

MS. JACOBO: According --

MS. PARK: Accordingly, for the record, I believe no. After they paid the fine on April 9th, we had an inspector out there on April 7th and they had ceased operations at that time.

MR. MITCHELL: Okay.

MS. PARK: So they paid the fines on the 9th. They received the cease and desist on March 13th or 16th per their representation. We sent it on March 8th. Um, we had an inspection on March 10th and March 25th. And they were still operating.

MS. JACOBO: [inaudible].

MALE 2: They stopped operating they said March 30th.

MS. PARK: That’s what this said.

MS. JACOBO: So when the inspector came on the 10th and the 25th, did they express at all that you guys are supposed to cease and desist? Or anything?

MALE 2: I think they'll answer, but there was confusion when we arrived over communication, I think, right Joe?

MR. DODGE: On the 10th --

MS. SORENSON: [inaudible] a quick comment about the timing. Um, I was -- so -- so, Kinex has, uh, has indicated right now we -- we mentioned the two different locations with March 13th and 16th.

So Kinex, uh, received notice, um, at least, um, on March 16th, um, they retained us by the -- the following Monday, which I think is March 22nd. And I did reach out to Ms. Lee. We had, um, some back and

forth and I think the inspection that happened, um, following the March 16th receipt of the letter was at the end of that week.

And Ms. Lee and I connected when, um, she was back in the office the following week on the 30th and that's when they, you know, confirmed that they were there.

So just to clarify that when Kinex received the letter, I did reach out to Ms. Lee, and it's no problem of Ms. Lee's, or anything.

I'm just making clear that I did reach out to Ms. Lee [inaudible] something [inaudible] happened to -- to immediately try to make contact and, um, and see what we could do. So that -- that March 25th inspection was -- was in between that period.

Um, so, it wasn't just that we -- that Kinex had not taken any, you know, concern or action in -- in that regard.

MALE 2: I asked a question to Joe, which we just have more experience with it. For -- so, we've done this model before where we do the additional inspections. So our success rate with the business either being pending or you walk out after you're feeling very comfortable with the business, what -- what's our ex- -- they don't always make it. But

what's our --

MALE 1: The majority make it and we feel very comfortable that we have a good handle as to what's taking place at the location.

Uh, most of the licensees at this point have taken the quarterly inspection process very seriously and understand that if they're not properly prepared for that inspection, they would lose their license. So it's been very successful at this point.

MR. DODGE: And I'll just make --

MALE 2: It's not much fun for the licensee.

MALE 1: It's not much fun for the licensee.

MR. DODGE: And I'll just make a quick comment to -- to Jade -- the question. So I'm the one that did the inspection on Mar- -- March 10th.

Uh, it wasn't really an inspection, it was just to confirm whether or not they were operating a business. I don't believe they had received the cease and desist at the -- at that site.

When I made my, uh, official visit on the 10th. So I was just confirming that they were operating. Which they were. Uh, Mr. Scheuber did the second visit on the 25th, uh, and Mr. Scheuber is ready, willing, and able to testify if necessary.

Um, but I believe the conversation that he had

with the staff members at that point were, are you aware that you should not be operating and that you received a cease and desist? They said, we don't know anything about a cease and desist at the location here in Las Vegas.

Um, we haven't received any information from our corporate office that we should not be operating. And just to confirm -- Ms. Lee sent the cease and desist to both the local office and the corporate office in Wisconsin?

MS. PARK: That is correct.

MS. JACOBO: That was sent March 8th. Were they emailed --

[talking over each other]

MALE 2: That's just confirming that if -- if we think there's a risk to the -- to the, uh, colleague, we have the ability to take action.

MALE 3: I'm the [inaudible] for second chances.

[all laughing]

MALE 3: I -- you know, again, um, I do believe, um, that Nevada residents, um, you know, need their practice, but, you know, um, so, but we do need to, um, give them -- you know, to make sure that they're going to be following, uh, you know, the rules.

So I'm open to whatever suggestions, you know,

the Board members, um, would like. Uh, in addition to being on probation and doing the, uh, quarterly, um, inspections. If there are -- if there is anything else, um, that, uh, any Board member, uh, requires.

MS. PARK: An- -- another thing I thought about is, um, perhaps a detailed corrective action plan. So knowing all of the, uh, deficiencies or concerns that were noted during this meeting, you know, we could ask, um, Kinex to, line by line, kind of tell us what their plan --

MR. MITCHELL: I like that. I like that. [talking over each other]

MS. PARK: Root cause analysis.

MALE 3: Well, Y- -- y- -- you know, it's like being on, you know, on Joint -- Joint Commission -- Joint Commission or, you know, [inaudible] there's a plan of correction. You know what?

That's actually a very good idea. And then -- and then they can say, you know, when to expect to be in compliance.

MS. PARK: Yeah.

MALE 3: So that's a very -- that's actually a very good idea.

MS. PARK: [inaudible] they know what the issues are, they recognize why [inaudible] and then, most

importantly, exactly how it's not going to happen again and what they're doing in response to it. Is that something, Board staff, that we could --

MALE 2: Yeah, I would just look at the inspection process for the record when you're doing discipline, or those kinds of things, you have certain things that you can reach for for discipline.

MS. PARK: Sure.

MALE 2: This is not discipline. This is conditional licensure. So it broadens your ability to be able to put conditions on a license.

MS. JACOBO: When would you like them to provide [inaudible]?

MALE 1: Uh, quarterly inspection.

MALE 2: I make the suggestion that they do it within ten days --

[talking over each other]

MALE 2: Then Joe can talk to them about that.

MS. PARK: Yeah. So we have quarterly inspections for one year at their expense.

MALE 1: And then the review of that action plan.

MS. PARK: Within ten days. And the action plan within ten days [review and quarterly inspection ?].

MALE 1: [inaudible] during the inspection. Yeah.

MS. JACOBO: So I move that we approve MDEG

application for Kinex Medical, uh, upon the condition of one year's probation in which the company will be subject to quarterly inspections at the cost of the company.

Um, also we will require an action plan and root cause analysis as to, um, why the company was operating unlicensed since 2019.

Um, how they plan on moving forward and line by line how they're going to take preventative action in the future to prevent that from happening both here and at other boards, um, and of course, um, Board staff will review that root cause analysis.

MS. PARK: Can you say within ten days?

MS. JACOBO: Within ten days.

MS. PARK: All right. We have a motion. Is there a second?

MR. TEJERO: I second.

MS. PARK: Okay. Motion by Ms. Jacobo. Second by Mr. Tejero. Any further discussions?

MALE 1: The inspections are at their expense.

MS. PARK: Yes. The inspections [inaudible]. Okay, hearing that, all those in favor?

[ayes]

MS. PARK: Any opposed?

MR. TOMASSO: Nay.

MS. PARK: All right. The motion -- the ayes have it, so the motion passes and, um, I recommend [inaudible] Mr. Buckholdt [inaudible] contact and work closely with the Board staff. I think you will find that they will be a very good resource for you, um, moving forward.

MS. SORENSON: Um, could you just clarify that -- that it's approved as of today that the condition that we comply, including the action plan within ten days and so on, so that Kinex may -- may operate? I -- I just didn't want there to be any misunderstanding.

MALE 1: You need an inspection.

MALE 2: You need an inspection beforehand --

MALE 1: Yeah.

MS. SORENSON: Okay.

MALE 2: -- so, you can reach out to Board staff, uh, later today to schedule that inspection.

MS. SORENSON: Okay. Thank you.

MS. PARK: Okay. Uh, thank you. And with that, we're going to break for lunch.

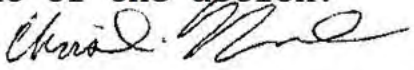
MALE 2: Oh, can we do one more?

MS. PARK: Oh, one more.

MALE 2: I pushed your lu- --

I, Chris Naaden, a transcriber, hereby declare under penalty of perjury that to the best of my ability the above 24 pages contain a full, true and correct transcription of the tape-recording that I received regarding the event listed on the caption on page 1.

I further declare that I have no interest in the event of the action.



December 1, 2021

Chris Naaden

(April 2021 Kinex Medical Co. Pharmacy Board Meeting)

HEALTH INFORMATION PRIVACY & SECURITY: CAUTIONARY NOTICE

Litigation Services is committed to compliance with applicable federal and state laws and regulations (“Privacy Laws”) governing the protection andsecurity of patient health information.Notice is herebygiven to all parties that transcripts of depositions and legal proceedings, and transcript exhibits, may contain patient health information that is protected from unauthorized access, use and disclosure by Privacy Laws. Litigation Services requires that access, maintenance, use, and disclosure (including but not limited to electronic database maintenance and access, storage, distribution/ dissemination and communication) of transcripts/exhibits containing patient information be performed in compliance with Privacy Laws. No transcript or exhibit containing protected patient health information may be further disclosed except as permitted by Privacy Laws. Litigation Services expects that all parties, parties’ attorneys, and their HIPAA Business Associates and Subcontractors will make every reasonable effort to protect and secure patient health information, and to comply with applicable Privacy Law mandates, including but not limited to restrictions on access, storage, use, and disclosure (sharing) of transcripts and transcript exhibits, and applying “minimum necessary” standards where appropriate. It is recommended that your office review its policies regarding sharing of transcripts and exhibits - including access, storage, use, and disclosure - for compliance with Privacy Laws.

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Kristopher Mangosing

To: Joe Dodge
Subject: RE: Items Requested

From: Dove, Kelly <kdove@swlaw.com>
Sent: Tuesday, May 11, 2021 12:46 PM
To: Joe Dodge <j.dodge@pharmacy.nv.gov>; Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Cc: Mike Buckholdt <Mike_Buckholdt@kinexmedical.com>; Kenneth C. Scheuber <KSCHEUBER@pharmacy.nv.gov>; Courtney K. Lee <c.lee@pharmacy.nv.gov>; David Wuest <dwuest@pharmacy.nv.gov>
Subject: RE: Items Requested

Hello Joe,

I am writing in response to your request for additional information.

(1) Explanation as to why the site continued to provide service to patients through April 16, 2021.

As a preliminary matter, based on the context of your request in which you call the Hauck Street location "the site" as distinguished from the requests below where you refer to the "off-site storage area," we interpret this question as referring to the Hauck Street location. Please let us know if we are incorrect in that interpretation so we may amend our response accordingly.

The Hauck Street location was closed on March 30, 2021 and no one provided services on site or directly from the site following that date, though products were taken from the site on or around March 30 to fulfill orders. Following March 30, the site was not open to the public and employees were not working at the site. As Mr. Buckholdt testified at the April Board meeting, following Kinex's receipt of the March 16 cease and desist letter, Kinex did continue to deliver certain prescribed and ordered products and services directly to doctors and patients who were post-surgical or otherwise expecting those products and services because he was concerned about the patient safety implications of failing to fulfill those orders and leaving those doctors and patients in the lurch. The products and services provided were handled remotely by a small number of setup people from storage or as they had already had some products in their vehicles. Kinex ceased all such activity immediately following the April 15th Board meeting and Kinex has provided no products or services of any kind since April 16, 2021.

(2) Address of the off-site storage area

6075 W. Wigwam Ave, Unit A089
Las Vegas, NV 89139

(3) Who has knowledge of and access to the off-site storage area

The following information is to the best of our knowledge.

Knowledge of the storage area:
Mike Buckholdt
Leann Wilhelm
Saundra Sorenson
Audra Foust
Charlie Rivero

Access to the storage area:
Saundra Sorenson
Anthony Adams
Joseph Palmer
Colton Tenney (no longer employed by Kinex)

(4) The purpose of the off-site storage area

The purpose of the off-site storage area was to store products and access products while the Hauck Street location was closed to the public and employees.

(5) Whether or not patients received services directly from the off-site storage area

Consistent with the above responses, no patient was directly serviced from the off-site storage area except in the sense that setup people delivered products to patients, some of which had been stored at the off-site storage area. Patients were set up with the products in their homes on in a facility upon discharge – not at Hauck Street or the off-site storage area.

Please let us know if there is any other information Kinex can provide or if you have any additional questions about the above.

Thank you again,
Kelly

Kelly H. Dove | Snell & Wilmer L.L.P. | P: (702) 784-5286 | F: (702) 784-5252

From: Joe Dodge <j.dodge@pharmacy.nv.gov>
Sent: Thursday, May 6, 2021 10:46 AM
To: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Cc: Mike Buckholdt <Mike_Buckholdt@kinexmedical.com>; Dove, Kelly <kdove@swlaw.com>; Kenneth C. Scheuber <KSCHEUBER@pharmacy.nv.gov>; Courtney K. Lee <c.lee@pharmacy.nv.gov>; David Wuest <dwuest@pharmacy.nv.gov>
Subject: RE: Items Requested

[EXTERNAL] j.dodge@pharmacy.nv.gov

Thanks for the submission. I will review the documents and let you know if I have any questions.

Please submit the following information request that we discussed earlier in the week at the site:

(1) Explanation as to why the site continued to provide service to patients through April 16th, 2021.
(2) Address of the off-site storage area
(3) Who has knowledge of and access to the off-site storage area (as a reminder all of the employees that were present for the inspection stated that they didn't know the address of the location)
(4) The purpose of the off-site storage area
(5) Whether or not patients received services directly from the off-site storage area

Thanks,

Joe Dodge, Pharm D
Inspector

Nevada State Board of Pharmacy
1050 E. Flamingo Ste E217
Las Vegas, NV, 89119

Office: 702.486.6420 Ext 157
Fax: 702.486.7903
E-mail: j.dodge@pharmacy.nv.gov
Web Page: www.bop.nv.gov

NOTICE: This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not establish an attorney-client relationship. This information does not override the specific provisions of Nevada law as applied to a particular set of facts.

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From: Leann Wilhelm, CHC <Leann_Wilhelm@kinexmedical.com>
Sent: Tuesday, May 4, 2021 5:06 PM
To: Joe Dodge <j.dodge@pharmacy.nv.gov>
Cc: Mike Buckholdt <Mike_Buckholdt@kinexmedical.com>; 'Dove, Kelly' <kdove@swlaw.com>
Subject: Items Requested

Hello Joe,

Thank you for your time today. Attached are the additional documents you requested. Please let me know if there is anything else needed.

Thank you,

Leann Wilhelm, CHC
Compliance Officer
Kinex Medical Company, LLC
Direct: 262-521-7338
Toll Free: 800-845-6364 ext. 7338
Fax: 866-588-8026
www.kinexmedical.com

KINEX

For Technical Support please call or email:
800-845-6364 ext. 7370
techsupport@kinexmedical.com

HIPAA PRIVACY NOTICE: The information contained in or attached to this email may be private, may contain Protected Health Information covered under the Health Insurance Portability and Accountability Act of 1996 (PL 104-191) and must be protected in

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway – Suite 206 • Reno, NV 89521

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

• Web Page: bop nv.gov

June 15, 2021

VIA EMAIL to counsel: lyn@lbeggslaw.com; kdove@swlaw.com

Michael Buckholdt
Saundra Sorenson
Kinex Medical Company
5985 Hauck Street # 107
Las Vegas, NV 89118

Kinex Medical Company
1801 Airport Road, Suite D
Waukesha, WI 53188

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada at storage unit

Dear Mr. Buckholdt and Ms. Sorenson:

The Nevada State Board of Pharmacy ("Board") has determined, based upon your admissions at Board meeting(s), documents submitted with your application, and/or inspections by Board's staff, that Kinex Medical Company ("Kinex") continued to engage in the business of furnishing medical devices in this State without a license after the initial cease and desist letter of March 8, 2021 (fine received on or about April 9, 2021), and after the date that the activity was represented to have ceased on March 30, 2021. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.233, NRS 639.288, NRS 639.310 and NAC 639.6944.

Kinex is hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST from engaging in the business of furnishing medical devices in this State from any unlicensed location. This letter shall serve as a CITATION pursuant to NRS 639.2895(2), for unlicensed operation of activity, including, but not limited to, transfer of equipment, *etc*., out of the Budget storage unit located at 6075 W. Wigwam Avenue, Unit A089, Las Vegas, NV 89139 from approximately April 1 – 16, 2021. The Board has assessed an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

Kinex 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.

Kinex has 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 letter. *See* NRS 639.2895(2).

Please be aware that the foregoing does not preclude a formal investigation or filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or c.lee@pharmacy.nv.gov.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

LAW OFFICES OF
LYN E. BEGGS
PLLC

June 29, 2021

Via Electronic Mail

David Wuest, Executive Secretary
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509
dwuest@pharmacy.nv.gov

Re: **Kinex Medical Company: Withdrawal of Application**

Dear Mr. Wuest:

This letter shall serve as notice that Kinex Medical Company ("Kinex") is withdrawing its previously submitted application for a Nevada Medical Device, Equipment & Gases ("MDEG") license as it has decided that it will no longer do any business in Nevada and is leaving the state. Kinex requests that consideration of the application be removed from the agenda for the Nevada State Board of Pharmacy's ("Board") upcoming meeting on July 15, 2021.

As described in the correspondence submitted by attorney Kelly Dove to the Board dated April 13, 2021, Kinex supplied durable medical equipment to patients in Nevada through its Nevada-licensed distributor, Gable Distributors, LLC, ("Gabel") for over twenty years. As previously explained, the two companies agreed to part ways in February 2019 which initiated the process of Gabel moving from the Hauck Street location in Las Vegas where the Kinex and Gabel and done business together. After Gabel was permitted to transfer its license to a new location, Kinex initiated the process to obtain an independent license for the Hauck Street location. Kinex's efforts were hampered by the state of emergency declared in Nevada by Governor Sisolak in March 2020 due to the pandemic and the application was not considered until earlier this year.

Due to the length of time that Kinex has done business in Nevada, it has a significant amount of durable medical equipment still in the state. Kinex is in the process of shutting down its Nevada business to leave the state completely. As Kinex closes all operations it will be required to recover all remaining equipment and ship it from Nevada to its headquarters in Wisconsin. Kinex intends

to complete this process as quickly as possible and wishes to notify the Board that any activities that Kinex is currently engaged in are solely for the purposes for removing all equipment from the State as expeditiously as possible.

We would respectfully request that the Board confirm that the application has been withdrawn at your earliest convenience. After submission of the fines associated with the recent Cease and Desist letters which will be provided submitted under separate cover, Kinex shall assume that all on-going matters with the Board shall be fully concluded. Should you have any concerns or questions regarding the withdrawal please do not hesitate to contact my office.

Sincerely,

Lyn E. Beggs, Esq.

cc: Courtney Lee, NVBOP General Counsel
Mike Buckholdt, Kinex Medical
Kelly Dove, Esq.

LAW OFFICES OF
LYN E. BEGGS
PLLC

RECEIVED
JUL 14 2021
NEVADA STATE BOARD
OF PHARMACY

July 13, 2021

Via USPS Priority Mail

Courtney Lee, General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

Re: Kinex Medical Company: Payment of Citation Fees

Dear Ms. Lee:

Please find enclosed two checks, each in the amount of $5,000.00, submitted in payment to satisfy the two Citations issued to Kinex Medical Company by the Nevada State Board of Pharmacy ("Board") on June 15, 2021, regarding alleged unlicensed activity. See Exhibit A. The payment of the fines in no way should be considered an admission by Kinex of any inappropriate activity.

As Kinex withdrew its application for a Nevada Medical Device, Equipment & Gases ("MDEG") license in writing on June 29, 2021, we shall assume that the enclosed payment of the citation fines shall conclude all business with the Board.

Should you require any additional information please do not hesitate to contact me.

Sincerely,

Lyn E. Beggs, Esq.

cc: Dave Wuest, NVBOP Executive Secretary
Mike Buckholdt, Kinex Medical
Kelly Dove, Esq.

M 316 California Ave #863 • Reno Nevada 89509 P 775.432.1918 F 775.473.3801 E lyn@lbeggslaw.com

EXHIBIT A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway – Suite 206 • Reno, NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
• Web Page: bop.nv.gov

June 15, 2021

VIA EMAIL to counsel: lyn@lbeggslaw.com; kdove@swlaw.com

Michael Buckholdt
Saundra Sorenson
Kinex Medical Company
5985 Hauck Street # 107
Las Vegas, NV 89118

Kinex Medical Company
1801 Airport Road, Suite D
Waukesha, WI 53188

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada at Hauck Street location

Dear Mr. Buckholdt and Ms. Sorenson:

The Nevada State Board of Pharmacy ("Board") has determined, based upon your admissions at Board meeting(s), documents submitted with your application, and/or inspections by Board's staff that Kinex Medical Company ("Kinex") has continued to engage in the business of furnishing medical devices in this State without a license after the initial cease and desist letter of March 8 (fine received on April 9, 2021), and after the date that the activity was represented to have ceased on March 30, 2021. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.233, NRS 639.288, NRS 639.310 and NAC 639.6944.

Kinex is hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST from engaging in the business of furnishing medical devices in this State from the unlicensed Hauck Street location. This letter shall serve as a CITATION pursuant to NRS 639.2895(2), for the continued unlicensed operation of activity from April 1 – 16, 2021, including, but not limited to, generation of invoices, transfer of equipment, *etc.*, out of the Hauck Street location. The Board has assessed an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

Kinex 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.

Kinex has 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 letter. *See* NRS 639.2895(2).

Please be aware that the foregoing does not preclude a formal investigation or filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or c.lee@pharmacy.nv.gov.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

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June 15, 2021

VIA EMAIL to counsel: lyn@lbeggslaw.com; kdove@swlaw.com

Michael Buckholdt
Saundra Sorenson
Kinex Medical Company
5985 Hauck Street # 107
Las Vegas, NV 89118

Kinex Medical Company
1801 Airport Road, Suite D
Waukesha, WI 53188

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada at storage unit

Dear Mr. Buckholdt and Ms. Sorenson:

The Nevada State Board of Pharmacy ("Board") has determined, based upon your admissions at Board meeting(s), documents submitted with your application, and/or inspections by Board's staff, that Kinex Medical Company ("Kinex") continued to engage in the business of furnishing medical devices in this State without a license after the initial cease and desist letter of March 8, 2021 (fine received on or about April 9, 2021), and after the date that the activity was represented to have ceased on March 30, 2021. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.233, NRS 639.288, NRS 639.310 and NAC 639.6944.

Kinex is hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST from engaging in the business of furnishing medical devices in this State from any unlicensed location. This letter shall serve as a CITATION pursuant to NRS 639.2895(2), for unlicensed operation of activity, including, but not limited to, transfer of equipment, *etc*., out of the Budget storage unit located at 6075 W. Wigwam Avenue, Unit A089, Las Vegas, NV 89139 from approximately April 1 – 16, 2021. The Board has assessed an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

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Please be aware that the foregoing does not preclude a formal investigation or filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or c.lee@pharmacy.nv.gov.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

5B

FILED
JAN 04 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DARREL FOTH, RPH,** **Certificate of Registration No. 15593,** **Respondent.**	**CASE NO. 21-186-RPH-N** **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 Darrel Foth, R.Ph., Certificate of Registration No. 15593, was a pharmacist registered by the Board.

FACTUAL ALLEGATIONS

2. On or about April 28, 2021, the California Board of Pharmacy (CA BOP) entered an order in Case No. 6889, and imposed discipline on Respondent's Pharmacist License No. RPH 52592 to practice pharmacy for violations of the California Business and Professions Code, the California Health and Safety Code, and the California Code of Regulations, related to Respondent's diversion and use of controlled substances, specifically Oxycodone and Amphetamine-dextroamphetamine from Walgreen's Pharmacy #5036 while employed as the pharmacist-in-charge.

3. As detailed in the CA BOP's order in Case No. 6889, Respondent admitted to the truth of each and every charge and allegation in the Accusation, and his Pharmacist License No.

RPH 52592 was revoked, the revocation was stayed, and Respondent was placed on probation for 4 years.

APPLICABLE LAW

4. It is a felony offense to acquire, possess or use a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 844; 42 U.S.C. § 12210; NRS 453.331(1)(d); NRS 453.336(1); NRS 453.391(1); NRS 453.411(1).

5. Diverting a controlled substance constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

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. 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).

8. 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).

COUNT ONE
Violations of Federal Controlled Substances Act

9. By diverting, acquiring, possessing and using controlled substances as detailed in CA BOP's order in Case No. 6889, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 844 42 U.S.C. § 12210 and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 639.210(11).

COUNT TWO
Violations of State Controlled Substances Act

10. By diverting, acquiring, possessing and using controlled substances as detailed in CA BOP's order in Case No. 6889, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.336(1), NRS 453.381(1), NRS 453.391(1) and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE
Unprofessional Conduct - Diversion

11. By diverting, acquiring, possessing and using controlled substances as detailed in CA BOP's order in Case No. 6889, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

COUNT FOUR
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

12. By diverting, acquiring, possessing and using controlled substances as detailed in CA BOP's order in Case No. 6889, 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 4th day of January 2022.

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, **Petitioner,** **v.** **DARREL FOTH, RPH,** **Certificate of Registration No. 15593,** **Respondent.**	**CASE NO. 21-186-RPH-N** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely:**

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

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 January 2022.

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 5th day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Darrel Foth, R.Ph.
7629 River Ranch Wy
Sacramento, CA 95831

SHIRLEY HUNTING

FILED 1856
JAN 20 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DARREL FOTH, RPH,** **Certificate of Registration No. 15593,** **Respondent.**	**CASE NO. 21-186-RPH-N** **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").

"NONE"

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I, Darrel Foth, admit to the accuracy of the accusations and violations listed in the "notice of intended action and accusation."

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 16 day of January, 2022.

Darrel Foth

DARREL FOTH, RPH

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
ANDREW M. STEINHEIMER
Deputy Attorney General
State Bar No. 200524
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7892
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DARREL WAYNE FOTH** [redacted] **Sacramento, CA 95823** **Pharmacist License No. RPH 52592** Respondent.	Case No. 6889 **STATEMENT TO RESPONDENT** [Gov. Code §§ 11504, 11505(b)]

TO RESPONDENT:

Enclosed is a copy of the Accusation that has been filed with the Board of Pharmacy of the Department of Consumer Affairs (Board), and which is hereby served on you.

Unless a written request for a hearing signed by you or on your behalf is delivered or mailed to the Board, represented by Deputy Attorney General Andrew M. Steinheimer, within fifteen (15) days after a copy of the Accusation was personally served on you or mailed to you, you will be deemed to have waived your right to a hearing in this matter and the Board may proceed upon the Accusation without a hearing and may take action thereon as provided by law.

The request for hearing may be made by delivering or mailing one of the enclosed forms entitled "Notice of Defense," or by delivering or mailing a Notice of Defense as provided in section 11506 of the Government Code, to

Andrew M. Steinheimer
Deputy Attorney General
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, California 94244-2550

You may, but need not, be represented by counsel at any or all stages of these proceedings.

The enclosed Notice of Defense, if signed and filed with the Board, shall be deemed a specific denial of all parts of the Accusation, but you will not be permitted to raise any objection to the form of the Accusation unless you file a further Notice of Defense as provided in section 11506 of the Government Code within fifteen (15) days after service of the Accusation on you.

If you file any Notice of Defense within the time permitted, a hearing will be held on the charges made in the Accusation.

The hearing may be postponed for good cause. If you have good cause, you are obliged to notify the Office of Administrative Hearings, Attn: General Jurisdiction, 2349 Gateway Oaks, Suite 200, Sacramento, CA 95833-4231, within ten (10) working days after you discover the good cause. Failure to notify the Office of Administrative Hearings within ten (10) days will deprive you of a postponement.

Copies of sections 11507.5, 11507.6, and 11507.7 of the Government Code are enclosed.

If you desire the names and addresses of witnesses or an opportunity to inspect and copy the items mentioned in section 11507.6 of the Government Code in the possession, custody or control of the Board you may send a Request for Discovery to the above designated Deputy Attorney General.

NOTICE REGARDING STIPULATED SETTLEMENTS

It may be possible to avoid the time, expense and uncertainties involved in an administrative hearing by disposing of this matter through a stipulated settlement. A stipulated

settlement is a binding written agreement between you and the government regarding the matters charged and the discipline to be imposed. Such a stipulation would have to be approved by the Board of Pharmacy but, once approved, it would be incorporated into a final order.

Any stipulation must be consistent with the Board's established disciplinary guidelines; however, all matters in mitigation or aggravation will be considered. A copy of the Board's Disciplinary Guidelines will be provided to you on your written request to the state agency bringing this action.

If you are interested in pursuing this alternative to a formal administrative hearing, or if you have any questions, you or your attorney should contact Deputy Attorney General Andrew M. Steinheimer at the earliest opportunity.

Dated: July 16, 2020

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General

ANDREW M. STEINHEIMER
Deputy Attorney General
Attorneys for Complainant

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XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
ANDREW M. STEINHEIMER
Deputy Attorney General
State Bar No. 200524
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7892
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DARREL WAYNE FOTH** [redacted] **Sacramento, CA 95823** **Pharmacist License No. RPH 52592** Respondent.	Case No. 6889 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about August 31, 2001, the Board issued Pharmacist License Number RPH 52592 to Darrel Wayne Foth (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2021, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise

indicated.

4. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

5. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

6. Section 4060 of the Code states in pertinent part:

A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

7. Section 4301 of the Code states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> ...
>
> (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
>
> ...
>
> (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
>
> ...
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> ...
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

8. Section 4327 of the Code states: "Any person who, while on duty, sells, dispenses or compounds any drug while under the influence of any dangerous drug or alcoholic beverages shall be guilty of a misdemeanor."

REGULATORY PROVISIONS

9. California Code of Regulations, title 16, (Regulations) section 1714, subdivision (d), states:

> (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

HEALTH AND SAFETY CODE SECTIONS

10. Health and Safety Code section 11170 states: "No person shall prescribe, administer, or furnish a controlled substance for himself."

DRUGS

11. *Oxycodone* is an opioid pain medication with a high risk for addiction and dependence. Oxycodone is a dangerous drug pursuant to Code section 4022, and a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M).

12. *Amphetamine-dextroamphetamine mixed salts* is a stimulate used to treat attention deficit disorders. Amphetamine-dextroamphetamine is a dangerous drug pursuant to Code section 4022, and a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (d)(1).

COST RECOVERY

13. Section 125.3 of the Code provides, in pertinent part, that the Board 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

14. At all times relevant to this matter, Respondent was employed by Walgreens Pharmacy # 5036 located in South Sacramento as the Pharmacist-In-Charge (PIC).

15. On or about June 26, 2019, the Board received a letter from E.R., District Manager South Sacramento for Walgreens, notifying the Board that Respondent tested positive for metabolites of amphetamine and oxymorphone during a random drug screening on June 10, 2019.

16. Walgreens offered Respondent a "last chance agreement" through First Advantage which requires the employee to attend counseling and rehab meetings and to submit to random drug screenings. During this period the employee is not allowed to work. Respondent accepted the "last chance agreement" and took a leave of absence from work.

17. Respondent returned to work in mid-September 2019, but then resigned from Walgreens on October 7, 2019.

18. On or about November 5, 2019, Board investigator J.F., conducted a telephone interview with Respondent. During the call, Respondent admitted that he took one tablet of Adderall (amphetamine-dextroamphetamine mixed salts) and four tablets of Percocet (oxycodone) from the safe at work. Respondent stated the medications were expired or had been returned and were waiting to be destroyed. Respondent admitted consuming the medications over the weekend prior to the random drug test, which occurred on a Monday, and stated "I guess the substances were not out of my system yet."

FIRST CAUSE FOR DISCIPLINE

(Consumption of Stolen Controlled Substances)

19. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in that Respondent violated Code section 4060 and Health and Safety Code section 11170 when he removed controlled substances Oxycodone and Amphetamine-dextroamphetamine from the safe at his place of employment and consumed them. The circumstances are set forth in paragraphs 15 and 18, above.

SECOND CAUSE FOR DISCIPLINE

(Self- Administration of Controlled Substance to an Extent or in a Manner to be Dangerous to Self or Others)

20. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (h), in that Respondent self-administered the controlled substance Oxycodone and Amphetamine-dextroamphetamine to an extent or in a manner as to be dangerous or injurious to himself or others. The circumstances are set forth in paragraphs 15 and 18, above.

THIRD CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

21. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that on or about a date unknown prior to June 10, 2019, Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption,

when he stole Oxycodone and Amphetamine-dextroamphetamine from his place of employment as set forth in paragraphs 15 and 18, above.

FOURTH CAUSE FOR DISCIPLINE

(Public Endangerment)

22. Respondent is subject to disciplinary action under Code section 4301, subdivision (j), in that Respondent violated Code section 4327 when he tested positive for controlled substances Oxycodone and Amphetamine-dextroamphetamine while at work. The circumstances are set forth in paragraphs 15 and 18, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Controlled Substances)

23. Respondent is subject to disciplinary action under Code section 4301, subdivision (j), in that Respondent violated Regulations section 1714(d), when he removed controlled substances Oxycodone and Amphetamine-dextroamphetamine from the safe at his place of employment and consumed them. The circumstances are set forth in paragraphs 15 and 18, above.

SIXTH CAUSE FOR DISCIPLINE

(Violating Laws Governing Pharmacy)

24. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4060, Health and Safety Code section 11170, and Regulations section 1714(d), as set forth above.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacist Number RPH 52592, issued to Darrel Wayne Foth;

2. Ordering Darrel Wayne Foth to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

3. Taking such other and further action as deemed necessary and proper.

DATED: July 15, 2020

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2020100103

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 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

March 29, 2021

CERTIFIED MAIL

Darrel Wayne Foth
[redacted]
Sacramento, CA 95822

RE: Administrative Case No. 6889

Dear Mr. Foth:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order regarding the above-referenced matter. Your attention is directed to pages 4 - 21 of the document.

Effective at 5:00 p.m. on April 28, 2021, Pharmacist License No. RPH 52592 issued to Darrel Wayne Foth is hereby revoked; however, said revocation is stayed, and the license is placed on probation for a period of four years, from April 28, 2021, through April 27, 2025, inclusive.

As required by the stipulated settlement, you shall by no later than 10 days after the effective date of this decision, contact the Pharmacist Recovery Program (PRP) at 1 (800) 522-9198. Additional information regarding the PRP can be found on the board's website at:
https://www.pharmacy.ca.gov/licensees/personal/pharmacist_recovery.shtml

You will be scheduled to appear before representatives of the Board. The purpose of your appearance is to explain to you the terms and conditions of your probation and your responsibilities as a probationer. The Board will contact you regarding the date of your appearance.

Upon successful completion of the probation period, or extension thereof, your license will be fully restored. However, upon violation or failure to comply with any of the terms and conditions of this stay, the Board may, after notice and opportunity to be heard is given to you, vacate the stay and re-impose the revocation, or take other action as it deems appropriate.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, Administrative Case Analyst, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Prior to the effective date of this decision, please email the board's probation unit at BOPprobation@dca.ca.gov with your current contact information including your full name, license number, and email address.

Sincerely,

Anne Sodergren
Executive Officer

By *Susan Cappello*

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Andrew M. Steinheimer, DAG
Paul Chan, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 6889
Darrel Wayne Foth, RPH 52592

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Darrel Wayne Foth [redacted] Sacramento, CA 95822	7018 3090 0000 5168 8051
Paul Chan, Esq. 1851 Heritage Ln., Ste. 128 Sacramento, CA 95815	7018 3090 0000 5168 8068

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on March 29, 2021, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on March 29, 2021 at Sacramento, California.

Lupe Baltazar, Administrative Case Analyst

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

April 12, 2021

EMAIL

Darrel Foth
[redacted]
Sacramento, CA 95822

RE: **AC 6889– Office Conference**

Dear Darrel Foth,

In accordance with the terms and conditions of your probation, you are hereby required to report **IN PERSON** at an office conference. Due to COVID 19, the office conference will be held via telephone conference on **April 29, 2021** at **8:30am.**

How to call into join the conference:

Dial (866) 252-6350
Enter in participant passcode 84036400
Press #

This conference has been scheduled to review and clarify the terms of probation and to allow the Board the opportunity to advise you of their functions and responsibilities in assisting you through this probationary period.

At least 48 hours prior to your scheduled conference email BOPprobation@dca.ca.gov the following:

- Confirmation that you will be in attendance.
- Best contact information for the duration of probation (email, phone number, work phone number).
- A PDF attachment of a copy of your Government issued identification (ex. California driver's license, passport etc.).
- If you hold a personal professional license with the Board (i.e., Pharmacist, Pharmacy Technician, etc.) a PDF copy of your license.

Please ensure the following for your scheduled conference:

- Locate a quiet distraction free location for the duration of the telephone conference.
- If using a cell phone, ensure it is fully charged and have charging capabilities, if needed.
- Have the following documents ready and in front of you for the duration of the telephone conference:
    - Your decision and order, please review prior.
    - This letter with the ancillary forms and guidelines that were attached, please review prior. These documents will be reviewed during the telephone conference and additional directions will be provided.

Pursuant to the terms and conditions of your probation, you shall appear for interviews with the board upon request at various intervals. Failure to appear for a scheduled interview without prior notification to the board shall be considered a violation of probation.

If you have any questions, you may contact your probation analyst at BOPProbation@dca.ca.gov.

Sincerely,

Joan Coyne
Supervising Inspector

By Autumn Ammann

Autumn Ammann
Probation Analyst

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
ANDREW M. STEINHEIMER
Deputy Attorney General
State Bar No. 200524
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7892
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DARREL WAYNE FOTH** [redacted] **Sacramento, CA 95822** **Pharmacist License No. RPH 52592** Respondent.	Case No. 6889 OAH No. 2020100090 **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. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Andrew M. Steinheimer, Deputy Attorney General.

2. Respondent Darrel Wayne Foth (Respondent) is represented in this proceeding by attorney Paul Chan, whose address is: 1851 Heritage Lane, Suite 128,

Sacramento, CA 95815-4996

3. On or about August 31, 2001, the Board issued Pharmacist License No. RPH 52592 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 6889, and will expire on April 30, 2021, unless renewed.

JURISDICTION

4. Accusation No. 6889 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on July 16, 2020. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 6889 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6889. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. 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 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.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 6889.

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10. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board 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 Board considers and acts upon it. If the Board 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 Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 52592 issued to Respondent Darrel Wayne Foth is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed,

probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6889 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of his employer(s), and the name(s) and telephone number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior

employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6889, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6889, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6889, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Pharmacist, or any position for which a Pharmacist License is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $7,455.00.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall

be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

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13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

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If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. **Pharmacists Recovery Program (PRP)**

By no later than ten (10) days after the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362 (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;

Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;

Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;

Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or

Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not resume the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. The board will provide notice of any such suspension or extension of probation.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice as a Pharmacist nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

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Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

17. **Drug and Alcohol Testing**

Respondent, at his own expense, shall participate in testing as directed by the board or its designee for the detection of alcohol, controlled substances, and dangerous drugs and/or dangerous devices. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the area where the approved testing vendor provides services, respondent shall seek and receive approval from the board or its designee to use an alternate testing vendor to ensure testing can occur. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide to that alternate vendor any documentation required by the vendor, including any necessary payment by respondent. During the period of absence of the area, respondent shall commence testing

protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of an illicit drug, controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a Pharmacist until notified by the board in writing that he may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform him to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or

any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices.

Failure to comply with any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

18. **Notification of Departure**

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

19. **Abstain from Drugs and Alcohol**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a necessary part of treatment. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia for which a legitimate prescription has not been issued as a necessary part of treatment, or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

20. **Prescription Coordination and Monitoring of Prescription Use**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history with the use of controlled substances, and/or dangerous drugs and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's Accusation and decision. A record of this notification must be provided to the board or its designee upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing supervision, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a Pharmacist, the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a Pharmacist until notified by the board

or its designee that practice may be resumed.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

21. **Facilitated Group Recovery and/or Support Meetings**

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises the respondent in writing that he may cease regular attendance. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as

required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

22. **Work Site Monitor**

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;

2) Interview other staff in the office regarding respondent's behavior, if applicable; and

3) Review respondent's work attendance.

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The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that he is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;

2) Interview other staff in the office regarding respondent's behavior, if applicable; and

3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

23. **Supervised Practice**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a Pharmacist by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 6889, and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week - REQUEST FOR REDUCTION WHEN APPROPRIATE

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a Pharmacist by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that

he or she has read the decision in case number 6889, and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;

Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;

Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or

Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any suspension shall be considered a violation of probation.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a Pharmacist and may not resume such practice until notified by the board or its designee in writing.

24. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation 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, Paul Chan. I understand the stipulation and the effect it will have on my Pharmacist License. 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 Board of Pharmacy.

DATED: 11/26/21

DARREL WAYNE FOTH
Respondent

I have read and fully discussed with Respondent Darrel Wayne Foth the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 1/26/21

PAUL CHAN
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General

ANDREW M. STEINHEIMER
Deputy Attorney General
Attorneys for Complainant

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SIRCY M. MOORE, DVM,** **Certificate of Registration No. CS23796,** **Respondent.**	**CASE NO. 21-111-CS-S** **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 and this respondent because at the time of the alleged events, Respondent Sircy M. Moore, DVM, held a Nevada controlled substance registration, Certificate No. CS23796, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about August 26, 2021, Board staff assisted Nevada Board of Veterinary Medical Examiners staff in investigating Respondent's practice, at Doc Mo's Kindred Spirits Animal Hospital, located at 2437 E. Cheyenne Avenue in North Las Vegas. The investigation revealed that Respondent was dispensing controlled substances and/or dangerous drugs for animal patients without a valid dispensing practitioner registration.

3. The investigation also revealed that controlled substances and dangerous drugs were not kept in a locked storage area with access restricted to authorized persons, and that Respondent failed to properly store, segregate and/or dispose of adulterated and/or expired drugs.

4. The investigation also revealed that Respondent failed to keep records and maintain inventories for controlled substances in conformance with the recordkeeping and inventory requirements of state and federal law.

5. On or about December 9, 2021, Respondent was ordered pursuant to NRS 639.2895(1) to cease and desist dispensing any controlled substances or dangerous drugs for animal patients.

APPLICABLE LAW

6. A licensed veterinarian who wishes to dispense controlled substances or dangerous drugs must register with the Board. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226; NRS 453.321; NRS 453.377; NRS 453.381; NRS 454.215; NRS 454.356; NRS 639.100; NRS 639.23505; NAC 639.7423.

7. All controlled substances and dangerous drugs in the possession of a dispensing practitioner must be kept in a locked storage area with access restricted to authorized persons. 21 CFR § 1301.71; NAC 453.410(1)(d); NAC 639.7423(5); NAC.639.745.

8. It is unlawful for any person to have in his or her possession, or under his or her control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which . . . is no longer safe or effective for use, as indicated by the expiration date appearing on its label. NRS 639.282(1)(d); *see also* 21 CFR § 211.137.

9. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier. NAC 639.601(1).

10. Persons registered to dispense controlled substances shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law; it is unlawful for a person to fail to make, keep or furnish any record, notification, order form, statement, invoice or information required by law. 21 U.S.C. §

842(a)(5); 21 CFR § 1304.04; 21 CFR § 1304.11; 21 CFR § 1304.21; NRS 453.246; NRS 453.326(1)(a); NAC 453.410(1); NAC 639.7423(5); NAC.639.745.

11. 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 453.236(1) and NRS 639.210(4).

12. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

13. 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).

14. 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).

15. 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. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Violation of Federal and State Law - Unlawful Dispensing

16. By dispensing controlled substances and/or dangerous drugs without a valid dispensing practitioner registration, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 CFR §

1306.03(a)(1), NRS 453.226, NRS 453.321, NRS 453.377, NRS 453.381, NRS 454.215, NRS 454.221, NRS 454.356, NRS 639.100, NRS 639.23505 and/or NAC 639.7423, and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11) and (12).

SECOND COUNT

Violation of Federal and State Law - Failure to Properly Store and Secure Drugs

17. By permitting unrestricted and unsecured access to the stock of controlled substances and/or dangerous drugs at his practice, and failing to properly store, segregate and/or dispose of adulterated and/or expired drugs to ensure they could not be administered to patients, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 211.137, 21 CFR § 1301.71, NRS 639.282(1)(d), NAC 453.410(1)(d), NAC 639.601(1), NAC 639.7423(5) and/or NAC.639.745, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

THIRD COUNT

Violation of Federal and State Law – Controlled Substance Inventories and Recordkeeping

18. By failing to keep records and maintain inventories for controlled substances in conformance with the recordkeeping and inventory requirements of state and federal law, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04, 21 CFR § 1304.11, 21 CFR § 1304.21, NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1), NAC 639.7423(5) and/or NAC.639.745, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

FOURTH COUNT

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

19. By his actions as alleged herein, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FIFTH COUNT

Unprofessional Conduct – Dispensing without a Valid Registration

20. By dispensing controlled substances and/or dangerous drugs without a valid dispensing practitioner registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k), and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

SIXTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By his actions as alleged herein, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 14th day of December, 2021.

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, **Petitioner,** **v.** **SIRCY M. MOORE, DVM,** **Certificate of Registration No. CS23796,** **Respondent.**	**CASE NO. 21-111-CS-S** **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, January 12, 2022, at 9:00 AM PST or soon thereafter at the following location:**

Pursuant to Governor Steve Sisolak's Emergency Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 14th day of December 2021.

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 14th day of December, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sircy Moore, DVM
Doc Mo's Kindred Spirits Animal Hospital
2437 E. Cheyenne Ave.
North Las Vegas, NV 89030

SHIRLEY HUNTING

FILED
FEB 04 2022
NEVADA STATE BOARD OF PHARMACY

John A. Hunt, Esq. (NSBN 1888)
Bert Wuester Jr., Esq. (NSBN 5556)
CLARK HILL, PLLC
3800 Howard Hughes Pkwy, Suite 500
Las Vegas, Nevada 89169
ph. (702) 862-8300; fax (702) 862-8400
email: jhunt@clarkhill.com
email: bwuester@clarkhill.com
Attorneys for Respondent, Bernard Kofi Addo-Quaye, MD

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

vs.

SIRCY M. MOORE, DVM, Certificate of Registration No. CS23796,

Respondent.

Case No. **21-111-CS-S**

ANSWER AND NOTICE OF DEFENSE OF RESPONDENT, SIRCY M. MOORE, DVM

Respondent, Sircy M. Moore, DVM, ("Dr. Moore"), by and through counsel, hereby submits his Answer and Notice of Defense ("Answer"), pursuant to NRS 639.244[1], to the *Notice of Intended Action and Accusation* filed December 14, 2021 ("Accusation"), with the Nevada State Board of Pharmacy (the "Board"), in the above-captioned action.

1. Pursuant to NRS 639.244(1)(a), Dr. Moore objects to the Accusation as being incomplete and failing to set forth clearly the charges against him.

[1] **NRS 639.244 Notice of Defense: Form; effect of failure to file.**
1. The form for the Notice of Defense must be prepared and furnished by the Board and permit the respondent, by completing and signing the notice, to:
(a) Object to the accusation as being incomplete and failing to set forth clearly the charges; and
(b) Deny or admit, in part or in whole, the violations alleged.
2. The Notice of Defense must be signed by the respondent or his or her attorney under penalty of perjury. Failure to file a Notice of Defense constitutes a waiver of the respondent's right to a hearing, but the Board may grant a hearing.

Clark Hill, PLLC
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169
Ph. (702) 862-8300
Fax. (702) 862-8400
www.clarkhill.com

2. Pursuant to NRS 639.244(1)(b), Dr. Moore denies in whole the violations alleged against him in the Accusation.

3. Pursuant to NRS 639.244(2), by filing this Answer, Dr. Moore has not waived the right to a hearing before the Board. Moreover, Respondent's undersigned counsel communicated with the Board's General Counsel regarding an extension of time to file this Answer.

AFFIRMATIVE DEFENSES

1. The allegations contained in the Board's Accusation fail to state a cause of action upon which relief can be granted.

2. The violations alleged against Respondent in the Board's Accusation are subject to a demand/application pursuant to NRS 233B.121(2)(d) for a more definite and detailed statement. By this defense, Dr. Moore specifically provides that he does not waive the right to such a demand/application even in light of this Answer.

3. Pursuant to NRS 622A.330, even though Dr. Moore has provided this Answer, he specifically reserves the right to request a copy of all documents and other evidence intended to be presented by the Board at the hearing in support of its Accusation, as well as a list of proposed witnesses it intends to call at the hearing.

4. The answering Respondent hereby incorporates by reference those affirmative defenses enumerated in Rule 8 of the Nevada Rules of Civil Procedure as if fully set forth herein. In the event further investigation or discovery reveals the applicability of such defenses, this answering

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Fax. (702) 862-8400
www.clarkhill.com

Respondent reserves the right to seek leave of the Board or appropriate authority to amend this Answer to specifically assert the same. Such defenses are herein incorporated by reference for the specific purpose of not waiving the same.

5. It has been necessary for this answering Respondent to employ the services of an attorney to defend this action and a reasonable sum should be allowed as and for attorney's fees, together with the costs expended in this action.

WHEREFORE, Dr. Moore prays the Accusation be dismissed, no discipline issue, that the initiating party take nothing by way of its Accusation and go hence with its costs.

Pursuant to NRS 639.244(2), this Answer is hereby signed by the answering Respondent's attorney.

Respectfully submitted this 4 day of February, 2022.

CLARK HILL, PLLC

By _____

John A. Hunt, Esq. (NSBN 1888)
3800 Howard Hughes Pkwy, Suite 500
Las Vegas, Nevada 89169
ph. (702) 862-8300; fax (702) 862-8400
email: jhunt@clarkhill.com
Attorneys for Respondent,
Sircy M. Moore, DVM

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 4 day of Feb, 2022, I caused the above and foregoing **ANSWER AND NOTICE OF DEFENSE OF RESPONDENT, SIRCY M. MOORE, DVM** to be served by placing a true and correct copy of the same in the U.S. Mail, at Las Vegas, Nevada, first class postage fully prepaid and addressed to the following **AND** via email as follows:

Brett Kandt, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

email: bkandt@pharmacy.nv.gov

J. David Wuest, R. Ph.
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

email: dwuest@pharmacy.nv.gov

By _____
An Employee of Clark Hill, PLLC

Clark Hill, PLLC
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169
Ph. (702) 862-8300
Fax. (702) 862-8400
www.clarkhill.com

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
PHONE (775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

December 9, 2021

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: nu4cuss@yahoo.com

Sircy Moore, DVM
Doc Mo's Kindred Spirits Animal Hospital
2437 E. Cheyenne Avenue
Las Vegas, NV 89030

CEASE and DESIST: Unlicensed Dispensing in Nevada

Dear Dr. Moore:

The Nevada State Board of Pharmacy (Board) has determined that you are engaged in dispensing prescription drugs for animal patients without a valid registration. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.23505 and NAC 639.7423.

You are hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST dispensing any controlled substances or dangerous drugs for animal patients.

Please be aware that the forgoing does not preclude the filing of administrative charges. 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

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LESLI HEWITT-SPEARS, DVM,** **Certificate of Registration No. CS11265,** **Respondent.**	**CASE NO. 21-112-CS-N** **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 and this respondent because at the time of the alleged events, Respondent Lesli Hewitt-Spears, DVM, held a Nevada controlled substance registration, Certificate No. CS11265, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about July 15, 2021, Board staff assisted U.S. Drug Enforcement Administration (DEA) special agents and Nevada Board of Veterinary Medical Examiners staff in an inspection of Respondent's practice, Quail Ridge Animal Hospital, located at 937 Mica Drive in Carson City. The investigation revealed that Respondent was dispensing controlled substances and/or dangerous drugs for animal patients without a valid dispensing practitioner registration.

3. The investigation also revealed that Respondent failed to maintain at least two years' worth of biennial inventories of controlled substances in conformance with federal and state law.

4. The investigation also revealed that Respondent failed to maintain complete and accurate DEA 222 Forms for the controlled substances purchased and received in conformance with federal and law.

APPLICABLE LAW

5. A licensed veterinarian who wishes to dispense controlled substances or dangerous drugs must register with the Board. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226; NRS 453.321; NRS 453.377; NRS 453.381; NRS 454.215; NRS 454.356; NRS 639.100; NRS 639.23505; NAC 639.7423.

6. Persons registered to dispense controlled substances shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law; it is unlawful for a person to fail to make, keep or furnish any record, notification, order form, statement, invoice or information required by law. 21 U.S.C. § 842(a)(5); 21 CFR § 1304.04; 21 CFR § 1304.11; 21 CFR § 1304.21; 21 CFR § 1305.13; NRS 453.246; NRS 453.326(1)(a); NAC 453.410(1); NAC 639.7423(5); NAC.639.745.

7. 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 453.236(1) and NRS 639.210(4).

8. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

9. 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).

10. 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).

11. 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. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Violation of Federal and State Law - Unlawful Dispensing

12. By dispensing controlled substances and/or dangerous drugs without a valid dispensing practitioner registration, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 CFR § 1306.03(a)(1), NRS 453.226, NRS 453.321, NRS 453.377, NRS 453.381, NRS 454.215, NRS 454.221, NRS 454.356, NRS 639.100, NRS 639.23505 and/or NAC 639.7423, and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11) and (12).

SECOND COUNT

Violation of Federal and State Law – Controlled Substance Inventories and Recordkeeping

13. By failing to maintain at least two years' worth of biennial inventories of controlled substances and complete and accurate records of controlled substances purchased and received, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04, 21 CFR § 1304.11, 21 CFR § 1305.13; 21 CFR § 1304.21, NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1), NAC 639.7423(5) and/or NAC.639.745, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

THIRD COUNT

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. By her actions as alleged herein, Respondent has performed her duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent

manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH COUNT

Unprofessional Conduct – Dispensing without a Valid Registration

15. By dispensing controlled substances and/or dangerous drugs without a valid dispensing practitioner registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k), and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By her actions as alleged herein, Respondent has committed acts that render her Nevada controlled substance registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January 2022.

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, **Petitioner,** **v.** **LESLI HEWITT-SPEARS, DVM,** **Certificate of Registration No. CS11265,** **Respondent.**	**CASE NO. 21-112-CS-N** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely:**

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

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 January 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, **Petitioner,** **v.** **LESLI HEWITT-SPEARS, DVM,** **Certificate of Registration No. CS11265,** **Respondent.**	**CASE NO. 21-112-CS-N** **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.

_____

LESLI HEWITT-SPEARS, DVM

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Lesli Hewitt-Spears, DVM
937 MICA DR #18
CARSON CITY, NV 89705

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LESLI HEWITT-SPEARS, DVM,** **Certificate of Registration No. CS11265,** **Respondent.**	**CASE NO. 21-112-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Lesli Hewitt-Spears, DVM, Certificate of Registration No. CS11265, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about January 21, 2022, 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.

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 her 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 her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be

accorded to her 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. Respondent dispensed controlled substances and/or dangerous drugs without a valid dispensing practitioner registration, in violation of 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 CFR § 1306.03(a)(1), NRS 453.226, NRS 453.321, NRS 453.377, NRS 453.381, NRS 454.215, NRS 454.221, NRS 454.356, NRS 639.100, NRS 639.23505 and/or NAC 639.7423; and

B. Respondent failed to maintain at least two years' worth of biennial inventories of controlled substances and complete and accurate records of controlled substances purchased and received, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04, 21 CFR § 1304.11, 21 CFR § 1305.13; 21 CFR § 1304.21, NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1), NAC 639.7423(5) and/or NAC.639.745.

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and NRS 639.255.

8. Respondent immediately applied for a dispensing practitioner registration, appeared before the Board, and was approved for a dispensing practitioner registration on January 12, 2022.

9. 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. The certificate of registration of Lesli Hewitt-Spears, DVM, Certificate of Registration No. CS11265, is hereby suspended. The suspension is stayed, and Respondent is placed on probation for one (1) year, subject to the following conditions:

A. Respondent shall pay a fine of Five Thousand Dollars ($5000.00), payable by *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, within ninety (90) days of the effective date of this Order;

B. 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. Payment shall be made by *cashier's check, certified 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 ninety (90) days of entry of this Order;

C. Board inspectors shall conduct quarterly inspections of Quail Ridge Animal Hospital, and Respondent shall bear and reimburse the Board for inspection costs in an amount not to exceed $500 per quarterly inspection; and

D. Respondent shall have no new charges filed against her while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS11265 will be fully restored.

10. 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.

11. 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 March 2, 2022. Respondent 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.

12. 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.

13. 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.

14. 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 15 day of February, 2022

LESLI HEWITT-SPEARS, DVM,
Certificate of Registration No. CS11265

Signed this ___ day of February, 2022

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 15th day of February, 2022

TOM DONALDSON, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Lesli Hewitt-Spears, DVM, Certificate of Registration No. CS11265, in Case No. 21-112-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5E

FILED
JAN 28 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PAUL H. HOWSE, RPH** **Certificate of Registration No. 18406,** **JUSTINE STANEVICH,** **Certificate of Registration No. PT18958,** **Respondents.**	**CASE NO. 20-135-RPH-S** **20-135-PT-S** **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 Paul H. Howse, RPh ("Howse"), Certificate of Registration No. 18406, held a registration as a pharmacist, and Justine Stanevich ("Stanevich"), Certificate of Registration No. PT18958, held a registration as a pharmaceutical technician, all issued by the Board.

FACTUAL ALLEGATIONS

2. Howse is/was the managing pharmacist at Smith's Food and Drug Store #351 ("Smith's") located at 6130 West Tropicana Avenue, Las Vegas, Nevada 89103 during the relevant timeframe.

3. Stanevich was employed as a pharmaceutical technician at Smith's during the relevant timeframe.

4. On or about February 12, 2020, Howse, was approached by Stanevich regarding an opioid prescription for a new patient. As indicated by protocol, Howse accessed and reviewed the new patient's Prescription Monitoring Program ("PMP") history using an interface with Smith's computer system. Howse left the computer station for a moment, with Stanevich left next to the computer, to explain to the new patient at the drop-off window that he needed more information from the prescribing practitioner. Upon Howse's return to the computer station, Howse noticed a second PMP window opened for patient P.S., who he had not checked the PMP database. Howse questioned Stanevich about the PMP inquiry on patient P.S., whereupon Stanevich admitted that she queried the PMP for patient P.S. under Howse's credentials. Stanevich stated that patient P.S. was someone personally known to her and not a patient of Smith's. Howse informed Stanevich that the PMP query was unacceptable, and against company policy and HIPAA.

5. Howse immediately reported Stanevich's PMP query to his district and division managers for Smith's. During investigation, which included review of videotape from Howse's computer workstation, and interviews of Smith's staff working at the time, it was determined that Stanevich violated company policy, and HIPAA. Stanevich was terminated on February 18, 2020.

APPLICABLE LAW

6. Performing any duties as the holder of a pharmacist 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).

7. The Board administers the PMP, which maintains a database of all transactions for controlled substances listed in schedules II, III, IV, and V which are prescribed and dispensed in Nevada. *See* NRS 453.162-.165.

8. Patient utilization reports and data in the PMP constitute Protected Health Information ("PHI") as defined in 45 CFR Part 160 and 164, Subparts A and E. The Health Insurance Portability and Accountability Act ("HIPAA") provides certain requirements regarding privacy of PHI and certain prohibitions against disclosure. 42 USC §1320d *et seq.* (HIPAA Privacy Act).

9. Patient utilization reports and all data in the PMP are also confidential and protected from unauthorized use or disclosure under state law. *See* NRS 453.164.

10. Unauthorized access, use, or disclosure of PHI carries civil and criminal penalties under federal law. *See* 42 USC § 1320d-5 and d-6.

11. Unauthorized access, use, or disclosure of information in the PMP also constitute a crime under state law. NRS 453.552(2).

12. The Board may suspend or revoke any certificate, license, registration or permit issued if the registrant is not of good moral character, is guilty of unprofessional conduct or conduct contrary to the public interest, willfully makes to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of NRS 639, and/or violates any provision of federal or state law. NRS 639.210; NRS 639.255.

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FIRST COUNT
Unprofessional Conduct
(Respondent Howse)

13. Howse engaged in unprofessional conduct in violation of NAC 639.945(1)(i) when he walked away from his computer, and failed to log out to prevent unlawful access to the PMP, and is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255.

SECOND COUNT
Unprofessional Conduct
(Respondent Stanevich)

14. By accessing patient P.S.'s confidential data in the PMP and obtaining P.S.'s utilization report, Stanevich, as a registered pharmaceutical technician, without authority and fraudulently under Howse's credentials, acted in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i). Stanevich is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

THIRD COUNT
Violation of State and Federal Law
(Respondent Stanevich)

15. By accessing patient P.S.'s confidential data in the PMP, Stanevich violated state law protecting patients from unauthorized disclosure of PMP information under NRS 453.164, and is subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

16. By accessing patient P.S.'s confidential data in the PMP, Stanevich violated federal law, HIPAA Privacy Rule pursuant to 42 USC §1320d *et seq.*, and is subject to discipline pursuant to NRS 453.236, NRS 453.241, 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 certificate of registrations of these Respondents.

Signed this 28th day of January 2022.

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, and to submit an 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, then 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, **Petitioner,** **v.** **PAUL H. HOWSE, RPH** **Certificate of Registration No. 18406,** **Respondent.**	**CASE NO. 20-135-RPH-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 28th day of January 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, **Petitioner,** **v.** **PAUL H. HOWSE, RPH** **Certificate of Registration No. 18406,** **Respondent.**	**CASE NO. 20-135-RPH-S** **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.

_____

PAUL H. HOWSE, 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 January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Justine Stanevich, PT
[redacted]Mandalay Springs Drive Apt.[redacted]
Las Vegas, NV 89120

Paul H. Howse, R.Ph.
[redacted]Montferrat Ln
Henderson, NV 89044

SHIRLEY HUNTING

5F

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH,** **Certificate of Registration No. PT18958,** **Respondent.**	**CASE NO. 20-135-RPH-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 28th day of January 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, **Petitioner,** **v.** **JUSTINE STANEVICH, PT** **Certificate of Registration No. PT18958,** **Respondent.**	**CASE NO. 20-135-PT-S** **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.

_____

JUSTINE STANEVICH, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Justine Stanevich, PT
[redacted] Mandalay Springs Drive Apt. [redacted]
Las Vegas, NV 89120

Paul H. Howse, R.Ph.
[redacted] Montferrat Ln
Henderson, NV 89044

SHIRLEY HUNTING

5G

FILED
JAN 21 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD WASHINSKY, MD,** **Certificate of Registration No. CS06491,** **Respondent.**	**Case No. 19-232-CS-S** **ORDER TO SHOW CAUSE**

1. On January 13, 2021, the Nevada State Board of Pharmacy (Board) entered an Order pursuant to stipulation with the Respondent, Richard Washinsky, MD, Certificate of Registration No. CS06491. The Order revoked Certificate of Registration No. CS06491, the revocation was stayed, and Respondent was placed on probation for two (2) years. Paragraph 9(D) states:

> Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Respondent has failed to comply with the terms of the Order.

2. On or about September 21, 2021, Board staff determined that Respondent has not reviewed his controlled substance prescription activity in the Prescription Monitoring Program (PMP) database since November 25, 2019, in violation of NRS 453.164(7).

3. Board staff further determined that for the period from September 21, 2020, to September 21, 2021, Respondent had 3,694 filled prescriptions in the PMP database for 306 unique patients, for which Respondent conducted only 119 patient reviews; only 39% of patients to whom he wrote controlled substance prescriptions were reviewed, in violation of NRS 639.23507.

4. Failure to comply with an order entered by the Board may result in the issuance by the Executive Secretary of an order to show cause directing the Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. NAC 639.965.

IT IS HEREBY ORDERED that Respondent Richard Washinsky, MD, Certificate of Registration No. CS06491, appear before the Board and show cause, if any, why Certificate of Registration No. CS06491 should not be subject to suspension or immediate revocation pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210, and/or NRS 639.255.

ENTERED this 21st day of January 2022.

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); NAC 639.968.

The Board has scheduled your show cause hearing on this matter for Wednesday, March 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

Pursuant to NRS 241.033 and NRS 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 enter 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.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Richard Washinsky, MD
2851 N. Tenaya Way Ste. 103
Las Vegas, NV 89128

Kevin Murphy, Esq.
5575 Lake Park Way, Ste. 218
La Mesa, CA 91942

Kevin Murphy, Esq.
2855 La Casita Avenue
Las Vegas, NV 89120

SHIRLEY HUNTING

NEVADA STATE BOARD OF PHARMACY
JAN 13 2021
FILED

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD WASHINSKY, MD,** **Certificate of Registration No. CS06491,** **Respondent.**	**Case No. 19-232-S** (CS-) **STIPULATION AND ORDER**

Courtney K. Lee, General Counsel for Petitioner the Nevada State Board of Pharmacy ("Board"), and Respondent Richard Washinsky, MD ("Washinsky"), Certificate of Registration No. CS06491, by and through counsel, Kevin Murphy, Esq. of Murphy Jones, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about November 17, 2020, and December 3, 2020, Board Staff served Respondent Washinsky 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. On or about December 7, 2020, Respondent Washinsky filed an Answer and Notice of Defense ("Answer") through counsel.

4. Respondent Washinsky 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.

5. Respondent Washinsky 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 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 Respondent Washinsky failed to

comply with the provisions of Paragraphs 9, 15 and/or 16 below, Respondent hereby freely and voluntarily waives his right 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.

7. Respondent Washinsky 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 certain of the violations alleged in the Accusation, that Respondent Washinsky:

A. Unlawfully prescribed controlled substance prescriptions and/or dangerous drugs issued to patients while Respondent was engaged in overseas travel, in violation of NRS 453.331(1)(f) and (h), NRS 453.401(l)(a), NRS 454.223(2), NAC 453.440, NAC 454.060, NAC 639.945, 21 CFR § 1306.03, 21 CFR § 1306.04 and/or 21 CFR § 1306.05.

B. Permitted an employee or staff to access/utilize his credentials by providing blank prescription pads with Washinsky's pre-printed name and/or signature, and/or to telephone prescriptions, in violation of NRS 453.226, NRS 453.321, NRS 453.381(1), NRS 453.401(1), NRS 639.100, NRS 639.235, NRS 639.2813(1), NAC 453.440(1)(c), NAC 639.945, 21 CFR § 1306.03, 21 CFR § 1306.04 and/or 21 CFR § 1306.05.

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, and with Washinsky not conceding or admitting to such allegations, the Board and Washinsky stipulate to the following penalties and conditions. The registration of Respondent Washinsky, MD, Certificate of Registration No. CS06491, is hereby revoked. The revocation is stayed, and Washinsky is placed on probation for two (2) years from the effective date of this signed Stipulation and Order, subject to the following conditions. Washinsky shall:

A. Accept this Stipulation and Order as a public reprimand regarding Respondent Washinsky's duties and responsibilities as a prescribing practitioner;

B. Pay a fine of Five-Thousand Dollars ($5,000.00) for the alleged violations;

C. Pay Two-Thousand Dollars ($2,000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter; and

D. Comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

10. Upon successful completion of probation, Respondent Washinsky's Certificate of Registration No. CS06491 will be fully restored, conditioned upon Washinsky's underlying medical license and DEA registration being active and in good standing.

11. 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 that 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 of revocation, and immediately revoke Washinsky's Certificate of Registration No. CS06491. The Board may impose additional discipline upon that Respondent consistent with the provisions of NRS Chapter 453 and/or 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 January 13, 2021. Respondent will appear telephonically or *via* Zoom 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 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.

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, Respondent shall pay the fines agreed to herein by *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, within thirty (30) of the effective date of this Order.

16. Upon approval of this Stipulation by the Board, Respondent shall pay the attorney's fees and costs agreed to herein by *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) of the effective date of this Order.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondent 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.

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 have freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 14 day of December, 2020

RICHARD WASHINSKY, MD
Certificate of Registration No. CS06491

APPROVED AS TO FORM AND CONTENT this 16th day of December, 2020

KEVIN MURPHY, ESQ.
Counsel for Respondent Richard Washinsky, MD

Signed this 13th day of ~~December~~ January, 2021

COURTNEY K. LEE, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Richard Washinsky, MD, Certificate of Registration No. CS06491, in Case No. 19-232-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 January, 2021.

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 21st day of January, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Kevin Murphy, Esq.
5575 Lake Park Way, Ste. 218
La Mesa, CA 91942

Kevin Murphy, Esq.
2855 La Casita Avenue
Las Vegas, NV 89120

SHIRLEY HUNTING

FILED
NOV 25 2020
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD WASHINSKY, MD,** **Certificate of Registration No. CS06491,** **Respondent.**	**CASE NO. 19-232-CS-S** **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 Richard Washinsky, MD ("Washinsky"), held a controlled substance registration, Certificate of Registration No. CS06491 issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent Washinsky operates a medical practice located at 2851 N. Tenaya Way, Suite 103, Las Vegas, Nevada 89128.

3. The Drug Enforcement Administration ("DEA") filed a referral for civil prosecution against Washinksy for forty-seven (47) violations of writing controlled substances prescriptions while out of the country.

4. Washinsky was outside of the United States from October 28-November 2, 2017, January 5-14, 2018, May 22-27, 2018, May 30-June 6, 2018, and December 19, 2018-January 3, 2019.

5. On August 3, 2017, Patient S.C. was seen by Washinsky with notes for Klonopin (generic clonazepam). Over four months later, on January 9, 2018, a prescription for clonazepam was called into the pharmacy while Washinsky was out of the country.

6. On August 31, 2017, Patient W.L. was seen by Washinsky. A prescription for Xanax 1 mg was called in by Isabelle, a member of Washinsky's staff, on October 30, 2017 while Washinsky was out of the country.

7. On October 10, 2017, Patient A.G. was seen by Washinsky with notes to continue Z-Pak and omeprazole. A prescription for promethazine-codeine syrup was called in by Isabelle, a member of Washinsky's staff, on October 30, 2017, while Washinsky was out of the country.

8. On November 13, 2017, Patient K.B. was seen by Washinsky. A prescription for Z-Pak 250 mg and Phenergan-codeine 240 cc was called in by Jordano, a member of Washinsky's staff, on January 9, 2018 while Washinsky was out of the country.

9. On January 2, 2018, Patient C.S. was seen by Washinsky with notes to "continue Xanax, amoxicillin." A prescription dated January 7, 2018 was written for Norco 10/325 mg while Washinsky was out of the country.

10. On January 3, 2018, Patient C.B. was seen by Washinsky with notes "will be out of town rx written for 1/11/18". A prescription for hydrocodone-acetaminophen 10-325 mg was written with the date of January 11, 2018 with no "do not fill until [date]" notation.

11. On January 4, 2018, Patient C.M. was seen by Washinsky with notes "Norco-written for 1-11-18". A prescription for Norco 10/325 mg was written with the date of January 11, 2018 by Washinsky's staff with no notation of "do not fill until [date]".

12. On January 4, 2018, Patient R.C. was seen by Washinsky with notes "Duragesic patch written for 1/11/18 as I will be out of town . . .Oxycodone written for 1/11/18". A prescription for fentanyl 100 mcg/hr patch and oxycodone hcl 30 mg was written on January 11, 2018 while Washinsky was out of the country. There is no notation for "do not fill until [date]". Patient R.C. was again seen on May 21, 2018 with notes for oxycodone 30 mg, Adderall 20 mg

stating "will be out of town rx written for 5/25/28". A prescription was written on May 25, 2018 for fentanyl 100 mcg/hr patch while Washinsky was out of the country.

13. On January 4, 2018, Patient J.D. was seen by Washinsky with notes to continue Xanax, zolpidem, and amlodipine. A prescription was called in by Isabelle, a member of Washinsky's staff, for alprazolam ER on January 8, 2018 while Washinsky was out of the country.

14. On April 26, 2018, Patient M.K. was seen by Washinsky with a note "Adderall 30 mg Gave rx written for 5/24/2018 as I will be out of town." A prescription pre-dated May 24, 2018 for Adderall 30 mg was written without a notation "do not fill before [date]", during a time when Washinsky was out of the country.

APPLICABLE LAW

15. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

16. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.331; NRS 453.431; NRS 453.381(1).

17. It is unlawful for a practitioner to prescribe a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 453.431; NRS 454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.

18. It is unlawful for a person to possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.

19. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).

20. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(1)(a).

21. 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).

22. 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).

23. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

24. 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).

25. 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).

26. 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. NRS 453.236(1)(d) and NRS 453.241(1).

FIRST CAUSE OF ACTION
Unprofessional Conduct – Party to a Fraudulent/Deceitful Practice/Transaction

27. By pre-signing controlled substance and/or dangerous drug prescriptions, providing blank prescription pads to staff, and/or allowing staff to call in or write prescriptions for patients while he was engaged in overseas travel, Washinsky was a party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), NRS 453.236(1), NRS 453.331, NRS 454.223, NAC 454.060, and is subject to discipline pursuant to NRS 639.210.

SECOND CAUSE OF ACTION
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

28. By pre-signing controlled substance and/or dangerous drug prescriptions, providing blank prescription pads to staff, and/or allowing staff to call in or write prescriptions for patients while he was engaged in overseas travel, Washinsky performed his duty as a holder of a Nevada 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 NRS 453.331, NRS 454.223 and NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210.

THIRD CAUSE OF ACTION
Violations of Federal Controlled Substances Act

29. By permitting his staff to prescribe controlled substances and dangerous drugs under Washinsky's name by providing blank or pre-signed prescription pads, and/or allowing staff to call in prescriptions, Washinsky violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C.

§ 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05, NRS 453.331, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11).

30. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel, Washinsky violated 21 USC § 822(a)(2), 21 USC § 823(f), 21 CFR § 1306.03 and CFR § 1306.05, NRS 453.331, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210.

FOURTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

31. As set forth herein. Washinsky has committed acts that render his registration to prescribe controlled substances inconsistent with the public interest pursuant to NRS 453.231, and is subject to discipline pursuant to NRS 453.236(1)(d) 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.

DATED this 25th day of November, 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, **Petitioner,** **v.** **RICHARD WASHINSKY, MD,** **Certificate of Registration No. CS06491,** **Respondent.**	**CASE NO. 19-232-CS-S** **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, January 13, 2021, 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 25th day of November, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF NEVADA

NEVADA STATE BOARD OF PHARMACY Petitioner, vs. RICHARD WASHINSKY, M.D. Certificate of Registration No. CS06291, Respondent.	CASE NO.: 19-232-CS-S ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION

Richard Washinsky, M.D., ("Dr. Washinsky"), by and through his counsel of record MURPHY JONES APC, in answer to the Notice of Intended Action and Accusation ("Accusation") filed in the above-entitled matter before the Nevada State Board of Pharmacy ("Board"), declares:

1. That his objection to the Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

Vague, Ambiguous, Lacks Specificity and/or Detail, .

2. That, in answer to the Accusation, Dr. Washinsky admits, denies and alleges as follows:

Dr. Washinsky has retained legal counsel who is conducting an independent investigation into the allegations espoused in the Accusation. Dr. Washinsky requests a hearing in the matter, on the merits of the case, and will provide additional information and produce relevant documentation after his legal counsel has been afforded the opportunity to adequately prepare a defense to the Accusation. With the afore-referenced reservation, Dr. Washinsky admits and denies the allegations espoused in the Notice of Intended Action and Accusation as follows:

I.

Dr. Washinsky admits that the Board has jurisdiction over this matter.

II.

Dr. Washinsky is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs II - XIV and therefore denies the same.

In addition, paragraphs XXVII - XXX call for legal conclusions and Dr. Washinsky therefore denies the same.

AFFIRMATIVE DEFENSES

FIRST AFIRMATIVE DEFENSE

1. Complainant fails to state a claim upon which relief can be granted.

SECOND AFIRMATIVE DEFENSE

2. Complainant's causes of action are barred by applicable statute of limitations

THIRD AFIRMATIVE DEFENSE

3. Complainant's causes of action are barred by the doctrine of unclean hands.

FOURTH AFIRMATIVE DEFENSE

4. Complainant's causes of action are barred by the doctrine of laches.

FIFTH AFIRMATIVE DEFENSE

5. Complainant's causes of action are barred by the doctrines of estoppel and/or waiver.

SIXTH AFIRMATIVE DEFENSE

6. The facts not having been fully developed, Respondent further affirmatively pleads the following affirmative defenses as may be applicable in this action: accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, statute of limitations, waiver, and any other matter constituting an avoidance or affirmative defense.

DATED: December 7, 2020

By:_____
Kevin C. Murphy, Esq.
Attorney for Respondent Richard Washinsky, M.D.

CERTIFICATE OF SERVICE

Case Name: **In the Matter of the Notice of Intended Action and Accusation Against: RICHARD WASHINSKY, M.D.**

Case No.: 19-232-CS-S

I declare:

I am employed in the law firm of MURPHY JONES APC, which is the office of a member of the Nevada State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter.

On December 7, 2020, I served the attached **ANSWER** via **EMAIL SERVICE** to the following person(s):

Courtney Lee, Esq., General Counsel
Nevada State Board of Pharmacy
1050 E. Flamingo Road, E-217
Las Vegas, NV 89119
Email: c.lee@pharmacy.nv.gov

I declare under penalty of perjury under the laws of the State of Nevada the foregoing is true and correct, and that this declaration was executed on December 7, 2020, at San Diego, California.

Kevin C. Murphy, Esq.
Declarant

5H

FILED
JAN 21 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM E. BANNEN, MD,** **Certificate of Registration No. CS25606,** **Respondent.**	**Case No. 21-213-CS-S** **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 and this respondent because at the time of the alleged events, Respondent William E. Bannen, M.D. ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS25606, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS25606, which expired on October 31, 2018.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after October 31, 2018, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS25606, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January, 2022.

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, **Petitioner,** **v.** **WILLIAM E. BANNEN, MD** **Certificate of Registration No. CS25606,** **Respondent.**	**CASE NO. 21-213-CS-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **WILLIAM E. BANNEN, MD** **Certificate of Registration No. CS25606,** **Respondent.**	**CASE NO. 21-213-CS-S** **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.

_____

WILLIAM E. BANNEN, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28 day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

William Bannen
2740 S Jones Blvd
Las Vegas, NV 89146

William Bannen
9133 W Russell Rd
Las Vegas, NV 89113

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

January 27, 2022

VIA CERTIFIED U.S. MAIL

Dr. William E. Bannen
2740 S. Jones Blvd.
Las Vegas, Nevada 89146

Dr. William E. Bannen
9133 W. Russell Road
Las Vegas, Nevada 89113

CEASE AND DESIST ORDER: Case No. 21-213-CS-S

Controlled Substance Registration CS 25606 – Expired 10/31/2018

Dr. William E. Bannen:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 21 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARCIA A. CLEVESY, APRN,** **Certificate of Registration No. CS14237,** **Respondent.**	**Case No. 21-214-CS-S** **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 and this respondent because at the time of the alleged events, Respondent Marcia A. Clevesy, APRN ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS14237, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS14237, which expired on October 31, 2018.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after October 31, 2018, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS14237, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January, 2022.

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, **Petitioner,** **v.** **MARCIA A. CLEVESY, APRN** **Certificate of Registration No. CS14237,** **Respondent.**	**CASE NO. 21-214-CS-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **MARCIA A. CLEVESY, APRN** **Certificate of Registration No. CS14237,** **Respondent.**	**CASE NO. 21-214-CS-S** **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.

_____

MARCIA A. CLEVESY, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28 day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Marcia Clevesy
1950 Pinto Ln
Las Vegas, NV 89106

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

January 27, 2022

VIA CERTIFIED U.S. MAIL
Marcia A. Clevesy, APRN
1950 Pinto Lane
Las Vegas, Nevada 89106

CEASE AND DESIST ORDER: Case No. 21-214-CS-S

Controlled Substance Registration CS 14237 – Expired 10/31/2018

Marcia A. Clevesy:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 21 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MAHENDRA DEFONSEKA, MD,** **Certificate of Registration No. CS02305,** **Respondent.**	**Case No. 21-215-CS-S** **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 and this respondent because at the time of the alleged events, Respondent Mehandra DeFonseka, MD, ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS02305, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS02305, which expired on October 31, 2016.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after October 31, 2016, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS02305, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January, 2022.

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, **Petitioner,** **v.** **MAHENDRA DEFONSEKA, MD** **Certificate of Registration No. CS02305,** **Respondent.**	**CASE NO. 21-215-CS-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **MAHENDRA DEFONSEKA, MD** **Certificate of Registration No. CS02305,** **Respondent.**	**CASE NO. 21-215-CS-S** **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.

_____

MAHENDRA DEFONSEKA, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 1 day of February, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Mahendra Defonseka
2839 St Rose Pkwy #130
Henderson, NV 89052

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

January 27, 2022

VIA CERTIFIED U.S. MAIL
Dr. Mahendra Defonseka
2839 St. Rose Pkwy #130
Henderson, Nevada 89052

CEASE AND DESIST ORDER: Case No. 21-215-CS-S

Controlled Substance Registration CS 02305 – Expired 10/31/2016

Dr. Mahendra Defonseka:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 21 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GEORGE M. DOCKENDORF, DO,** **Certificate of Registration No. CS20768,** **Respondent.**	**Case No. 21-216-CS-S** **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 and this respondent because at the time of the alleged events, Respondent George M. Dockendorf, DO, ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS20768, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS20768, which expired on October 31, 2018.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after October 31, 2018, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS20768, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January, 2022.

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, **Petitioner,** **v.** **GEORGE M. DOCKENDORF, DO** **Certificate of Registration No. CS20768,** **Respondent.**	**CASE NO. 21-216-CS-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **GEORGE M. DOCKENDORF, DO** **Certificate of Registration No. CS20768,** **Respondent.**	**CASE NO. 21-216-CS-S** **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.

_____

GEORGE M. DOCKENDORF, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28 day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

George Dockendorf
7391 W Charleston Blvd #140
Las Vegas, NV 89117

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

January 27, 2022

VIA CERTIFIED U.S. MAIL
Dr. George M. Dockendorf
7391 W. Charleston, Blvd. #140
Las Vegas, Nevada 89117

CEASE-AND-DESIST ORDER: Case No. 21-216-CS-S

Controlled Substance Registration CS 20768 – Expired 10/31/2018

Dr. George M. Dockendorf:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE-and-DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 21 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM C. TORCH, MD,** **Certificate of Registration No. CS02202,** **Respondent.**	**Case No. 21-227-CS-N** **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 and this respondent because at the time of the alleged events, Respondent William C. Torch, MD, ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS02202, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS02202, which expired on October 31, 2018.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after October 31, 2018, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS02202, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing herself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 21st day of January, 2022.

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, **Petitioner,** **v.** **WILLIAM C. TORCH, MD** **Certificate of Registration No. CS02202,** **Respondent.**	**CASE NO. 21-227-CS-N** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **WILLIAM C. TORCH, MD** **Certificate of Registration No. CS02202,** **Respondent.**	**CASE NO. 21-227-CS-N** **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.

_____

WILLIAM C. TORCH, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28 day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

William Torch
75 Pringle Way #701
Reno, NV 89502

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

January 27, 2022

VIA CERTIFIED U.S. MAIL
Dr. William C. Torch
75 Pringle Way #701
Reno, Nevada 89502

CEASE AND DESIST ORDER: Case No. 21-227-CS-N

Controlled Substance Registration CS 02202 – Expired 10/31/2018

Dr. William C. Torch:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 26 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYDIA E. O'CONNOR-SANDERS, DO,** **Certificate of Registration No. CS05298,** **Respondent.**	**Case No. 21-225-CS-S** **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 and this respondent because at the time of the alleged events, Respondent Lydia E. O'Connor-Sanders, DO, ("Respondent"), held an expired Nevada controlled substance registration, Certificate of Registration No. CS05298, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew Certificate of Registration No. CS05298, which was closed on December 24, 2018.

3. Respondent wrote one or more controlled substance prescriptions for Nevada patients after December 24, 2018, without a valid registration.

APPLICABLE LAW

4. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual 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 profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

6. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration 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).

8. 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).

9. 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).

10. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to timely submit the application for renewal. NRS 639.210(13).

11. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

FIRST COUNT

Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew Certificate of Registration CS05298, Respondent is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(13).

SECOND COUNT

Violation of Federal Controlled Substances Act

13. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

THIRD COUNT

Violation of State Controlled Substances Act

14. By prescribing controlled substances without a valid registration as alleged herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

FOURTH COUNT

Unprofessional Conduct – Prescribing without a Valid Registration

15. By prescribing controlled substances without a valid registration as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(l) and/or NRS 639.210(4).

FIFTH COUNT

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By prescribing controlled substances without a valid registration as alleged herein, and by falsely representing herself as a practitioner entitled to write prescriptions in this state, Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) 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.

DATED this 26th day of January, 2022.

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, **Petitioner,** **v.** **LYDIA E. O'CONNOR-SANDERS, DO** **Certificate of Registration No. CS05298,** **Respondent.**	**CASE NO. 21-225-CS-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

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 January, 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, **Petitioner,** **v.** **LYDIA E. O'CONNOR-SANDERS, DO** **Certificate of Registration No. CS05298,** **Respondent.**	**CASE NO. 21-225-CS-S** **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.

_____

LYDIA E. O'CONNOR-SANDERS, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28 day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Lydia O'Connor-Sanders
3343 S Eastern Ave
Las Vegas, NV 89169

Lydia O'Connor-Sanders
3109 Palmdesert Way
Las Vegas, NV 89120

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

January 27, 2022

VIA CERTIFIED U.S. MAIL

Dr. Lydia E. O'Connor-Sanders
3109 Palm Desert Way
Las Vegas, Nevada 89120

Dr. Lydia E. O'Connor-Sanders
3343 S. Eastern Avenue
Las Vegas, Nevada 89169

CEASE AND DESIST ORDER: Case No. 21-225-CS-S

Controlled Substance Registration CS 05298 – Expired 10/31/2018

Dr. Lydia O'Connor-Sanders:

The Nevada State Board of Pharmacy ("Board") has determined that you wrote and/or authorized controlled substance prescriptions for Nevada patients after the expiration of your controlled substance registration.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 629.515, NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients until you hold the requisite controlled substance registration.

Please be aware that the forgoing cease and desist order does not preclude further investigation or the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or p.keegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
Assistant General Counsel
Nevada State Board of Pharmacy

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FILED
JAN 21 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSE DASTAS, RPH,** **Certificate of Registration No. 16114, and** **VERTISIS CUSTOM PHARMACY, LLC,** **Pharmacy License No. PH03778,** **Respondents.**	**CASE NOS. 18-130-RPH-S** **18-130-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, R.Ph., 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 Jose Dastas, R.Ph. (Dastas), Certificate of Registration No. 16114, was a pharmacist registered with the Board, and Respondent Vertisis Custom Pharmacy, LLC ("Vertisis"), License No. PH03778, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent Vertisis is an out-of-state 503A compounding pharmacy located in Arizona. Respondent Dastas was the managing pharmacist of Vertisis at the time of the events alleged herein.

3. On or about August 20, 2018, a Board staff inspection of a Las Vegas medical practice providing intravenous hydration therapy revealed that Vertisis routinely compounded sterile products on a patient-specific prescription for administration to multiple patients.

4. In one instance, 30 ml vials of B Vitamin Complex Injection compounded by Vertisis were discovered without a patient name on the label. Records revealed that a total of 750 ml of B Vitamin Complex Injection (or 25 – 30 ml vials) were compounded by Vertisis on a prescription for one patient.

5. The investigation further revealed that Vertisis compounded the following sterile products on a patient-specific prescription submitted on or about January 24, 2018: 70 vials of ascorbic acid 50 ml (3500 ml total); 15 vials of dexpanthenol 250 mg/ml 30 ml (450 ml); 30 vials of glutathione 200 mg/ml 30 ml (900 ml); 100 vials of ascorbic acid 500 mg/ml 100 ml (10,000 ml); and sublingual sermorelin 300 mcg/ml 30 ml.

APPLICABLE LAW

6. Section 503A of the Federal Food, Drug, and Cosmetic Act permits a pharmacy to compound a drug product for an identified individual patient based upon a valid prescription. 21 USC § 353a.

7. No pharmacist should fill a prescription for a dangerous drug for use by any person other than the person for whom the prescription was originally issued or fill a prescription which is not genuine. NRS 454.231; NRS 454.311(3)(b).

8. Performing any duties as the holder of a license or 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).

9. The Board may suspend or revoke a license or registration pursuant to NRS 639.210(11) 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.

10. The Board may suspend or revoke a license or registration pursuant to NRS 639.210(12) 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.

11. A managing pharmacist is responsible for violations committed by the pharmacy's employees. NRS 639.210(15); NRS 639.220(1), NRS 639.230(5); NAC 639.702.

12. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230(5); NAC 639.945(2); NAC 639.702.

COUNT ONE
Violations of Federal and State Law

13. Respondents violated 21 USC § 353a, NRS 454.231 and/or NRS 454.311(3)(b) when they compounded or permitted compounding of sterile products on patient-specific prescriptions for administration to multiple patients and are therefore subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT TWO
Unprofessional Conduct
(Respondent Dastas)

14. Respondent Dastas engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he compounded or permitted compounding of sterile products on patient-specific prescriptions for administration to multiple patients and is therefore subject to discipline pursuant to NRS 639.210(4).

COUNT THREE
Managing Pharmacist Responsibilities
(Respondent Dastas)

15. As the managing pharmacist of Vertisis at the time of the violations alleged herein, Dastas is responsible for those violations, including all errors and omissions of the pharmacy's employees, pursuant to NRS 639.210(15), NRS 639.220(1), and/or NRS 639.230(5).

COUNT FOUR
Pharmacy/Owner Responsibilities
(Respondent Vertisis)

16. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Vertisis is responsible for those violations, including all errors and omissions of Respondent Dastas and/or other pharmacy employees, 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 licenses/registrations of these Respondents.

Signed this 21st day of January 2022.

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, and to submit an answer to 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, then 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, **Petitioner,** **v.** **JOSE DASTAS, RPH,** **Certificate of Registration No. 16114,** **Respondent.**	**CASE NO. 18-130-RPH-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671

or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

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 January 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, **Petitioner,** **v.** **JOSE DASTAS, RPH,** **Certificate of Registration No. 16114,** **Respondent.**	**CASE NO. 18-130-RPH-S** **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.

_____

JOSE DASTAS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jose Dastas, R.Ph.
4616 E Buckboard Ct
Gilbert, AZ 85297

Vertisis Custom Pharmacy, LLC
9343 E. Bahia Dr., Suite200
Scottsdale, AZ 85260

SHIRLEY HUNTING

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VERTISIS CUSTOM PHARMACY, LLC, Pharmacy License No. PH03778,** **Respondent.**	**CASE NO. 18-130-PH-S** **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 2, 2022, at 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671

or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

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 January 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, **Petitioner,** **v.** **VERTISIS CUSTOM PHARMACY, LLC, Pharmacy License No. PH03778,** **Respondent.**	**CASE NO. 18-130-PH-S** **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 VERTISIS CUSTOM PHARMACY, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of January, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jose Dastas, R.Ph.
4616 E Buckboard Ct
Gilbert, AZ 85297

Vertisis Custom Pharmacy, LLC
9343 E. Bahia Dr., Suite200
Scottsdale, AZ 85260

SHIRLEY HUNTING

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6A

Status update to be provided by Board Staff.

6B

Status update to be provided by Board Staff.

7

Johnathon Fayeghi, Esq.
Nevada Bar No.: 12736
SKLAR WILLIAMS PLLC
410 South Rampart Boulevard, Suite 350
Las Vegas, Nevada 89145
Telephone: (702) 360-6000
Facsimile: (702) 360-0000
Email: cpomerantz@sklar-law.com
jfayeghi@sklar-law.com

Attorneys for Dhaval Shah, MD

FILED
JAN 18 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DHAVAL SHAH, MD, Certificate of Registration Nos. CS15290 and PD00165, Respondent.	CASE NO.: 20-222-CS-S **PETITION FOR REINSTATEMENT OF CONTROLLED SUBSTANCE REGISTRATION AND DISPENSING PRACTITIONER REGISTRATION AND REQUEST TO APPEAR BEFORE THE BOARD**

Comes Now, Petitioner Dhaval Shah, M.D. ("Dr. Shah"), by and through his counsel, Johnathon Fayeghi, Esq., of the law firm Sklar Williams PLLC, hereby petitions the Nevada State Board of Pharmacy for reinstatement of Dr. Shah's Controlled Substance Registration and Dispensing Practitioner Registration pursuant to NRS 639.257 based on the following:

I. Nevada State Board of Medical Examiners Proceeding

On July 12, 2019, the Investigative Committee (the "IC") of the Nevada Board of Medical Examiners (the "NBME") filed a formal Complaint – Case No. 19-32539-01 ("Complaint 1") charging Dr. Shah with one (1) violation of NRS 630.301(4), Malpractice (Count I), and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Timely, Legible, Accurate and Complete Medical Records (Count II). Subsequently, the IC advised that it intended to proceed with the filing of a formal Complaint ("Complaint 2") charging Dr. Shah with one (1) violation of NRS 630.301(4), Malpractice (Count I), one (1) violation of NRS 630.3062(1)(a), Failure to Maintain

Accurate and Complete Medical Records (Count II), one violation of NRS 630.301(4), Malpractice – Respondeat Superior (Count III, and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Accurate and Complete Medical Records – Respondeat Superior (Count IV).

In light of Complaint 1 and the impending Complaint 2 and in an attempt to fully cooperate with the IC, on March 4, 2020, Dr. Shah voluntarily placed his medical license in inactive status to allow the IC to conduct its investigation regarding Complaint 2. On March 16, 2020, the IC formally filed Complaint 2 against Dr. Shah. That same day, Dr. Shah entered into a settlement agreement (the "Settlement Agreement") with the IC which was to be considered by the NBME's Judiciary Committee at its June 5, 2020 meeting. Under the terms of the Settlement Agreement, Dr. Shah: (i) admitted to Count II of Complaint 1 (failure to maintain timely, legible, accurate and complete medical records) and all counts of Complaint 2 (Count I – malpractice, Count II – failure to maintain accurate and complete medical records, Count III – malpractice – respondeat superior, and Count IV – failure to maintain accurate and complete medical records – respondeat superior); (ii) agreed to pay a fine in the amount of $10,000.00; (iii) agreed to pay the costs and expenses incurred in the investigation and prosecution of Complaint 1 and Complaint 2 in the amount of $23,246.70; and (iv) agreed to the revocation of his medical license for a period of one year from the date of the Judiciary Committee's acceptance of the Settlement Agreement. A true and correct copy of the Settlement Agreement is attached hereto as **Exhibit 1**.

However, on or about March 13, 2020, Nevada Governor Steve Sisolak declared a state of emergency in response to the global pandemic of COVID-19 and as a result, the NBME was required to close and postpone the June 5, 2020 meeting. Moreover, due to the extraordinary and emergent circumstances surrounding the global pandemic of COVID-19 and the State of Emergency declared by Governor Sisolak and the significant need for professional infectious disease treatment for the people of the State of Nevada, the IC and Dr. Shah entered into a Stipulation and Order for Active License, With Conditions on March 16, 2020 (the "Stipulation") which permitted Dr. Shah to resume the practice of medicine in Nevada provided that Dr. Shah (i)

limit his practice to the treatment of infectious disease patients related to the COVID-19 infection and any other infectious disease patients as such circumstances require and medical activities directly related thereto; and (ii) provide written reports to the IC at least twice monthly regarding his medical activities.

Pursuant to the Stipulation, Dr. Shah's medical license was reactivated to "active" status on March 16, 2020. Although not required under the Stipulation, Dr. Shah decided that he would not provide professional medical services for profit and instead focused all of his time and effort to providing volunteer professional medical services to assist Nevada in the public health response to COVID-19. Although Dr. Shah's medical license with the NBME was technically in "active" status from March 16, 2020 through August 26, 2020, Dr. Shah's practice of medicine during this time solely consisted of the provision of volunteer professional medical services with the Southern Nevada Health District ("SNHD") as an infectious disease expert at SNHD's Camp Covid ISO Cashman Center site. At Camp Covid, Dr. Shah's volunteer services included: (i) admitting new patients; (ii) conducting patient rounds; (iii) conducting COVID-19 blood tests at the site; (iv) assistance with the preparation of the site's patient admission, patient discharge, patient testing and infection control policies. In addition, during this time, Dr. Shah devoted a considerable amount of time and resources to the formation of Las Vegas Health Center, a Nevada nonprofit corporation, established to assist uninsured patients in receiving coordinated medical care at no cost. Although Dr. Shah did not provide any medical services for Las Vegas Health Center, he donated the initial funding to the organization, obtained 501(c)(3) status for the organization, prepared marketing materials and various policies and procedures and applied for federal and state grants for the organization during this time.

Due to the Governor's State of Emergency, the NBME's June 5, 2020 meeting to consider the acceptance and approval of the Settlement Agreement was postponed nearly three months until August 26, 2020. At such meeting, the NBME approved and accepted the Settlement Agreement and as a result the NBME entered its order (the "NBME Order") as of August 26, 2020 which

provided the following: (i) Dr. Shah's license shall be immediately revoked and pursuant to NRS 622A.410(1), Dr. Shah may not apply for reinstatement of his medical license for a period of one (1) year from the date of the NBME's acceptance of the Settlement Agreement as an Order of the NBME; (ii) Dr. Shah shall pay a fine of $2,000 per count admitted to, consisting of five (5) counts, for a total of $10,000, within sixty (60) days of the NBME's acceptance, adoption and approval of the Settlement Agreement; (iii) Dr. Shah shall pay the costs and expenses incurred in the investigation and prosecution of Complaint 1 and Complaint 2 within sixty (60) days of the NBME's acceptance, adoption and approval of the Settlement Agreement, the current amount being $23,246.70; (iv) Dr. Shah shall receive a Public Letter of Reprimand; and (v) the remaining counts of Complaint 1 and Complaint 2, and any other claims arising therefrom or from pending Board Investigations, Case Nos. 20-19416, 20-19375, 19-19162, 19-19137, 19-18542, 18-17919 and 15-15920, shall be dismissed with prejudice. A true and correct copy of the NBME Order is attached hereto as **Exhibit 2**.

On September 10, 2021, Dr. Shah appeared at a hearing before NBME related to his application for licensure to practice medicine in the State of Nevada. At such hearing, the NBME approved Dr. Shah's application for licensure and subsequently entered its Order Granting Application for Licensure (the "Order Granting Licensure"), which granted Dr. Shah's application for licensure subject to the following conditions:

1. Dr. Shah's license will be subject to a term of probation of two (2) years, during which Dr. Shah shall be prohibited from:

   a. Committing any new violations of the Medical Practice Act, Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC);

   b. Supervising any physician assistant pursuant to NAC 630.490; and

   c. Collaborating with any advanced practice registered nurse pursuant to NAC 630.490.

A true and correct copy of the Order Granting Licensure is attached hereto as **Exhibit 3**. As a result of the Order Granting Licensure, the NBME issued Dr. Shah NBME License No. 21492 on or about September 14, 2021. *See* **Exhibit 4**.

II. Nevada State Board of Pharmacy Proceeding

As a result of the revocation of Dr. Shah's medical license pursuant to the NBME Order, Dr. Shah surrendered his DEA Certificate of Registration No. BS9611333 to the U.S. Drug Enforcement Administration by executing a DEA Form 104 on or about October 13, 2020.

On or about October 27, 2020, the Nevada State Board of Pharmacy (the "Board") served Dr. Shah with a Notice of Intended Action and Accusation – Case No. 20-222-CS-S (the "Accusation"), alleging the following causes of action against Dr. Shah: (1) First Cause of Action – Violations of state Law (violation of NRS Chapter 630 as detailed in the NBME Order); (2) Second Cause of Action – Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties (by violating NRS Chapter 630 as detailed in the NBME Order, Dr. Shah has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct); (3) Third Cause of Action – Commission of Acts that Render Registration Inconsistent with the Public Interest (by violating NRS Chapter 630 as detailed in the NBME Order, Dr. Shah has committed acts that render his registrations to prescribe and dispense controlled substances inconsistent with the public interest; Dr. Shah no longer qualifies for registration to dispense controlled substances under federal or state law); (4) Fourth Cause of Action – Revocation of License to Practice Medicine (by the revocation of his NBME license, Dr. Shah has committed acts that render his registration to dispense controlled substances inconsistent with the public interest and Dr. Shah no longer qualifies for registration to dispense controlled substances under federal or state law; and (5) Fifth Cause of Action – Surrender of DEA Registration for Cause (by surrendering his DEA Certificate of Registration for cause, Dr. Shah committed an act that would render his registration to dispense controlled substances inconsistent with the public interest and is no longer authorized by Federal

law to dispense controlled substances). A true and correct copy of the Accusation is attached hereto as **Exhibit 5**.

On or about December 4, 2020, Dr. Shah filed an Answer and Notice of Defense to the Accusation. A true and correct copy of Dr. Shah's Answer and Notice of Defense is attached hereto as **Exhibit 6**. However, on or about December 8, 2021, in an attempt to fully cooperate with the Board, Dr. Shah entered into a stipulation (the "Pharmacy Board Stipulation") with Brett Kandt, General Counsel for the Board, which was to be considered by the Board at its January 13, 2021 meeting. Under the Pharmacy Board Stipulation, Dr. Shah acknowledged that the Board staff could present evidence to establish a factual basis for the following: (i) The Nevada State Board of Medical Examiners has entered an order in Case Nos. 19-32539-01 and 20-32539-1, and revoked Respondent's License No. 12305 to practice medicine for violations of NRS Chapter 630; (ii) Respondent has surrendered his DEA Certificate of Registration No. BS9611333 to the U.S. Drug Enforcement Administration by executing a DEA Form 104; and (iii) Respondent is no longer authorized by Federal or state law to prescribe or dispense controlled substances. In addition, Dr. Shah agreed to the following: (a) the revocation of his Certificate of Registration Nos. CS15290 and PD00165; (b) he shall not prescribe any controlled substance or dispense any controlled substance or dangerous drug until he petitions the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his controlled substance registration and dispensing practitioner registration; and (c) he may not petition for reinstatement of his certificate of registration for a period of one (1) year from the Board's acceptance of the Stipulation. A true and correct copy of the Pharmacy Board Stipulation is attached hereto as **Exhibit 7**.

On January 13, 2021, the Board approved and accepted the Pharmacy Board Stipulation and as a result the Board entered its decision and order accepting the terms of the Pharmacy Board Stipulation as of January 15, 2021 (the "Board Order"). A true and correct copy of the Board Order is attached hereto as **Exhibit 8**.

III. Law

NRS 639.257 entitled "Reinstatement of revoked certificate, license or permit" provides the following:

> 1. A person whose certificate, license or permit has been revoked may petition the Board for reinstatement after a period of not less than 1 year has lapsed since the date of revocation.
>
> 2. The petition shall state such facts as may be required by the Board and shall be heard by the Board at its next regular meeting held not earlier than 30 days after the petition is filed. Such petition may be considered by the Board while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on probation or parole, only if the Board members, by a majority vote, find that the public interest would best be served by such reinstatement.
>
> 3. In considering reinstatement the Board may investigate and consider all activities of the petitioner since the time the original certificate, license or permit was issued and his or her ability, character and reputation. The affirmative vote of at least three members is necessary for reinstatement of a certificate, license or permit with or without terms, conditions and restrictions.

IV. Reasons Why Reinstatement Is Justified

In accordance with the terms and conditions of the Board Order, Dr. Shah files this Petition for Reinstatement of his Controlled Substance Registration and Dispensing Practitioner Registration and respectfully submits that reinstatement of his Controlled Substance Registration and Dispensing Practitioner Registration is justified based upon the following:

1. Dr. Shah has complied with the terms and conditions of the NBME Order as:
   a. He provided volunteer medical services exclusively in the area of COVID-19 from March 16, 2020 through May 26, 2020;
   b. He completely refrained from the practice of medicine since May 27, 2020; and
   c. He paid the fine in the amount of $10,000 and the costs and expenses in the amount of $23,246.70 to NSBME on September 11, 2020.

2. On September 10, 2021, the NBME issued the Order Granting Licensure and as a result the NBME issued Dr. Shah NBME License No. 21492 on or about September 14, 2021.

3. Dr. Shah has complied with the terms and conditions of the Board Order as:

a. He has not possessed, administered, prescribed and/or dispensed any controlled substance or dangerous drug since August 26, 2020; and

b. over one (1) year has lapsed since the date of revocation of his Controlled Substance Registration and Dispensing Practitioner Registration, that date being January 15, 2021.

V. Conclusion

Dr. Shah accepts full responsibility for his actions. Since last appearing before the Board on this matter, Dr. Shah has taken significant steps to earn the Board's trust and to demonstrate his contrition and commitment to improvement. Dr. Shah has – and will – continue to take any steps the Board deems appropriate to earn the trust of the Board. Dr. Shah has the utmost respect for the medical community, and for the role of the Board in regulating the prescribing and dispensing of medications and in ensuring that the residents of this great State receive the best possible care. This has been a very humbling experience for Dr. Shah which has driven home the fact that the practice of medicine is a privilege and not a right. The Board can rest assured that Dr. Shah is committed to maintaining the highest prescribing and dispensing standards from this point forward in the event his Petition for Reinstatement is approved.

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Based on the foregoing, Dr. Shah respectfully requests that the Board reinstate his Controlled Substance Registration and Dispensing Practitioner Registration.

Dated this 15th day of January, 2022.

Reviewed and approved:

Dhaval J. Shah, MD

Respectfully Submitted,

SKLAR WILLIAMS PLLC

Johnathon Fayeghi, Esq.
Nevada Bar No.: 12736
410 S. Rampart Blvd., Ste 350
Las Vegas, NV 89145
Attorney for Dhaval J. Shah, MD

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaints Against DHAVAL JASVANTBHAI SHAH, M.D., Respondent.	**Case Nos. 19-32539-01 20-32539-1**

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Senior Deputy General Counsel for the Board and attorney for the IC, and Dhaval Jasvantbhai Shah, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorneys, Crane Pomerantz, Esq., and Johnathon Fayeghi, Esq., of the law firm of Sklar Williams PLLC, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. Background

1. Respondent is a medical doctor currently licensed in inactive status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act). His license was originally issued on June 15, 2007 (License No. 12305).

2. On July 12, 2019, in Case No. 19-32539-01, the IC filed a formal Complaint (Complaint One) charging Respondent with violating the Medical Practice Act. Specifically, Complaint One alleges one (1) violation of NRS 630.301(4), Malpractice (Count I), and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Timely, Legible, Accurate and Complete

[1] All agreements and admissions made by Respondent are solely for final disposition of these matters and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Medical Records (Count II). On March 16, 2020, in Case No. 20-32539-1, the IC filed a formal Complaint (Complaint Two) charging Respondent with violating the Medical Practice Act. Specifically, Complaint Two alleges one (1) violation of NRS 630.301(4), Malpractice (Count I), one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Accurate and Complete Medical Records (Count II), one (1) violation of NRS 630.301(4), Malpractice – Respondeat Superior (Count III), and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Accurate and Complete Medical Records – Respondeat Superior (Count IV). Complaints One and Two are hereinafter referred to collectively as the "Complaints."

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of the Complaints, has reviewed and understands the Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaints.

5. Respondent is hereby advised of his rights regarding these administrative matters, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in these administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

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Nevada State Board of Medical Examiners
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7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. Terms & Conditions

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with these administrative matters. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaints filed in this matter, including defense of the Complaints, adjudication of the

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaints remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges that Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts that if these matters were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve these Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count II of Complaint One, Failure to Maintain Timely, Legible, Accurate and Complete Medical Records, and all counts of Complaint Two, Count I, Malpractice, Count II, Failure to Maintain Accurate and Complete Medical Records, Count III, Malpractice – Respondeat Superior, and Count IV, Failure to Maintain Accurate and Complete Medical Records – Respondeat Superior.

b. Respondent's license shall be immediately revoked. Pursuant to NRS 622A.410(1), Respondent may not apply for reinstatement of his medical license for a period of one (1) year from the date of the Board's acceptance of this Agreement as an Order of the Board.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
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(775) 688-2559

c. Respondent shall pay a fine of $2,000 per count admitted to hereby, consisting of five (5) counts, for a total of $10,000, within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement

d. Respondent shall pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matters within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being $23,246.72, not including any costs that may be necessary to finalize this Agreement.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. The remaining counts of the Complaints, and any other claims arising therefrom or from pending Board Investigations, Case Nos. 20-19416, 20-19375, 19-19162, 19-19137, 19-18542, 18-17919 and 15-15920, shall be dismissed with prejudice.

6. Release From Liability. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. Procedure for Adoption of Agreement. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of the Complaints. In the course of seeking Board acceptance, approval and adoption

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of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the cases shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering the Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court,

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State of Nevada, Washoe County.

12. Attorneys' Fees and Costs. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. Failure to Comply With Terms. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order To Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

Dated this 16 day of March, 2020.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
Aaron Bart Fricke, Esq., Senior Deputy General Counsel
Attorney for the Investigative Committee

Dated this 13th day of March 2020.

Sklar Williams PLLC

By: _____
Crane Pomerantz, Esq.
Johnathon Fayeghi, Esq.
Attorneys for Respondent

Dated this 13 day of March, 2020.

_____
Dhaval Jasvantbhai Shah, M.D., Respondent

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EXHIBIT 2

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaints Against DHAVAL JASVANTBHAI SHAH, M.D., Respondent.	Case Nos. 19-32539-01 20-32539-1

FILED
AUG 2 6 2020
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Senior Deputy General Counsel for the Board and attorney for the IC, and Dhaval Jasvantbhai Shah, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorneys, Crane Pomerantz, Esq., and Johnathon Fayeghi, Esq., of the law firm of Sklar Williams PLLC, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. Background

1. Respondent is a medical doctor currently licensed in inactive status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act). His license was originally issued on June 15, 2007 (License No. 12305).

2. On July 12, 2019, in Case No. 19-32539-01, the IC filed a formal Complaint (Complaint One) charging Respondent with violating the Medical Practice Act. Specifically, Complaint One alleges one (1) violation of NRS 630.301(4), Malpractice (Count I), and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Timely, Legible, Accurate and Complete

[1] All agreements and admissions made by Respondent are solely for final disposition of these matters and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

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Medical Records (Count II). On March 13, 2020, in Case No. 20-32539-1, the IC filed a formal Complaint (Complaint Two) charging Respondent with violating the Medical Practice Act. Specifically, Complaint Two alleges one (1) violation of NRS 630.301(4), Malpractice (Count I), one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Accurate and Complete Medical Records (Count II), one (1) violation of NRS 630.301(4), Malpractice – Respondeat Superior (Count III), and one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Accurate and Complete Medical Records – Respondeat Superior (Count IV). Complaints One and Two are hereinafter referred to collectively as the "Complaints."

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of the Complaints, has reviewed and understands the Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaints.

5. Respondent is hereby advised of his rights regarding these administrative matters, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in these administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

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7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. Terms & Conditions

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with these administrative matters. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaints filed in this matter, including defense of the Complaints, adjudication of the

allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaints remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges that Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts that if these matters were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve these Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count II of Complaint One, Failure to Maintain Timely, Legible, Accurate and Complete Medical Records, and all counts of Complaint Two, Count I, Malpractice, Count II, Failure to Maintain Accurate and Complete Medical Records, Count III, Malpractice – Respondeat Superior, and Count IV, Failure to Maintain Accurate and Complete Medical Records – Respondeat Superior.

b. Respondent's license shall be immediately revoked. Pursuant to NRS 622A.410(1), Respondent may not apply for reinstatement of his medical license for a period of one (1) year from the date of the Board's acceptance of this Agreement as an Order of the Board.

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c. Respondent shall pay a fine of $2,000 per count admitted to hereby, consisting of five (5) counts, for a total of $10,000, within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement

d. Respondent shall pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matters within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being $23,246.7, not including any costs that may be necessary to finalize this Agreement.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. The remaining counts of the Complaints, and any other claims arising therefrom or from pending Board Investigations, Case Nos. 20-19416, 20-19375, 19-19162, 19-19137, 19-18542, 18-17919 and 15-15920, shall be dismissed with prejudice.

6. **Release From Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of the Complaints. In the course of seeking Board acceptance, approval and adoption

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of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the cases shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering the Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court,

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State of Nevada, Washoe County.

12. Attorneys' Fees and Costs. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. Failure to Comply With Terms. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order To Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

Dated this 16 day of MARCH, 2020.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
Aaron Bart Fricke, Esq., Senior Deputy General Counsel
Attorney for the Investigative Committee

Dated this 13th day of March, 2020.

Sklar Williams PLLC

By: _____
Crane Pomerantz, Esq.
Johnathon Fayeghi, Esq.
Attorneys for Respondent

Dated this 13th day of March, 2020.

_____
Dhaval Jasvantbhai Shah, M.D., Respondent

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IT IS HEREBY ORDERED that the foregoing Settlement Agreement (19-32539-01 and 20-32539-1) is approved and accepted by the Nevada State Board of Medical Examiners on the 26th day of August, 2020, with the final total amount of costs due of $23,246.70.

D Prabhu Rachakonda M.D.

Rachakonda D. Prabhu, M.D., President
NEVADA STATE BOARD OF MEDICAL EXAMINERS

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EXHIBIT 3

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Application for Licensure to Practice Medicine of:

DHAVAL JASVANTBHAI SHAH, M.D.,

Applicant.

FILED

SEP 10 2021

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By:

ORDER GRANTING APPLICATION FOR LICENSURE

The application of Dhaval Jasvantbhai Shah, M.D. (Dr. Shah), for licensure to practice medicine in the State of Nevada came before the Nevada State Board of Medical Examiners ("Board") on September 10, 2021, for possible action. Upon review of the application, and following discussion with Dr. Shah and his counsel, Johnathon Fayeghi, Esq., and Crane Pomerantz, Esq., of the law firm of Sklar Williams PLLC, good cause appearing, the Board hereby enters its Order as follows:

IT IS HEREBY ORDERED that Dr. Shah's application for licensure is hereby GRANTED, subject to the following conditions:

1. Dr. Shah's license will be subject to a term of probation of two (2) years from the date of this Order (Probationary Period), during which Dr. Shah shall be prohibited from:

   a. Committing any new violations of the Medical Practice Act, Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC);

   b. Supervising any physician assistant pursuant to NAC 630.490; and

   c. Collaborating with any advanced practice registered nurse pursuant to NAC 630.490.

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IT IS HEREBY FURTHER ORDERED, that should the Investigative Committee (IC) of the Board determine that it has a reasonable basis to allege that Dr. Shah has failed to comply with any term, or condition, of this Order during the Probationary Period, the IC shall be authorized to immediately suspend Dr. Shah's license to practice medicine pending a duly noticed Order To Show Cause Hearing on maintaining the suspension pending final adjudication by the Board of the alleged violation. Failure to comply with the terms of this Order is a failure to comply with an order of the Board, which may result in additional disciplinary action. *See* NRS 630.3065(2)(a).

DATED this 10th day of September, 2021.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

VICTOR M. MURO, M.D.
Board President

EXHIBIT 4

Dhaval Jasvantbhai SHAH

License Number:	21492
License Type:	Medical Doctor
License Status:	Active-Probation
Initial License Date:	Sep-14-2021
Expiration Date:	Jun-30-2023
Public Address:	7452 Grassy Field Court
Public City:	Las Vegas
Public State:	Nevada
Public ZIP Code:	89131
Public Country:	United States
Public Phone Number:	(702) 578-5737

Specialties

Specialty
Infectious Diseases
Infectious Diseases

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
SHETH CHIMANLAL NAGINDAS VIDHAYALAYA	High School Diploma	Jul-01-1985	Jun-30-1987
M.P. SHAH MEDICAL COLLEGE	Medical Doctor Degree	Sep-09-1991	Apr-30-1996

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
NORTH SHORE UNIVERSITY HOSPITAL AT FOREST HILLS	Internship	Internal Medicine	Jul-01-2002	Jun-30-2003
NORTH SHORE UNIVERSITY HOSPITAL AT FOREST HILLS	Residency	Internal Medicine	Jul-01-2003	Jun-30-2005
MONTEFIORE MEDICAL CENTER	Fellowship	Infectious Diseases	Jul-01-2005	Jun-30-2007

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
PROBATIONARY CONDITIONS September 10, 2021 The Board approved Dhaval Jaasvantbhai Shah, M.D.'s application for medical licensure with the following probationary conditions: * License on probation for a period of two years from the date of this Order. Dr. Shah is prohibited from: (a) Committing any new violations of the Medical Practice Act, Chapter 630 of the Nevada Revised Statues (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (b) Dr. Shah is prohibited from supervising any physician assistant pursuant to NAC 630.490 and (c) Dr. Shah is prohibited from collaborating with any advance practice registered nurse pursuant to NAC 630.490. Failure to comply with the terms of this Order is a failure to comply with an order of the Board, which may result in additional disciplinary action.	Order 9-10-2021.pdf (/rest/public/data/downloadannotation/index.php?id=61425ba6fee73402bc63b0f0&entity=$2y$10$1ejvZdsn/RO260OYPjDVue

Powered by Thentia Cloud (https://www.thentia.com)

EXHIBIT 5

FILED
OCT 27 2020
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DHAVAL SHAH, MD, Certificate of Registration Nos. CS15290 and PD00165, Respondent.	CASE NO. 20-222-CS-S 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 Dhaval Shah, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS15290, and a Nevada dispensing practitioner registration, Certificate of Registration No. PD00165, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about August 26, 2020, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case Nos. 19-32539-01 and 20-32539-1, and revoked Respondent's License No. 12305 to practice medicine for violations of NRS Chapter 630.

3. On October 13, 2020, Respondent surrendered his DEA Certificate of Registration No. BS9611333 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

4. 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.

5. On or about October 23, 2020, Board staff served Respondent with notice that the revocation of his NSBME License No. 12305 and his surrender of his DEA Certificate of Registration No. BS9611333 for cause operated as an immediate suspension of his Certificate of Registration Nos. CS15290 and PD00165 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering, prescribing and/or dispensing controlled substances and dangerous drugs for Nevada patients.

FIRST CAUSE OF ACTION
Violations of State Law

6. Respondent has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS Chapter 630 as detailed in the NSBME's order in Case Nos. 19-32539-01 and 20-32539-1, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

SECOND CAUSE OF ACTION
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

7. By violating NRS Chapter 630 as detailed in the NSBME's order in Case Nos. 19-32539-01 and 20-32539-1, 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) and NRS 639.210(4).

THIRD CAUSE OF ACTION
Commission of Acts that Render Registration Inconsistent with the Public Interest

8. By violating NRS Chapter 630 as detailed in the NSBME's order in Case Nos. 19-32539-01 and 20-32539-1, Respondent has committed acts that render his registrations to prescribe and dispense controlled substances inconsistent with the public interest pursuant to

NRS 453.231, 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).

FOURTH CAUSE OF ACTION
Revocation of License to Practice Medicine

9. 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 dispense any controlled substance. NRS 453.226(1); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f).

10. By the revocation of his NSBME License No. 12305 to practice medicine, Respondent has committed acts that render his registration to dispense controlled substances inconsistent with the public interest pursuant to NRS 453.231, 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).

FIFTH CAUSE OF ACTION
Surrender of DEA Registration for Cause

11. By surrendering his DEA Certificate of Registration No. BS9611333 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).

12. The suspension of Respondent's Certificate of Registration Nos. CS15290 and PD00165 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 27th 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, **Petitioner,** **v.** **DHAVAL SHAH, MD,** **Certificate of Registration Nos. CS15290 and PD00165,** **Respondent.**	**CASE NO. 20-222-CS-S** **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 27th day of October, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

EXHIBIT 6

Crane M. Pomerantz, Esq.
Nevada Bar No.: 14103
Johnathon Fayeghi, Esq.
Nevada Bar No.: 12736
SKLAR WILLIAMS PLLC
410 South Rampart Boulevard, Suite 350
Las Vegas, Nevada 89145
Telephone: (702) 360-6000
Facsimile: (702) 360-0000
Email: cpomerantz@sklar-law.com
jfayeghi@sklar-law.com

Attorneys for Dhaval Shah, MD

FILED
DEC 4 2020
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DHAVAL SHAH, MD, Certificate of Registration Nos. CS15290 and PD00165, Respondent.	CASE NO.: 20-222-CS-S **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-titled matter before the Nevada States Board of Pharmacy (the "Board"), declares:

1. That his objections to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: None.

2. That, in response to the Notice of Intended Action and Accusation, Respondent admits, denies, and alleges as follows:

a. Answering Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that at the time of the events alleged in the Notice of Intended Action and Accusation he held a Nevada controlled substance registration (Certificate of Registration No. CS15290) and a Nevada dispensing practitioner registration (Certificate of Registration No.

PD00165), and thus, falls within the jurisdiction of the Board.

b. Answering Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits the allegations set forth therein.

c. Answering Paragraph 3 of the Notice of Intended Action and Accusation, Respondent admits the allegations set forth therein.

d. Answering Paragraph 4 of the Notice of Intended Action and Accusation, Respondent admits that on October 13, 2020 he executed the DEA Surrender for Cause due to the Nevada State Board of Medical Examiners' August 26, 2020 Order revoking Respondent's License No. 12305. The remaining allegations of Paragraph 4 of the Notice of Intended Action and Accusation call for a legal conclusion and therefore Respondent need not respond to such allegations. To the extent an answer is required, Respondent denies the remaining allegations in this paragraph.

e. Answering Paragraph 5 of the Notice of Intended Action and Accusation, Respondent is without sufficient information to admit or deny the allegations in this paragraph. Respondent affirmatively states that he has not possessed, administered, prescribed and/or dispensed controlled substances or dangerous drugs for any patients since August 26, 2020.

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f. Answering Paragraphs 6 through 12 of the Notice of Intended Action and Accusation, these paragraphs contain conclusions of law for which no answer is required. To the extent an answer is required, Respondent denies the allegations in these paragraphs.

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 best of my knowledge.

Dated this 3rd day of December, 2020.

DHAVAL SHAH MD

On behalf of Respondent:

SKLAR WILLIAMS PLLC

Crane M. Pomerantz, Esq.
Nevada Bar No.: 14103
Johnathon Fayeghi, Esq.
Nevada Bar No.: 12736
410 South Rampart Blvd., Suite 350
Las Vegas, Nevada 89145
Telephone: (702) 360-6000
Facsimile: (702) 360-000

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of SKLAR WILLIAMS PLLC, and that on this 4th day of December, 2020, I caused two true and correct copies of the foregoing **Answer and Notice of Defense** to be sent via overnight mail to the Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

An employee of SKLAR WILLIAMS PLLC

EXHIBIT 7

NEVADA STATE BOARD OF PHARMACY
JAN 11 2021
FILED

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DHAVAL SHAH, MD, Certificate of Registration Nos. CS17603 and PD00165, Respondent.	CASE NO. 20-222-CS-S STIPULATION AND ORDER

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Dhaval Shah, MD, Certificate of Registration Nos. CS15290 and PD00165, by and through counsel, Johnathon Fayeghi, Esq. and Crane M. Pomerantz, Esq., HEREBY STIPULATE AND AGREE THAT:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about October 27, 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.

3. On or about December 4, 2020, Respondent filed an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of his right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of his right to a hearing on the matters alleged in the Accusation, his right to reconsideration, his 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).

6. 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).

7. 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*:

A. The Nevada State Board of Medical Examiners has entered an order in Case Nos. 19-32539-01 and 20-32539-1, and revoked Respondent's License No. 12305 to practice medicine for violations of NRS Chapter 630;

B. Respondent has surrendered his DEA Certificate of Registration No. BS9611333 to the U.S. Drug Enforcement Administration by executing a DEA Form 104; and

C. Respondent is no longer authorized by Federal or state law to prescribe or dispense controlled substances.

8. Those violations are plead with particularity in the Accusation, and are grounds for revocation of Certificate of Registration Nos. CS15290 and PD00165 pursuant to NRS 453.236(1), NRS 453.241(1)(b) and/or NRS 639.255(1).

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, and without Respondent admitting to the allegations in the Accusation, the Board and Respondent stipulate to the following penalties. The registrations of Respondent Dhaval Shah, MD, Certificate of Registration Nos. CS15290 and PD00165, are hereby revoked pursuant to NRS 453.241(1)(b) and/or NRS 639.255(1)(d).

10. Respondent may not prescribe any controlled substance or dispense any controlled substance or dangerous drug until he petitions to the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his controlled substance registration pursuant to NRS 453.226 and dispensing practitioner registration pursuant to NRS 639.23505.

11. 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.

12. In the event Respondent petitions for reinstatement, or for any other registration or certificate with the Board, he shall appear before the Board to answer questions and give testimony regarding his petition, his compliance with this Order, and the facts and circumstances underlying this matter.

13. Any failure by Respondent to comply with the terms of this Stipulation may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that 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 Stipulation by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

14. 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 January 13, 2021. Respondent 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 the Stipulation, even if Respondent is not present at the meeting.

15. 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.

16. 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.

17. 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 8th day of ~~January,~~ December 2021

DHAVAL SHAH, MD,
Certificate of Registration Nos. CS17603 and PD00165

Signed this 8th day of January, 2021

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 8th day of ~~January,~~ December 2021

JOHNATHON FAYEGHI, ESQ.
CRANE POMERANTZ, ESQ.
Counsel for Respondent

EXHIBIT 8

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby accepts the foregoing Stipulation as its decision as to Dhaval Shah, MD, Certificate of Registration Nos. CS17603 and PD00165, in Case No. 20-222-CS-S. The Board hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 15th day of January, 2021.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (05/19/2021)

What types of drug(s) will you be prescribing?
☒ Dangerous Drugs ONLY
☐ Dangerous Drugs AND Controlled Substances (CS) II, III, IV and/or IV

Section 1: Personal Information (NAC 639.850)

First: Blake Middle: Joseph Last: Kigerl

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

Home Address: [redacted] Snake River. Dr.

City: Reno State: NV. Zip Code: 89503

Telephone: [redacted] Email: [redacted]

APRN License #: 818196 Specialty: Family

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: RenewMD

Practice Address: 5060 Meadowood Mall Circle Suite #: 100

City: Reno State: NV. Zip: 89502

Telephone: (775) 852 4500 Fax: _____ Email: _____

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☐ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: _____

Collaborating Physician Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

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: 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 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?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide

Board Administrative Action:	State:	Date:	Case #:
Accusation	CA	08/05/2021	400201900564B

Criminal Action:	State:	Date:	Case #:	County:	Court:

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.

Blake Nigerl

Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/12/2022

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: _____ Amount: $50 Check # 126

01/06/2022

Statement of Explanation

I have an accusation with the California Board of Nursing related to medication mismanagement and a previous DUI in 2015 which has since been expunged. I am currently in a monitoring agreement with the Nevada Board of Nursing related to drug diversion. I have actively participated in the program since October of 2019 with strict drug testing and monitoring requirements. I have had all negative drug tests and have been working for DaVita without any disciplinary issues since December of 2019. I have included a copy of the California accusation as well as the Nevada Board of Nursing monitoring agreement.

Thank you,

Blake Kigerl

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF BLAKE KIGERL LICENSED PROFESSIONAL NURSE NEVADA LICENSE NO. RN818196 RESPONDENT	AGREEMENT FOR MONITORING CASE NO. 201905061

This Agreement is hereby entered into between BLAKE KIGERL, (RESPONDENT) and the NEVADA STATE BOARD OF NURSING, (BOARD).

It is hereby stipulated and agreed, by and between the parties to the above-entitled matter, that the following statements are true:

1. Respondent is aware of, understands, and has been advised of the effect of this Agreement, which Respondent herein has carefully read and fully acknowledges. No coercion has been exerted on the Respondent. Respondent acknowledges his right to an attorney at his own expense. Respondent has had the benefit at all times of obtaining advice from competent counsel of his choice.

2. Respondent understands the nature of the allegations under investigation by the Nevada State Board of Nursing. Respondent freely admits that while licensed and working as a Registered Nurse at a hospital in Reno, Nevada he diverted Hydromorphone from his employer for his own personal use. Respondent freely admits that he is addicted to alcohol and/or controlled substances and sought treatment for addiction. Respondent acknowledges this conduct constitutes a violation of the Nevada Revised Statutes 632.347 (1)(e) controlled substances and/or alcohol, (1)(g) unprofessional conduct, and Nevada Administrative Code 632.890 (18) diversion of equipment or drugs. Respondent further acknowledges that such acts and admissions subject him to disciplinary action by the Board.

3. Respondent is aware of the Respondent's rights, including the right to a hearing on any charges and allegations, the right to an attorney at his own expense, the right to examine

witnesses who would testify against him, the right to present evidence in his favor and call witnesses on his behalf, or to testify himself, the right to contest the charges and allegations, the right to reconsideration, appeal or any other type of formal judicial review of this matter, and any other rights which may be accorded to his pursuant to the Nevada Administrative Procedures Act and the provisions of Chapter 632 of the Nevada Revised Statutes and the Nevada Administrative Code. **Respondent agrees to waive the foregoing rights upon acceptance of this Agreement by the Board.**

4. Respondent understands that the Board is free to accept or reject this Agreement, and if rejected by the Board, a disciplinary proceeding may be commenced. It is agreed that presentation to and consideration by the Board of such proposed Agreement, shall not disqualify the Board, or any of its members, from further participation, consideration, adjudication or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias therefore. This Agreement shall only become effective when both parties have duly executed it and unless so executed, this Agreement will not be construed as an admission.

5. This Agreement shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.

6. This Agreement shall cover any nursing license or certificate issued by the State of Nevada. Based upon the foregoing stipulations and recitals, it is hereby agreed that the Board may issue the following decision and order:

DECISION AND ORDER

IT IS HEREBY ORDERED that Nevada Licensed Professional Nurse, license number RN818196, issued in the name of BLAKE KIGERL is placed on monitoring for a minimum of five (5) years with the following terms and conditions:

1. **COMPLETION OF COURSES**

Respondent shall take, and submit documentation of successful completion of the National Council of State Boards of Nursing Understanding Substance Use Disorder in Nursing, and the

Nevada Nurse Practice Act course **within (30) days** of acceptance and execution of the Agreement by the Board.

2. **ABSTINENCE AND DRUG TESTING**

Respondent shall abstain from the use of alcohol and all mood-altering drugs and controlled substances except when legally prescribed by a treating practitioner who is knowledgeable about the disease of addiction and the Respondent's history. This treatment must be reported to the Board, in writing, within seven (7) days, accompanied by documentation from the practitioner regarding the medical treatment and all other methods of alternative treatment having been tried first. The Board may require additional testing and reporting until Respondent documents sobriety after periods of prescribed drug use.

Respondent shall register with the Board approved drug-screening program and submit to random urine, blood or other tests for drugs of abuse and/or alcohol on the day requested by the drug testing company, his counselor, or representative of the Board. These tests shall occur no less than twenty-four (24) times per year and shall be treated as forensic specimens by a Board-approved laboratory. Respondent shall cause test results to be provided to the requesting party and the Board. Any confirmed positive finding shall be reported immediately to the Board.

3. **PARTICIPATION IN BOARD-APPROVED AFTERCARE PROGRAM AND QUARTERLY REPORT**

Respondent shall participate in a Board-approved aftercare program for a minimum of one year. Such program shall include a minimum of weekly aftercare group and a minimum of twice per month individual counseling sessions with a Board approved provider who shall submit progress reports related to the plan of treatment every three (3) months. At the completion of one (1) year of counseling, the respondent may discontinue individual counseling upon the provider's submission of a discharge summary to the Board.

4. **ATTENDANCE AT MEETINGS AND SUBMISSION OF QUARTERLY REPORTS TO THE BOARD**

Respondent shall comply with required attendance at meetings and shall cause all reports to be submitted in writing to the Board on a quarterly basis as follows. These reports must be

submitted no later than the last day of March, June, September and December. The Executive Director or the Compliance Coordinator and the Director of Nursing Practice may evaluate and approve or deny changes in the frequency of reporting. Respondent shall:

a. Attend a minimum of two (2) meetings per week of Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) and shall submit documentation of all meetings attended **whether working or not.** The Compliance Coordinator will evaluate consideration for alternative recovery support groups;

b. Cause his AA or NA sponsor to submit reports addressing Respondent's progress in recovery on forms provided by the Board **whether working or not;**

c. Attend weekly meetings of a Board-approved Nurse Support Group and submit documentation of all meetings attended **whether working or not;**

d. Submit self reports in a detailed format as provided by the Board, **whether working or not;**

e. Cause his direct nursing supervisor to submit written reports to the Board addressing work attendance, reliability, nursing competence, and any other information the supervisor identifies as appropriate to report to the Board for evaluation of compliance.

5. **LIMITATIONS AND RESTRICTIONS ON EMPLOYMENT**

The Board shall approve all employment sites requiring a nursing license/certificate (including changes within the same worksite or unit) **prior to commencement of work.** Respondent shall:

a. Provide a complete copy of this Agreement to his employer and direct supervisor **prior to commencement of work;**

b. Be employed in a setting in which direction is provided by a Registered Nurse. Direction shall mean: the intermittent observation, guidance and evaluation of the nursing practice by a licensed professional nurse who may only occasionally be physically present;

c. Cause his direct nursing supervisor to submit a job description and an initial written report on a form provided by the Board **prior to the commencement of employment,** and by each additional or subsequent supervisor;

d. Work only day or evening shift that ends prior to midnight. Respondent may not work for a nursing registry, in home health, for a traveling agency, or any other temporary employing agencies, float pool, per diem, or position that requires on-call status. Respondent shall not be self-employed or contract for services as a nurse. Multiple employers are prohibited;

e. Not work more than ninety (90) hours in nursing in a two (2) week period for a **minimum of one (1) year;**

f. Not function as a supervisor, including as a head nurse or charge nurse for a **minimum of one (1) year;**

g. Have no access to controlled substances during his employment as a licensed nurse for a **minimum of one (1) year;**

h. Notify the Board in writing within seventy-two (72) hours after termination of any nursing employment for any reason and include a full explanation of the circumstances surrounding the termination.

Upon receipt of a written request by the Respondent at the successful completion of one year of this Agreement, the Executive Director or the Compliance Coordinator and the Director if Nursing Practice may evaluate and approve or deny changes in the above employment limitations and restrictions that indicate a term of a minimum of one year.

6. **REQUIREMENT TO ATTEND ORIENTATION AND MEET WITH THE BOARD OR STAFF**

Respondent shall attend a **mandatory orientation** meeting within thirty days of execution of this Agreement by the Board to facilitate understanding and accountability of the terms and conditions of this Agreement as scheduled by the Compliance Coordinator. Upon request, Respondent shall meet with the Board or its representatives and cooperate with representatives of the Board in their supervision and investigation of Respondent's compliance with the terms and conditions of this Agreement.

7. **FINANCIAL RESPONSIBILITY**

Respondent shall be financially responsible for all requirements of this Agreement.

8. **REQUIRED NOTIFICATION OF OTHER STATES OF LICENSURE**

Respondent shall, upon execution of this Agreement, provide a copy of this Agreement to any other state Board of Nursing in whose jurisdiction he has been issued a nursing license/certificate (current or not). Respondent shall also provide a copy of this Agreement to any other regulatory agency in whose jurisdiction he has applied or will apply for a license/certificate.

9. **VIOLATIONS OF THIS AGREEMENT - CONSEQUENCES**

Respondent acknowledges that if he violates any of the terms and conditions of this Agreement, the Board may revoke, or invoke other appropriate discipline against his license to practice nursing, subject to a hearing in accordance with the Nevada Nurse Practice Act for the purpose of establishing that there has, in fact, been a violation of the stipulations of this Agreement. Respondent acknowledges that any violation of the Nevada Nurse Practice Act, any dilute urine or positive drug screen may be considered a violation of this Agreement and subject to further action by the Board.

10. **AGREEMENT TO SURRENDER LICENSE**

In the event that a violation of the terms and conditions of this Agreement is alleged, Respondent agrees to surrender his license to the Executive Director, or the Compliance Coordinator, if they so request, and refrain from practicing nursing until requirements have been met, violations resolved, or entry of a final order of the Board or a court of competent jurisdiction, whichever last occurs, regarding a potential violation.

Respondent acknowledges that pursuant to NRS 632.405, this Agreement shall become a public record if an entry of a final order of the Board results in disciplinary action against his license/certificate for violation of this agreement.

11. **COMPLETION AND TERMINATION OF MONITORING**

Respondent shall only receive credit toward service of his monitoring period while employed in a capacity for which nursing licensure is required and subject to adequate supervision approved by the Board. Respondent acknowledges he is not eligible for early termination of this Agreement. The Agreement shall be terminated at the time the Board receives documentation

verifying the Respondent's completion of all terms and conditions of the Agreement and when respondent receives notice of termination from the Board.

The NEVADA STATE BOARD OF NURSING retains jurisdiction in this case until all conditions have been met to the satisfaction of the Board.

Dated this 31 day of Oct., 2019

RESPONDENT
BLAKE KIGERL

State of Nevada

County of Washoe

This instrument was acknowledged before me on October 31, 2019, by Blake Kigerl.

GAIL TRUJILLO
Notary Public, State of Nevada
Appointment No. 10-3395-2
My Appt. Expires Oct 28, 2022

Notary Public

Accepted and approved this 31st day of October, 2019

NEVADA STATE BOARD OF NURSING

By: Cathy Dinauer
Cathy Dinauer, MSN, RN
Executive Director

ROB BONTA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
CRISTINA FELIX
Deputy Attorney General
State Bar No. 195663
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
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Attorneys for Complainant

I hereby certify that
the foregoing is a true copy
of the documents on file in our office

BOARD OF REGISTERED NURSING

Loretta Melby, RN, MSN
Acting Executive Officer

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **BLAKE KIGERL** **[redacted] Snake River Dr** **Reno, NV 89503** **Registered Nurse License No. 95126261** Respondent.	Case No. 4002019005648 **ACCUSATION**

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing, Department of Consumer Affairs.

2. On or about April 11, 2017, the Board of Registered Nursing issued Registered Nurse License Number 95126261 to Blake Kigerl (Respondent). The Registered Nurse License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2022, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board of Registered Nursing (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2750 of the Code provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with section 2750) of the Nursing Practice Act.

5. Section 2764 of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license. Under section 2811(b) of the Code, the Board may renew an expired license at any time within eight years after the expiration.

STATUTORY PROVISIONS

6. Section 2761 of the Code states:

"The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:

(a) Unprofessional conduct, which includes, but is not limited to, the following:

(1) Incompetence, or gross negligence in carrying out usual certified or licensed nursing functions.

. . .

(d) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violating of, or conspiring to violate any provision or term of this chapter [the Nursing Practice Act] or regulations adopted pursuant to it.

. . .

(f) Conviction of a felony or of any offense substantially related to the qualifications, functions, and duties of a registered nurse, in which event the record of the conviction shall be conclusive evidence thereof.

..."

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7. Section 2762 of the Code states:

"In addition to other acts constituting unprofessional conduct within the meaning of this chapter [the Nursing Practice Act], it is unprofessional conduct for a person licensed under this chapter to do any of the following:

...

(b) Use any controlled substance as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug or dangerous device as defined in Section 4022, or alcoholic beverages, to an extent or in a manner dangerous or injurious to himself or herself, any other person, or the public or to the extent that such use impairs his or her ability to conduct with safety to the public the practice authorized by his or her license.

(c) Be convicted of a criminal offense involving the prescription, consumption, or self-administration of any of the substances described in subdivisions (a) and (b) of this section, or the possession of, or falsification of a record pertaining to, the substances described in subdivision (a) of this section, in which event the record of the conviction is conclusive evidence thereof.

...

(e) Falsify, or make grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a) of this section."

REGULATORY PROVISIONS

8. California Code of Regulations, title 16, section 1442, states:

"As used in Section 2761 of the code, 'gross negligence' includes an extreme departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent registered nurse. Such an extreme departure means the repeated failure to provide nursing care as required or failure to provide care or to exercise ordinary precaution in a single situation which the nurse knew, or should have known, could have jeopardized the client's health or life."

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9. California Code of Regulations, title 16, section 1443, states:

"As used in Section 2761 of the code, 'incompetence' means the lack of possession of or the failure to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by a competent registered nurse as described in Section 1443.5."

10. California Code of Regulations, title 16, section 1443.5 states:

"A registered nurse shall be considered to be competent when he/she consistently demonstrates the ability to transfer scientific knowledge from social, biological and physical sciences in applying the nursing process, as follows:

(1) Formulates a nursing diagnosis through observation of the client's physical condition and behavior, and through interpretation of information obtained from the client and others, including the health team.

(2) Formulates a care plan, in collaboration with the client, which ensures that direct and indirect nursing care services provide for the client's safety, comfort, hygiene, and protection, and for disease prevention and restorative measures.

(3) Performs skills essential to the kind of nursing action to be taken, explains the health treatment to the client and family and teaches the client and family how to care for the client's health needs.

(4) Delegates tasks to subordinates based on the legal scopes of practice of the subordinates and on the preparation and capability needed in the tasks to be delegated, and effectively supervises nursing care being given by subordinates.

(5) Evaluates the effectiveness of the care plan through observation of the client's physical condition and behavior, signs and symptoms of illness, and reactions to treatment and through communication with the client and health team members, and modifies the plan as needed.

(6) Acts as the client's advocate, as circumstances require, by initiating action to improve health care or to change decisions or activities which are against the interests or wishes of the client, and by giving the client the opportunity to make informed decisions about health care before it is provided."

11. California Code of Regulations, title 16, section 1444 states:

"(a) For the purposes of denial, suspension, or revocation of a license or certificate pursuant to section 141, Division 1.5 (commencing with section 475), or Sections 2761 or 2765 of the code, a crime, professional misconduct, or act shall be considered to be substantially related to the qualifications, functions or duties of a person holding a license or certificate under the Nursing Practice Act (Chapter 6 of Division 2 of the code), if to a substantial degree it evidences the present or potential unfitness of a person holding a license or certificate to perform the functions authorized and/or mandated by the license or certificate, or in a manner consistent with the public health, safety, or welfare.

(b) In making the substantial relationship determination required under subdivision (a) for a crime, the board shall consider the following criteria:

(1) The nature and gravity of the offense;

(2) The number of years elapsed since the date of the offense; and

(3) The nature and duties of a registered nurse, or the license or certificate type sought or held by the person.

(c) For purposes of subdivision (a), substantially related crimes, professional misconduct, or acts shall include, but are not limited to, the following:

(1) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of the Nursing Practice Act and its implementing regulations.

. . .

(7) Use of drugs or alcohol to an extent or in a manner dangerous to the individual or the public.

. . ."

COST RECOVERY

12. Section 125.3 of the Code provides, in pertinent part, that the Board 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DEFINITIONS

13. Ativan a Schedule IV controlled substance pursuant to Health and Safety Code Section 11057. Ativan is a brand name for Lorazepam. It is a benzodiazepine used for the relief of anxiety, Panic attacks, and chronic sleeplessness.

14. Dilaudid is a Schedule II controlled substance pursuant to Health and Safety Code Section 11055. Dilaudid is a brand name for Hydromorphone. It is a narcotic analgesic used for the relief of severe pain.

15. Percocet (Oxycontin), is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1) and a dangerous drug pursuant to Business and Professions Code section 4022. Percocet is a brand name for Acetaminophen and Oxycodone.

16. The Pyxis System is an automated and computerized medication dispensing system which operates similar to an Automated Teller Machine (ATM). Pyxis medication dispensing machines are serviced by the facility's pharmacy. Medications are placed in the Pyxis machines, which are usually stationed throughout the hospital. These medications can only be accessed by an authorized medical staff person using their own unique personalized access code and assigned account number.

FACTUAL ALLEGATIONS

17. In 2018, Respondent worked for Palmdale Medical Center (Palmdale) as a registered nurse.

18. Patient 1 (MRN 0552[1]): Patient 1 was admitted to Palmdale for shoulder surgery and his medication orders included Percocet every four hours as needed for pain and .5 mg to 1 mg injection of Dilaudid every four hours as needed for pain. On December 13, 2018 at 0732 hours, Respondent removed 2 mg of Dilaudid which he documented as wasted at 0732 hours, the same

[1] Pyxis patient ID number 1290.

time of removal. However, Respondent also documented at 0815 hours that he administered Dilaudid to Patient 1.

19. On that same date, Charge Nurse KG went to give Percocet to Patient 1 at approximately 0930 and she noticed that patient had Dilaudid scanned as being given at 0803 hours by Respondent. However, the Patient alleged that he never received Dilaudid. After being questioned by Palmdale staff regarding Patient 1, Respondent advised that he mistakenly scanned the medication for the wrong patient but administered the medication to the correct patient. Respondent did not identify the patient.

20. Patient 2 (MRN 8673[2]): Patient 2 was admitted to Palmdale for a surgical resection and his medication orders included .5 mg to 1 mg of Dilaudid every six hours as needed for pain and 1 mg Ativan every four hours as needed. On December 13, 2018, at 0920 hours, Respondent removed 1 mg of Dilaudid. On that same date, December 13, 2018, at 1013 hours, Respondent removed 2 mg of Ativan, which he documented as wasted at 1013 hours, the same time as the removal.

21. On that same day, Patient 2 alerted Palmdale staff that he did not feel the pain medication. When questioned by Palmdale staff, Respondent stated that he may have mistakenly placed the medication in the IV port above the filter for the Potassium Phosphate and as a result of his mistake, he believed that the Dilaudid he administered to the patient was ineffective.

22. Patient 3 (MRN 3738[3]): Patient 3 was admitted to Palmdale for bowel obstruction from an incisional hernia and had medication orders of Dilaudid 2 mg injection every three hours as needed, Tramadol 50 mg tablet every four hours as needed, and Norco 5 mg tablet every six hours as needed. On November 29, 2018, Respondent removed Dilaudid 2 mg at 0750 hours but he failed to document the administration. Also, the medical record for Patient 3 showed that another nurse had already given the same dose at 0626 hours.

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[2] Pyxis patient ID number 5466
[3] Pyxis patient ID number 0758

23. Palmdale's Policies and Procedures required nurses to 1) accurately scan the medication, 2) that the correct medication be given to the correct patient, 3) accurately document all aspects of medication administration in the electronic medical record (eMAR), 4) accurately document the amount of medication used and wasted, and 5) that the wastage must be witnessed.

24. On December 17, 2018, Palmdale staff conducted an audit of Respondent's administration, wastage and documentation of controlled substances finding that Respondent chose 2 mg vials over 1 mg vials for dosing on 21 transactions, he was the only nurse giving Dilaudid to four patients and he administered various pain medications close in time to each other in three patients, including Patient 3. The audit also revealed that Respondent had several prior incidents involving mismanagement of controlled substances at Palmdale.

25. On December 20, 2018, Palmdale staff interviewed Respondent. With regard to Patient 1, Respondent again advised Palmdale staff that he scanned the medication under the wrong patient but administered the medications to the right patient. He also alleged that he used a piece of paper to scan the medication.

26. Palmdale staff also asked Respondent to take a drug test. Although Respondent initially agreed to take the test, he changed his mind, left the premises at 1230 hours and submitted a letter of resignation at 1310 hours. On that same date at 1530 hours, a little over two hours after resigning and six hours from the initial interview, a second interview was held at Respondent's request. Respondent informed Palmdale staff that he was regularly taking prescription medications. Prior to the drug test, Respondent consumed large quantities of water without explanation and disobeyed the monitoring nurse's verbal instructions which specifically required him to provide his first specimen sample for testing. Instead, Respondent intentionally flushed his first urine specimen down the toilet without explanation. Respondent then provided a second urine sample which later came back negative for controlled substances including those substances he admittedly was taking.

27. In February of 2019, Palmdale filed a complaint regarding Respondent with the Board of Nursing.

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FIRST CAUSE FOR DISCIPLINE

(Incompetence)

28. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a)(1), and section 2762, subdivision (e), in conjunction with California Code of Regulations, title 16, section 1443, on the grounds of unprofessional conduct, in that, while on duty as a registered nurse at Palmdale, Respondent was incompetent and failed to exercise the degree of skill ordinarily possessed and exercised by a competent nurse, as follows:

a. Respondent failed to follow the standard of nursing practice and the policies and procedures of Palmdale when he failed to accurately scan the correct medication for the correct patients. Respondent also allegedly used a piece of paper to scan the medication for Patient 1, which, even if possible, is not the standard of practice. This departure could have resulted in harm to patients.

b. Respondent failed to follow the standard of nursing practice and the policies and procedures of Palmdale when he failed to properly document medication administration in the patient's record. This departure places patients at risk for medication errors and could have resulted in harm to patients.

Complainant refers to and by this reference incorporates the allegations set forth above in paragraphs 17 through 27, inclusive, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Gross Negligence)

29. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a)(1), on the grounds of unprofessional conduct, in that while on duty as a registered nurse at Palmdale, Respondent was guilty of gross negligence within the meaning of Regulation 1442, as set forth in paragraphs 17 through 28 above.

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THIRD CAUSE FOR DISCIPLINE

(Convictions of Substantially Related Crimes)

30. Respondent is subject to disciplinary action under section 2761, subdivision (f), and section 2762, subdivision (c), in conjunction with California Code of Regulations, title 16, section 1444, in that Respondent was convicted of crimes substantially related to the qualifications, functions or duties of a registered nurse which to a substantial degree evidences his present or potential unfitness to practice in a manner consistent with the public health, safety, or welfare, as follows:

a. On or about February 1, 2016, after pleading nolo contendere, Respondent was convicted of one misdemeanor count of violating Vehicle Code section 23152(b) [drive with an equal to or greater than .08% BAC] in the criminal proceeding entitled The *People of the State of California v. Blake Joseph Kigerl* (Super. Ct. Los Angeles County, No. 5NW02058). The Court placed Respondent on 36 months' probation, and ordered him to complete a 3-Month Alcohol Program. On or about February 1, 2019, the Court dismissed the matter pursuant Penal Code section 1203.4. The circumstances underlying the conviction are that on or about July 5, 2015, following a traffic stop, Respondent was unable to perform field sobriety tests, and had bloodshot/watery eyes, smelled of alcohol, had an unsteady gait, and had slow speech. It was subsequently determined that Respondent drove a vehicle while under the influence and the breath alcohol analysis report showed a .13% BAC and a .11% BAC.

FOURTH CAUSE FOR DISCIPLINE

(Alcohol Related Convictions)

31. Respondent is subject to disciplinary action under sections 2761, subdivision (a), and 2762, subdivision (c), on the grounds of unprofessional conduct, in that on or about February 1, 2016, Respondent sustained a conviction involving alcohol. Complainant refers to and by this reference incorporates the allegations set forth above in paragraph 30, inclusive, as though set forth fully.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

32. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a), on the grounds of unprofessional conduct, in that Respondent engaged in unprofessional conduct, as set forth above in paragraphs 17 through 31.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 95126261, issued to Blake Kigerl;

2. Ordering Blake Kigerl to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as deemed necessary and proper.

DATED: _____

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

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Back To Dashboard

Renewal Application
Pharmacist

Application Fee : $200.00
Convenience Fee : $10.00
License Number : 15593
License Type : Pharmacist
New Expiration Date : 10/31/2023

Renewal Type

Please confirm the status that you are renewing before moving to the next section.

Active Inactive Proceed to Renew

Personal Information

First Name : Darrel
Middle (initial only) : Wayne
Last Name : Foth
License # : 15593

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA :
Military Address :
Street : [redacted] RIVER RANCH WY
Country : United States
City : SACRAMENTO
State : California
Zip : 95831
Practice Phone : (XXX) XXX-XXXX
Practice Fax : (XXX) XXX-XXXX

Select if the Practice Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Home Address :

Military Address :
Street : [redacted] RIVER RANCH WY
Country : United States
City : SACRAMENTO
State : California
Zip : 95831
Home Phone : [redacted]
Cell Phone : [redacted]
Email Address : d.foth@comcast.net
Fax : (XXX) XXX-XXXX

☑ Select if the Home Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Sex : Male
Practice License Number:
Specialty:

Nevada Business License Information - Check appropriate answer

- **I DO NOT** have a Nevada Business license number.
- **I HAVE APPLIED** for a Nevada Business License with the Nevada Secretary of State in Compliance with provisions of NRS Chapter 76 and my application is pending.
- I have a Nevada Business License number assigned by the Secretary of State in compliance with the provisions of NRS Chapter 76789066.

Name on Business License :
Business License # :

Child Support Information – Check appropriate answer

- (•) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	( ) Yes (•) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	( ) Yes (•) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	( ) Yes (•) No

Legal Information

1. Since your last renewal or recent licensure 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? (•) Yes ( ) No

My California License was put on probationary status in April 2021 for a failed random drug screening at Walgreens in June 2019. I am currently working at CVS in Sacramento under the restrictions of the California State Board run by Maximus recovery program. I will be putting my license on inactive status in Nevada until my probation is finished in California. Please note, I have never worked in Nevada as a Pharmacist, and I will not be working there until my probationary period in California is complete.

Document Name	Document Type	Date	Link	Action
Stipulated Settlement and Disciplinary Order	Legal - Question 1	10/25/2021	Document Details	

Document Name :

Document Type : -Select DocumentType-

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select

Date : 01/26/2021

Case # : 6889

Criminal Action :

State : Select

Date : MM/DD/YYYY

Case # :

County :

Court :

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ( ) Yes (•) No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? (•) Yes ( ) No

Administrative action. See Stipulated Settlement and Disciplinary Order.

Document Name	Document Type	Date	Link	Action
Stipulated Settlement and Disciplinary Order	Legal - Question 3	10/25/2021	Document Details	

Document Name :

Document Type : -Select DocumentType-

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select

Date : 01/26/2021

Case # : 6889

Criminal Action :

State : Select

Date : MM/DD/YYYY

Case # :

County :

Court :

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? (•) Yes ( ) No

I've been subjected to disciplinary action by the California State Board of Pharmacy. 4 years probation. See stipulated settlement and disciplinary order.

Document Name	Document Type	Date	Link	Action
Stipulated Settlement and Disciplinary Order	Legal - Question 4	10/25/2021	Document Details	

Document Name :

Document Type : -Select DocumentType-

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select

Date : 01/26/2021

Case # : 6889

Criminal Action :

State : Select

Date : MM/DD/YYYY

Case # :

County :

Court :

CE Hours

Inactive - By checking this box you certify that you are NOT practicing in Nevada and do not wish to comply with the CE requirements of Nevada and would like your license changed to inactive status. Before re-activating your license it will be necessary to submit an application and to become compliant with current CE requirements (NAC 639.219).

Acknowledgement and Declaration

I understand that it is a violation of Nevada law to falsify this application, and sanctions may be imposed for fraud or misrepresentation. I affirm that I have read this application and the statements made are true and correct. I understand and will comply with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe injection practices. I understand that NRS 432B.220 requires that if, in my professional capacity, I know or have reason to believe that a child has been abused or neglected, I am mandated to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Signature : Darrel Foth

Date Of Application : 10/25/2021

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2021 to 10/31/2023	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : 43018927692

InvoiceDate : 10/26/2021

Paid

Pay & Submit

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DARREL WAYNE FOTH** **P.O. Box [redacted]** **Sacramento, CA 95822** **Pharmacist License No. RPH 52592** Respondent.	Case No. 6889 OAH No. 2020100090 **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. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Andrew M. Steinheimer, Deputy Attorney General.

2. Respondent Darrel Wayne Foth (Respondent) is represented in this proceeding by attorney Paul Chan, whose address is: 1851 Heritage Lane, Suite 128,

Sacramento, CA 95815-4996

3. On or about August 31, 2001, the Board issued Pharmacist License No. RPH 52592 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 6889, and will expire on April 30, 2021, unless renewed.

JURISDICTION

4. Accusation No. 6889 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on July 16, 2020. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 6889 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6889. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. 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 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.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 6889.

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10. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board 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 Board considers and acts upon it. If the Board 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 Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 52592 issued to Respondent Darrel Wayne Foth is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed,

probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6889 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of his employer(s), and the name(s) and telephone number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior

employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6889, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6889, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6889, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Pharmacist, or any position for which a Pharmacist License is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $7,455.00.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall

be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

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13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

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If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. **Pharmacists Recovery Program (PRP)**

By no later than ten (10) days after the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362 (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;

Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;

Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;

Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or

Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not resume the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. The board will provide notice of any such suspension or extension of probation.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice as a Pharmacist nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

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Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

17. **Drug and Alcohol Testing**

Respondent, at his own expense, shall participate in testing as directed by the board or its designee for the detection of alcohol, controlled substances, and dangerous drugs and/or dangerous devices. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the area where the approved testing vendor provides services, respondent shall seek and receive approval from the board or its designee to use an alternate testing vendor to ensure testing can occur. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide to that alternate vendor any documentation required by the vendor, including any necessary payment by respondent. During the period of absence of the area, respondent shall commence testing

protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of an illicit drug, controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a Pharmacist until notified by the board in writing that he may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform him to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or

any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices.

Failure to comply with any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

18. **Notification of Departure**

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

19. **Abstain from Drugs and Alcohol**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a necessary part of treatment. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia for which a legitimate prescription has not been issued as a necessary part of treatment, or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

20. **Prescription Coordination and Monitoring of Prescription Use**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history with the use of controlled substances, and/or dangerous drugs and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's Accusation and decision. A record of this notification must be provided to the board or its designee upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing supervision, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a Pharmacist, the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a Pharmacist until notified by the board

or its designee that practice may be resumed.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

21. **Facilitated Group Recovery and/or Support Meetings**

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises the respondent in writing that he may cease regular attendance. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as

required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

22. **Work Site Monitor**

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;

2) Interview other staff in the office regarding respondent's behavior, if applicable; and

3) Review respondent's work attendance.

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The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that he is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;

2) Interview other staff in the office regarding respondent's behavior, if applicable; and

3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

23. **Supervised Practice**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a Pharmacist by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 6889, and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week - REQUEST FOR REDUCTION WHEN APPROPRIATE

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a Pharmacist by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that

he or she has read the decision in case number 6889, and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;

Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;

Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or

Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any suspension shall be considered a violation of probation.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a Pharmacist and may not resume such practice until notified by the board or its designee in writing.

24. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation 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, Paul Chan. I understand the stipulation and the effect it will have on my Pharmacist License. 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 Board of Pharmacy.

DATED: 11/26/21

DARREL WAYNE FOTH
Respondent

I have read and fully discussed with Respondent Darrel Wayne Foth the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 1/26/21

PAUL CHAN
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General

ANDREW M. STEINHEIMER
Deputy Attorney General
Attorneys for Complainant

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

4

Complete Name (**no abbreviations**):

First: Brandy Middle: Moore Last Baker

Home Address: [redacted] Steelwood LN Apt#: [redacted]

City: Reno State: NV Zip Code: 89512

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Carson City Sex: ☐ M or ☒ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: _____

I am requesting registration at the following pharmacy:

Pharmacy: CVS Pharmacy Store #: 9974

Address: 3360 S McCarran Blvd

City: Reno State: NV Zip Code: 89502

Signature of Managing Pharmacist: [signature] Lic #: 20276 Date: 10/9/21

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☒ No ☐
2. Are you a high school graduate or the equivalent? Yes ☒ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
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?	☐	☒
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked **YES** to any of the numbered questions (3-5) above, include the following information &

	State	Date:	Case #:	County	Court
Board Administrative Action:		/ /			
Criminal Action:		/ /			

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☒	☐
IF you marked **YES** to the question, above are you in compliance with the court order?	☑	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know 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.

Brandy Baker — Original Signature, no copies or stamps accepted

Oct 9, 2021 — Date

Board Use Only Date Processed: _____ Amount: 50 cc

backgroundprofiles
a culture of service

Background Screening Report

Background Profiles Inc.
3478 Buskirk Avenue
Suite 332
Pleasant Hill, CA 94523
Phone: 925-974-1820 / 800-800-0197
Fax: 925-974-1840 / 800-800-0143

FILE NUMBER	248633	REPORT DATE	- Vanessa Bagley
REPORT TO	Renown Health (A415000) 1155 Mill St Mail Code H-9B Reno, NV 89502 Phone: 775-982-4816 Fax: 775-982-6389	ORDER DATE	10-04-2019 Carmen Roth
		REFERENCE	10/14/2019 PT
		TYPE	wmnat - ss, 7 yr county & federal, national search, 3 emp,FACIS

Application Information

APPLICANT	BAKER, BRANDY MOORE	SSN	[redacted]	DOB	[redacted]
E-MAIL	[redacted]				
ADDRESS(ES)	[redacted]	CITY / STATE / ZIP	RENO, NV 89512 RENO, NV 89512		

Executive Summary

Overall Result: PENDING

REQUESTOR	Roth, Carmen	
REFERENCE	10/14/2019 PT	

Search Type		Status	
Executive Summary	BAKER, BRANDY MOORE	PENDING	
Social Security Trace	SOCIAL SECURITY TRACE	COMPLETE	
County Criminal Felony and Misdemeanor Records Search	NV-CARSON CITY	PENDING	
	NV-WASHOE	REVIEW	SEE REPORT
Federal Criminal Records Search	NEVADA	COMPLETE	
Multi-State Criminal/Sex Offender/Patriot Act Search	NATIONWIDE	COMPLETE	
PROVIDE A MAXIMUM OF 3 EMPLOYMENTS	HOME DEPOT	COMPLETE	
	MDX HAWAII	REVIEW	SEE REPORT
	UNITED BLOOD	REVIEW	SEE REPORT

File # 248633 : BAKER, BRANDY MOORE

SERVICES

Healthcare Sanctions Search	BAKER, BRANDY COMPLETE MOORE
Quality Assurance Audit	BAKER, BRANDY COMPLETE MOORE

COMMENT

Investigative

County Criminal Felony and Misdemeanor Records Search

RESULTS **Pending**
NAME SEARCHED BAKER, BRANDY MOORE
DOB SEARCHED [redacted]
JURISDICTION NV-CARSON CITY
PENDING NOTES
SEARCH DATE 10-07-2019 8:19 AM MDT
SEARCH SCOPE 7 Years

RESULTS **Records Found**
NAME SEARCHED BAKER, BRANDY MOORE
DOB SEARCHED [redacted]
JURISDICTION NV-WASHOE
SEARCH DATE 10-11-2019 6:30 AM MDT
SEARCH SCOPE 7 Years

***** Abstract *****

NAME ON RECORD BRANDY MOORE BAKER
DOB ON RECORD [redacted]
OTHER IDENTIFIERS
OTHER INFO
CASE NUMBER 14CR05156
COURT RENO MUNICIPAL COURT
FILE DATE 3/18/14

Count

TYPE MISDEMEANOR
DISPOSITION FOUND GUILTY
DISPOSITION DATE 7/9/15
SENTENCE 5 DAYS JAIL
OTHER INFO
COMMENT VERIFIED BY NAME AND DOB
OFFENSE PETIT LARCENY, VALUE LESS THAN $650
OFFENSE DATE 3/8/14

Count

TYPE MISDEMEANOR
DISPOSITION FOUND IN CONTEMPT
DISPOSITION DATE 7/9/15
SENTENCE 5 DAYS JAIL
OTHER INFO
COMMENT
OFFENSE FAILURE TO APPEAR WARRANT
OFFENSE DATE 4/23/14

VERIFIED BY NAME AND DOB

***** Abstract *****

NAME ON RECORD	BRANDY MOORE BAKER	CASE NUMBER	15CR09931
DOB ON RECORD	[redacted]	COURT	RENO MUNICIPAL COURT
OTHER IDENTIFIERS		FILE DATE	7/9/15
OTHER INFO			

Count

TYPE	MISDEMEANOR	OFFENSE	PETIT LARCENY VALUE LESS THAN $650
DISPOSITION	FOUND GUILTY		
DISPOSITION DATE	7/9/15	OFFENSE DATE	7/8/15
SENTENCE	30 DAYS JAIL		
OTHER INFO			
COMMENT	VERIFIED BY NAME AND DOB		

***** Abstract *****

NAME ON RECORD	BRANDY MOORE BAKER	CASE NUMBER	15CR11761
DOB ON RECORD	[redacted]	COURT	RENO MUNICIPAL COURT
OTHER IDENTIFIERS		FILE DATE	8/18/15
OTHER INFO			

Count

TYPE	MISDEMEANOR	OFFENSE	PETIT LARCENY VALUE LESS THAN $650
DISPOSITION	GUILTY		
DISPOSITION DATE	9/21/15	OFFENSE DATE	8/15/15
SENTENCE	60 DAYS JAIL SUSPENDED FOR ONE YEAR, FINES/FEES $305		
OTHER INFO			
COMMENT	VERIFIED BY NAME AND DOB		

Count

TYPE	MISDEMEANOR	OFFENSE	USE/POSS DRUG PARAPHERNALIA
DISPOSITION	FOUND GUILTY		
DISPOSITION DATE	9/21/15	OFFENSE DATE	8/15/15
SENTENCE	60 DAYS JAIL SUSPENDED FOR ONE YEAR, FINES/FEES $305		
OTHER INFO			
COMMENT	VERIFIED BY NAME AND DOB		

WARNING: Search Pending.

Federal Criminal Records Search

RESULTS	**No Reportable Records Found**		
NAME SEARCHED	BAKER, BRANDY MOORE	SEARCH DATE	10-07-2019 8:16 AM MDT
DOB SEARCHED	[redacted]	SEARCH SCOPE	7 Years

JURISDICTION NEVADA

CAUTION: Based on the information provided Background Profiles Inc. searched for public records in the sources referenced herein for criminal history information as permitted by federal and state law. 'No Reportable Records Found' means that our researchers could not locate a record that matched at least two personal identifiers (i.e., Name, SSN, Date of Birth, Address) for the subject in that jurisdiction. Further investigation into additional jurisdictions, or utilization of additional identifying information, may be warranted. Please call for assistance.
*The "scope" of the criminal records investigation may deviate from the time specified (ie, "7 years") depending on local or state law and/or the requirements of the employer for whom the report was prepared.

Multi-State Criminal/Sex Offender/Patriot Act Search

RESULTS **No Reportable Records Found**
NAME SEARCHED BAKER, BRANDY MOORE
SEARCH DATE 10-07-2019 7:59 AM MDT
DOB SEARCHED [redacted]
SEARCH SCOPE
JURISDICTION NATIONWIDE
JURISDICTION(S) SEARCHED
The search you have selected is a search of our criminal database(s) and may not represent 100% coverage of all criminal records in all jurisdictions and/or sources. Coverage details available upon request.

CAUTION: Based on the information provided Background Profiles Inc. searched for public records in the sources referenced herein for criminal history information as permitted by federal and state law. 'No Reportable Records Found' means that our researchers could not locate a record that matched at least two personal identifiers (i.e., Name, SSN, Date of Birth, Address) for the subject in that jurisdiction. Further investigation into additional jurisdictions, or utilization of additional identifying information, may be warranted. Please call for assistance.
*The "scope" of the criminal records investigation may deviate from the time specified (ie, "7 years") depending on local or state law and/or the requirements of the employer for whom the report was prepared.

Identity Development

Person Search

RESULTS **Records Found**
SSN SEARCHED XXX-XX-0907
SEARCH DATE 10-04-2019 4:42 PM MDT

Applicant Information

FULL NAME	DOB	COUNTY	CITY/STATE	REPORTED DATE(S) RECORDS
BRANDY M BAKER	[redacted]	WASHOE	RENO, NV	First: 2008-05-08 9 Last: 2019-10-04
BRANDY M BAKER	[redacted]	CARSON CITY	CARSON CITY, NV	First: 2003-09-01 1 Last: 2019-09-06

SSN Information

SSN	VALID	ISSUED LOCATION	ISSUED DATE RANGE
[redacted]	Y	CALIFORNIA	1983

WARNING: This Social Security Number Trace/Person search may not be used as the basis for an adverse action on an applicant. It should only be used to verify or correct an applicant's information, or as a tool to further research of public records or other verifications.

JURISDICTION NEVADA

CAUTION: Based on the information provided Background Profiles Inc. searched for public records in the sources referenced herein for criminal history information as permitted by federal and state law. 'No Reportable Records Found' means that our researchers could not locate a record that matched at least two personal identifiers (i.e., Name, SSN, Date of Birth, Address) for the subject in that jurisdiction. Further investigation into additional jurisdictions, or utilization of additional identifying information, may be warranted. Please call for assistance.

*The "scope" of the criminal records investigation may deviate from the time specified (ie, "7 years") depending on local or state law and/or the requirements of the employer for whom the report was prepared.

Multi-State Criminal/Sex Offender/Patriot Act Search

RESULTS **No Reportable Records Found**
NAME SEARCHED BAKER, BRANDY MOORE
SEARCH DATE 10-07-2019 7:59 AM MDT
DOB SEARCHED [redacted]
SEARCH SCOPE
JURISDICTION NATIONWIDE
JURISDICTION(S) SEARCHED

The search you have selected is a search of our criminal database(s) and may not represent 100% coverage of all criminal records in all jurisdictions and/or sources. Coverage details available upon request.

CAUTION: Based on the information provided Background Profiles Inc. searched for public records in the sources referenced herein for criminal history information as permitted by federal and state law. 'No Reportable Records Found' means that our researchers could not locate a record that matched at least two personal identifiers (i.e., Name, SSN, Date of Birth, Address) for the subject in that jurisdiction. Further investigation into additional jurisdictions, or utilization of additional identifying information, may be warranted. Please call for assistance.

*The "scope" of the criminal records investigation may deviate from the time specified (ie, "7 years") depending on local or state law and/or the requirements of the employer for whom the report was prepared.

Identity Development

Person Search

RESULTS **Records Found**
SSN SEARCHED [redacted]
SEARCH DATE 10-04-2019 4:42 PM MDT

Applicant Information

FULL NAME	DOB	COUNTY	CITY/STATE	REPORTED DATE(S)	RECORDS
BRANDY M BAKER	[redacted]	WASHOE	RENO, NV	First: 2008-05-08 Last: 2019-10-04	9
BRANDY M BAKER	[redacted]	CARSON CITY	CARSON CITY, NV	First: 2003-09-01 Last: 2019-09-06	1

SSN Information

SSN	VALID	ISSUED LOCATION	ISSUED DATE RANGE
XXX-XX-0907	Y	CALIFORNIA	1983

WARNING: This Social Security Number Trace/Person search may not be used as the basis for an adverse action on an applicant. It should only be used to verify or correct an applicant's information, or as a tool to further research of public records or other verifications.

File # 248633 : BAKER, BRANDY MOORE

Verification

PROVIDE A MAXIMUM OF 3 EMPLOYMENTS

RESPONSE RECEIVED	**Yes**		
NAME	BAKER, BRANDY MOORE	SEARCH DATE	10-07-2019 8:17 AM MDT
EMPLOYER NAME	**HOME DEPOT**	HOW VERIFIED	Automated System
SUPERVISOR	SHANNON HIGHLINE	DATE VERIFIED	10/07/2019
EMPLOYER STREET		VERIFIED BY	WN
EMPLOYER CITY	RENO	VERIFIER TITLE	Third Party Vendor
EMPLOYER STATE	NV		
EMPLOYER ZIP			
EMPLOYER PHONE	7756742900		
EMPLOYER FAX			
EMPLOYER E-MAIL			

	SUBJECT-PROVIDED INFORMATION	EMPLOYER-PROVIDED INFORMATION
EMPLOYER TYPE	Previous	Previous
POSITION	CASHIER	Cashier
HIRE DATE	MAR 2018	03/22/2018
END DATE	JUL 2019	07/23/2019
TYPE/STATUS		Not Available
REASON FOR LEAVING	MISSING WORK DUE TO COULD CARE	Not Available

QUESTIONS

Is he/she eligible for re-hire?

Not Available

Have you, at any time in the last year, worked for a Medicare fiscal intermediary or carrier for Renown Health in a managerial , accounting, auditing, or similar capacity?

Not Available

RESPONSE RECEIVED	**No**		
NAME	BAKER, BRANDY MOORE	SEARCH DATE	10-10-2019 9:54 AM MDT
EMPLOYER NAME	**MDX HAWAII**	HOW VERIFIED	
SUPERVISOR	ASHLEIGH	DATE VERIFIED	
EMPLOYER STREET		VERIFIED BY	
EMPLOYER CITY	HONOLULU	VERIFIER TITLE	
EMPLOYER STATE	HI		
EMPLOYER ZIP			
EMPLOYER PHONE	808-522-7500		
EMPLOYER FAX			
EMPLOYER E-MAIL			

SUBJECT-PROVIDED INFORMATION

EMPLOYER TYPE	Previous
POSITION	DATA ENTRY CLERK
HIRE DATE	OCT 2016
END DATE	MAR 2017
TYPE/STATUS	
REASON FOR LEAVING	HAD TO MOVE BACK TO NEVADA, TOO EXPENSIVE

As of 10/10/2019 no response has been received, once a response is received the file will be updated.

RESPONSE RECEIVED	**Yes**		
NAME	BAKER, BRANDY MOORE	SEARCH DATE	10-07-2019 8:21 AM MDT
EMPLOYER NAME	**UNITED BLOOD SERVICES**	HOW VERIFIED	Automated System
SUPERVISOR	BETH JACOBY	DATE VERIFIED	10/07/2019
EMPLOYER STREET		VERIFIED BY	CCCVerify
EMPLOYER CITY	RENO	VERIFIER TITLE	Third Party Vendor
EMPLOYER STATE	NV		
EMPLOYER ZIP			
EMPLOYER PHONE	775-329-6451		
EMPLOYER FAX			
EMPLOYER E-MAIL			

	SUBJECT-PROVIDED INFORMATION	EMPLOYER-PROVIDED INFORMATION
EMPLOYER TYPE	Previous	Previous
POSITION	DONOR CARE SPECIALIST	Donor Care Specialist III
HIRE DATE	MAR 2006	03/20/2006
END DATE	SEP 2012	03/24/2011
TYPE/STATUS		Full Time
REASON FOR LEAVING	MEDICAL	Not Available

QUESTIONS

Is he/she eligible for re-hire?

Not Available

Have you, at any time in the last year, worked for a Medicare fiscal intermediary or carrier for Renown Health in a managerial , accounting, auditing, or similar capacity?

Not Available

Background Profiles Inc. verified the dates of employment provided above are the only dates available for the applicant.

Credentials

Healthcare Sanctions Search

RESULTS	**No Reportable Records Found**		
NAME SEARCHED	BAKER, BRANDY MOORE	SEARCH DATE	10-07-2019 7:59 AM MDT
DOB SEARCHED	[redacted]	SEARCH SCOPE	

TYPE Premium

CAUTION: Based On The Information Provided Background Profiles Inc. Searched The Above Mentioned Applicant For State & Federal Sanction Listings And Found No Individual By This Identification. This is a name based search of available Data Sources. Further Investigation May Be Warranted. Call For Assistance!

Quality Assurance Audit

Disclaimer

This report is furnished to you pursuant to the Agreement for Service between the parties and in compliance with the Fair Credit Reporting Act. This report is furnished based upon your certification that you have a permissible purpose to obtain the report. The information contained herein was obtained in good faith from sources deemed reliable, but the completeness or accuracy is not guaranteed.

***** End Of Report *****

Olivia Mora

From: [redacted]
Sent: Wednesday, October 27, 2021 5:11 PM
To: Olivia Mora
Subject: Re: Pharmaceutical Techncian in Training - Need more information - Brandy Baker
Attachments: 20211027_163603.jpg; 20211027_163645.jpg; 20211027_163727.jpg

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

During this time period when I had committed all 3 petite larceny charges and the 1 possession of paraphernalia charge I was making bad choices and I was considered homeless living with different friends and family members. I was not sober, but completed treatment at Step 2 a second time in 2017 then moved into my apartment late 2018.

The possession charge was for a Marijuana Pipe I had in my purse during my last petite Larceny. I was holding it for someone and I honestly do not remember why. I realize now that it was all very preventable if I just got myself a job and the good, positive support system I have today. Thank you!

On Oct 27, 2021 3:54 PM, Olivia Mora <o.mora@pharmacy.nv.gov> wrote:

Hello Brandy,

I received your application for Pharmaceutical Technician in Training, and I see that you marked YES in one of the questions regarding "Been charged, arrested or convicted of a felony or misdemeanor in any state".

However, we need an explanation of the events that occurred with your disclosure along with court documents.

Our Deputy and Executive Secretary will review and determine if we can license you then and there or if you need to appear in front of the Board.

If you are unable to get these documents, this will be an automatic appearance before the Board.

Please let me know if you are able to provide.

Regards,

Olivia Mora

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

11

NEVADA STATE BOARD OF PHARMACY

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

Temporary Pharmacist Registration Request Application

Rev (08/04/2021)

Section 1: General Information

First: Kurt Middle: Allen Last: Howe

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

Mailing Address: [redacted] PINE MOUNTAIN RD NW STE [redacted]

City: KENNESAW State: GA Zip: 30152

Telephone: 800-547-1399 Email: [redacted]

Reason for Temporary License: COMPOUND/DISPENSE TO NV PATIENTS & CHANGE OF PHARMACY OWNERSHIP APPLICATION

Section 2: Employment Information

Pharmacy Name: INNOVATION COMPOUNDING PHARMACY, LLC DBA INNOVATION COMPOUNDING NV Pharmacy License # (if applicable): PENDING OLD - PH03021

Address: 6095 PINE MOUNTAIN RD NW STE 108

City: KENNESAW State: GA Zip: 30152

Telephone: 800-547-1399 Email: RJOHNSON@INNOVATIONCOMPOUNDING.COM

Section 3: License/Registration Reciprocation Information.

Original State of licensure/registration you will be reciprocating from must be active and issued by exam (passing NAPLEX and that state's MPJE).

State: Georgia Date of issuance: 11/25/2020

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.

Original Signature, no copies or stamps accepted

1/4/22
Date

Board Use Only	Date Received: _____ Temporary License Issued: _____ Temporary License Expiry: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

APPLICATION BY RECIPROCATION AS A PHARMACIST

4

If you are requesting licensure by reciprocation (i.e. You have a current pharmacist license from another state and wish to transfer license information and only need to take the Nevada MPJE), complete this application:

Total Fee: $250.00 (Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: Kurt Middle: Allen Last: Howe

Mailing Address: [redacted] Woodmore Dr. SW

City: Marietta State: GA Zip Code: 30008

Telephone: [redacted] E-mail Address: [redacted]

Date of Birth: [redacted] Place of Birth: Akron, Ohio

SS# or ITIN: [redacted] Sex: ☒ M or ☐ F

(Full Number Required)

Original State of Licensure you are reciprocating from must be active and issued by exam; State:

Georgia Date of Issuance: 11/25/2020

College of Pharmacy Information

Graduation Date: 12/1/2003 (mm/dd/yy)

Degree Received: ☒ PharmD ☐ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: University of South Carolina

Location of School: Columbia, SC

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information

Board Use Only

Processed: _____ Amount: 250 cc Entity #: _____

Email _____ MPJE _____

Other states where you are (or were) licensed as a pharmacist or print "none"

State	Lic#	Is the license Active?	State	Lic #	Is the License Active?
GA	RPh032617	Yes ☒ No ☐			Yes ☐ No ☐
SC	10857	Yes ☐ No ☒			Yes ☐ No ☐

**Attach separate sheet if needed

Have you ever served in the military, either active, reserve or retired? Yes ☐ No ☒

Branch:_____
Military Occupation/Specialty:_____
Dates of Service:_____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

	Yes	No
1. 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. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
3. Been the subject of a board citation or an administrative action or board citation whether completed or pending in any state?	☒	☐
4. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☒	☐

If you marked **YES** to any of the numbered questions **(1-3)** above, include the following information & **provide an explanation & documentation**:

Board Administrative Action:	State	Date:	Case #:
Consent agreement	SC	6/25/09	2008-142
Temp Revocation	SC	6/01/2014	2014-57

Criminal Action:	State	Date:	Case #:	County	Court
Mis	SC	7/8/2014 ~~12/10/2008~~	2014A3210600068	Lexington	Lexington County Court General Sessions

FEDERALLY MANDATED REQUIREMENTS

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications.

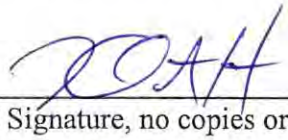
4. Are you the subject of a court order for the support of a child?.....Yes ☐ No ☒
4a. If you marked Yes, to the question 4, are you in compliance with the court order?.....Yes ☐ No ☐

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 my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, its members, servants or employees because or by reason of the use of the authorization.

I attest to 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.

I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know 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.



Original Signature, no copies or stamps accepted

1/4/22

Date

1/4/2022

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

To Whom It May Concern,

In 2009 I was under a consent agreement because I diverted hydrocodone without a physician's prescription. It initially started out to control physical pain and then turned into a physical dependence.

June 26th of 2014, I filled my prescription of Vyvanse 5 days before it was due for a refill; without the consent of my physician by covering up the do not fill before date. I was taking more than prescribed after developing a tolerance for the medication. I was upfront and transparent about what I did. It was a decision that I tremendously regret. I also volunteered when discussing with the Board of Pharmacy that I had left a prescription for Vyvanse in a hotel room, I went to my long time physician and received a 30 day supply. I subsequently went to my regularly scheduled psychiatrist appointment about a week later and received an additional refill from him and failed to notify him that I had received an additional prescription from my primary care physician. Due to these infractions South Carolina Board Of Pharmacy revoked my license but they chose not to do a permanent revocation.

This resulted in a misdemeanor for possession of a controlled substance. (This conviction is currently in the process of being expunged.)

Following my revocation I voluntarily enrolled into a Recovering Professionals Program (RPP). They did random drug testing and monitored my meeting attendance. Dr. James Graham (Medical Director of RPP) stated that I was safe to return to pharmacy.

I have since become a licensed Pharmacist in Georgia and am under the direct supervision of my pharmacy advocate Mark Clayton, where I am monitored with random drug test.

Respectfully,

Kurt A. Howe

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING & REGULATION
BEFORE THE BOARD OF PHARMACY

In the Matter of: **KURT ALLEN HOWE, R. Ph.** **License # 10857** **OIE# 2008-142** **Respondent**	**CONSENT AGREEMENT**

By agreement of the Board of Pharmacy (the Board) and the above named Respondent, the following disposition of this matter is entered pursuant to the provisions of S.C. Code of Laws. §1-23-320(f) (1976, as amended) of the South Carolina Administrative Procedures Act:

FINDINGS OF FACT

1. Respondent is licensed to practice as a Pharmacist in South Carolina, was so licensed at all times relevant to the matters asserted in this case and is subject to the jurisdiction of the Board.

2. Respondent admits that while employed by and working for Palmetto Long-Term care Pharmacy in Columbia, SC, he diverted controlled substance, specifically Hydrocodone, for his personal use.

3. Respondent entered into treatment at Cornerstone of Recovery in Tennessee. Respondent enrolled in the Recovering Professional Program on December 12, 2008, and is compliant with all requirements.

4. Respondent surrendered his license on April 02, 2009.

5. Respondent has not worked in South Carolina as Registered Pharmacy since December 12, 2008.

6. Respondent waives any further findings of fact with respect to this matter.

06-09-2009

CONCLUSIONS OF LAW

Respondent further admits that as a result of the previous admissions herein ground for discipline of a license exist under S.C. Code of Laws §40-1-110(h)(i) (1976, as amended). Respondent waives any further conclusions of law with respect to this matter.

THEREFORE, IT IS ORDERED WITH RESPONDENT'S CONSENT THAT:

1. Respondent's license to practice as a pharmacist in this State is suspended for a period of one (1) year beginning on December 12, 2008. The suspension may be stayed after the one (1) year period and placed on probation for a period of five (5) years with the following conditions:

    a. Respondent shall pay a Civil Penalty of $500.00 within (60) days from the date of the Board's action on this Agreement. Said penalty shall not be deemed paid until received by the Board in the form of a money order or cashier's check.

    b. Respondent may not hold a pharmacy permit or serve as a pharmacist in charge during the period of probation.

    c. Respondent shall completely abstain from the consumption of mood-altering substances, including alcohol, except as prescribed by a duly licensed practitioner for a documented legitimate medical purpose. All use of such substances is to be reported by Respondent to the Board or its designee within 48 hours of initiation. All such medical treatment and prescribing shall be reported directly to the Board in writing by the treating practitioner within ten (10) days after the date of treatment. Respondent must inform the treating practitioner of this responsibility, provide a copy of this Consent Agreement to the treating practitioner, and ensure timely compliance.

    d. Respondent shall be subject to periodic, unannounced blood and urine alcohol and/or drug analysis as desired by the Board or its designee, the purpose being to ensure that the Respondent remains drug and/or alcohol-free. The cost of such blood and urine alcohol and/or drug analyses and reports will be borne by Respondent, which costs shall be paid within thirty (30) days after the date of the invoice therefore.

    e. Respondent must have a written contract with and be an active participant in the activities of the Recovering Professional Program (hereafter the Program), as approved in advance in writing by the Board, until a period of not less than five years of documented continuous sobriety and compliance with this Consent Agreement has been satisfactorily established by Respondent and until this Consent Agreement has been terminated as provided herein. Such contract shall include provisions for any assessment, treatment, monitoring and aftercare activities, and other activities as the Program shall deem appropriate. The level of

participation that is appropriate for Respondent shall be determined by the Program. Respondent must fully comply with all requirements and recommendations of the Program. If required or recommended by the Program, Respondent shall submit, at Respondent's expense, to an evaluation at a facility approved by the Program, any treatment deemed appropriate by the Program at an approved facility, and any monitoring and aftercare activities specified by the Program. The Program shall submit regular written reports documenting Respondent's full compliance with the terms of the contract with the Program and this Consent Agreement.

2. It is understood and agreed that if Respondent fails to meet the conditions agreed to in this Consent Agreement, Respondent's license may be administratively suspended pending compliance. Non-compliance may result in further discipline. Any license law violation by Respondent constitutes a failure to meet the conditions of this Consent Agreement.

3. It is further understood and agreed that, pursuant to the South Carolina Freedom of Information Act, this Consent Agreement is a public document.

4. It is further understood and agreed that this Consent Agreement does not satisfy, prejudice, or stay any disciplinary action currently pending before the Board or which may be filed in the future.

5. It is further understood and agreed that Respondent has full knowledge that he has the right to a hearing and to be represented by counsel in this matter, and freely, knowingly, and voluntarily waives such rights by entering into this Consent Agreement. Respondent understands and agrees that by entering into this Consent Agreement he voluntarily relinquishes any right to judicial review of this or any other Board action(s) which may be taken concerning this and any related matters. Respondent understands and agrees that this Consent Agreement will not become effective unless and until approved by the Board. Respondent understands and agrees that this Consent Agreement, if approved, will be disseminated as a public action of the Board in the manner provided by law. Respondent understands and agrees that if this Consent Agreement is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the right of the Board to adjudicate this matter.

6. This Consent Agreement shall take effect immediately upon acceptance by the Board.

AND IT IS SO ORDERED.

SOUTH CAROLINA BOARD OF PHARMACY

6/25, 2009

Davis C. Hook Jr

Davis C. Hook, Jr., R. Ph.
Chairman of the Board

I CONSENT:

Kurt Allen Howe, RPh., Respondent
Dld 06/03/2009

06/3/2009
Date

Attorney for the Board

6/25/09
Date

CERTIFICATE OF SERVICE BY MAIL
This is to certify that the undersigned has this date served this Consent in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party (ies) or their attorney (s), to the last known address (es) provided to LLR.
This 9 day of July 2009
By: Melissa Church - Prog Asst.
Printed name, title & signature
185 Knotts Rd.
Lexington, SC 29073

CERTIFICATE OF PERSONAL SERVICE
This is to certify that the undersigned has this date served this Consent Agreement in the above entitled action upon the above named by personally delivering a copy thereof and leaving the same with the above named at the following address: 101 Centurious Drive, Columbia, SC.
This 3rd day of June 2009
By: Brenda Lee Dunn
Printed name, title & signature
Brenda Lee Dunn

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY

In the Matter of: **KURT ALLEN HOWE,** License No. PH. 10857 (Voluntarily Surrendered), Case # 2014-57, Respondent.	**MEMORANDUM OF AGREEMENT AND STIPULATIONIONS**

WHEREAS, the State Board of Pharmacy (the "Board") has received an initial complaint with respect to Kurt Allen Howe ("Respondent"); and

WHEREAS, the Board is prepared to file and serve a Formal Accusation alleging that, among other things, Respondent has violated S.C. Code Ann. §§ 40-1-110(1)(d), (f), (g), (h) and (i) (1996, as amended); and

WHEREAS, Respondent will participate in a Final Order Hearing at such time as the Board shall require in order to determine an appropriate sanction in this matter. Respondent hereby waives his right to (30) thirty days notice of the hearing in respect to this matter.

THEREFORE, RESPONDENT STIPULATES AND ADMITS to the following facts, along with the exhibits and other material referenced herein, to be considered by the Board in determining an appropriate sanction in connection with the disciplinary matter pending against Respondent:

1. At all times relevant to these matters, Respondent was duly licensed by the Board to practice pharmacy in the State of South Carolina. The Board has jurisdiction over Respondent and all issues relevant to these matters.

2. On or about December 12, 2008, Respondent was arrested by the Department of Health and Environmental Control's Drug Control Unit for diverting Hydrocodone from Palmetto Long Term Health Care Pharmacy. Respondent completed a treatment program at Cornerstone of Recovery and entered the South Carolina Recovering Professional Program ("RPP").

3. On or about June 25, 2009, Respondent entered into a Consent Agreement with the Board. Respondent was placed on five (5) years of probation, but was allowed to continue the practice of pharmacy.

4. While on probation, Respondent was prescribed Vyvanse by his psychiatrist. Respondent's prescriptions were issued for 30-day supplies of Vyvanse. After developing a tolerance for the medication, Respondent began taking the medication at a rate greater than prescribed and filled the prescriptions more often than scheduled. On or about June 18, 2014, Respondent completed the terms of his Consent Agreement with the Board and was released from the Consent Agreement. A copy of the Consent Order will be attached and incorporated as **EXHIBIT #1**

5. On or about June 26, 2014, Respondent received a prescription for a 30-day supply of Vyvanse

from his psychiatrist. The prescription included the notation "May Fill 7-02-14." Respondent immediately took the prescription to the pharmacy in which he worked, covered the notation "May Fill 7-02-14," and scanned the altered prescription. Respondent did not fill the prescription, but did check the prescription after it was filled by the technician in the control room. When Respondent left for the day, he took the unaltered, hard copy of the prescription with him. A copy of the unaltered prescription received by Respondent on or about June 26, 2014, is attached and incorporated as **EXHIBIT #2**. A copy of the altered prescription that was scanned and filled by Respondent on or about June 26, 2014, is attached and incorporated as **EXHIBIT # 3**.

6. After filling the altered prescription on or about June 26, 2014, Respondent went on vacation. On or about July 1, 2014, Respondent returned to work at the pharmacy. Respondent gave the hard copy of his prescription to the Pharmacist-In-Charge. Respondent had stained the prescription with ink to cover up the notation that his psychiatrist had made ("May Fill 7-02-2014"). A copy of the ink-stained prescription is attached and incorporated as **EXHIBIT #4**.

7. On or about July 1, 2014, Respondent stated that he would contact the RPP during an interview with Investigator Ray Trotter from the Department of Labor, Licensing and Regulation. Respondent worked from July 1, 2014, to July 3, 2014, but did not attempt to re-enroll with the RPP until noon on July 3. RPP was closed for the holiday at that time. . He was in touch with Chris McCoy of RPP before re-enrolling.

8. On or about July 3, 2014, Respondent voluntarily surrendered his license. A copy of the voluntary surrender is attached and incorporated as **EXHIBIT #5**

9. On or about July 7, 2014, Respondent re-entered the RPP and was referred to Pavilion for evaluation. A copy of the evaluation is attached and incorporated as **EXHIBIT #6.**

10. When traveling in the past, Respondent left his supply of Vyvanse in his hotel room when he returned home. After returning home without his medication, Respondent went to his longtime primary care physician and requested a prescription to replace the medication that he left in his hotel room. The physician issued Respondent a prescription for a 30-day supply of Vyvanse. Respondent informed his physician that he would notify his psychiatrist of the new prescription when he met with him again. Within days of receiving the prescription for Vyvanse from a physician, Respondent went to his regularly scheduled appointment with his psychiatrist. Respondent failed to notify his psychiatrist that his primary care physician had recently filled his prescription for Vyvanse. Respondent allowed his psychiatrist to issue him a second prescription for Vyvanse within days of receiving a prescription for Vyvanse from another physician.

RESPONDENT ADMITS that the aforementioned acts of Respondent present grounds that constitute misconduct under S.C. Code Ann. §§ 40-1-110(1)(d), (f), (g), (h) and (i) (1996, as amended) as alleged.

RESPONDENT AGREES, admitting the statutory allegations contained herein above, that he wishes to waive formal hearing procedures, waive the filing and service of a Formal Accusation, and further waives the requirement for thirty (30) days notice of the Board Hearing as well as formal hearing procedures and to dispose of this matter pursuant to S.C. Code Ann. § 1-23-320(f) (1976, as amended), in lieu of, *inter alia*, a fully contested hearing before the Board.

RESPONDENT AGREES that, at the Hearing, Respondent shall appear and answer questions, if any, under oath, by members of the Board or its counsel, and be subject to cross-examination regarding this matter and Respondent's pharmacy practice. The Board may consider Respondent's answers in rendering its decision. Respondent may present mitigating testimony and other evidence to the Board regarding an appropriate sanction in this matter.

IN WITNESS WHEREOF, the parties hereto, having agreed to the matters related above, have executed this Memorandum of Agreement and Stipulations, to be effective the latter date appearing below.

AND IT IS SO AGREED.

_____, 2015

KURT ALLEN HOWE
RESPONDENT

_____, 2015

WITNESS OR ATTORNEY

_____, 2015

PATRICK D. HANKS
Disciplinary Counsel
South Carolina Department of Labor,
Licensing and Regulation
P.O. Box 11329
Kingstree Bldg., 110 Centerview Drive
Columbia, S.C. 29211-1329
(803) 896-4477

Lexington County
Eleventh Judicial Circuit
Public Index

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Switch View

The State of South Carolina VS Kurt Allen Howe

Case Number:	2014A3210600068	**Court Agency:**	General Sessions	**Filed Date:**	07/10/2014
Case Type:	Criminal-Clerk	**Case Sub Type:**			
Status:	Disposed	**Assigned Judge:**	Clerk Of Court C P, G S, And Family Court	**Disposition Judge:**	Magistrates General Sessions Court
Disposition:	Pled Guilty				
Disposition Date:	02/04/2015	**Date Received:**	07/10/2014	**Arrest Date:**	07/08/2014
Law Enf. Case:		**True Bill Date:**		**No Bill Date:**	
Prosecutor Case:		**Indictment Number:**	2015GS3200393	**Waiver Date:**	
Probation Case:					

Case Parties **Charges** **Sentencing** **Associated Cases** **Actions** **Financials** **Bonds**

Name	Charge Code - Charge Description	Original Charge Code - Original Charge	Disposition Date
Howe, Kurt Allen	0179-Drugs / Poss. of other controlled sub. in Sched. I to V - 1st offense	0561-Drugs / Viol. Drug Distribution Law noncontrolled imitation controlled substance Prohibited Acts C	02/04/2015

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Licensee Information

Name: Kurt Allen Howe

Owner:

Address: 1593 Woodmore Drive SW
Marietta GA 30008

Primary Source License Information

Profession:	Pharmacy	**License No:**	RPH032617	**License Status:**	Active
License Type:	Pharmacist	**Obtained By Method:**	Application/Examination	**License Subtype:**	
Issue Date:	11/25/2020	**Expiration Date:**	12/31/2022	**Last Renewal Date:**	

Discipline Information
- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

No data available

You may close this window to return to your search results

Data current as of: January 5, 2022 14:12:12
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

12

NEVADA STATE BOARD OF PHARMACY

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

Y

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Non-Refundable $150 fee

Rev (06/09/2021)

What types of drug(s) will you be dispensing?

☒ Dangerous Drugs AND Controlled Substances

☐ Dangerous Drugs ONLY

Section 1: Personal Information

First: Sircy Middle: Mc Samuel Last: Moore

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

Home Address: [redacted] Gentle Pines Court

City: Las Vegas State: NV Zip: 89130

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: 2174 (NV)

(You MUST have a current and active license with your respective BOARD to apply for and maintain a dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Doc Mo's Kindred Spirits Animal Hospital

Practice Address: 2437 E. Cheyenne Ave Suite #:

City: North Las Vegas State: NV Zip: 89030

Telephone: (702) 642-5353 Fax: (702) 642-0669 Email: DocmoKindredSpiritsAH@yahoo.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?	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?		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?		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 4: 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?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

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 #:
Letter of Reprimand	NV	2019	#10-2019DVM-89

Criminal Action:	State:	Date:	Case #:	County:	Court:

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.

Sincy M. Moore
Print Name (First, Last)

Sincy M. Moore, DVM
Original Signature (electronic, copies or stamps not accepted)

10-21-21
Date

Board Use Only Received: _____ Amount: 150 cc

Sircy Moore

Legal First Name: Sircy

Legal Last Name: Moore

Previous or Other Name(s):

Licenses

License Number	License Category	License Status	Initial Licensure Date	License Expiry Date
2174-A	Veterinarian	Active	Jun-03-2013	Dec-31-2021

Notices, Restrictions and Findings

Type	Effective Date	Summary	Completion Date	Attachments
Disciplinary Finding	Jun-20-2016	File Number: 06-2016DVM-19 Please contact the Board for further information	Jan-26-2017	Moore, S LOR 06-2016DVM-19.pdf (/rest/public/data/downloadannotation/index.php?id=bcc0f22242a505c05a7a46c4932c29c3bf5c8087c0162af858fa73a9b3ba43254(
Disciplinary Finding	Oct-18-2018	File Number: 07-2017DVM-34	N/A	Moore, S LOR 05-2017DVM-34.pdf (/rest/public/data/downloadannotation/index.php?id=67a640fb7288e07c02e21ae313249958b56bce58616a415a0e4eedb60b9bfd57
Disciplinary Finding	Jul-20-2019	File Number: 10-2019DVM-89	N/A	Moore, S LOR 10-2019DVM-89.pdf (/rest/public/data/downloadannotation/index.php?id=199a8ef2218ceae8d25fdac899d8cb83da811afbd84861fea1adfd462399cc6128

Places of Work

Name	Street Address	City	Postal Code	Start Date	End Date
Tropicana Animal Hospital	2385 East Tropicna Ave	Las Vegas	89119	May-29-2013	Dec-19-2013
Green Valley Animal Hospital	6150 Mountain Vista St.	Henderson	89014	Dec-19-2013	Dec-23-2015
Parkway Springs Animal Hospital	2231 Green Valley Parkway	Henderson	89014	Dec-23-2015	Jul-25-2016
The Greatful Pet Animal Clinic	707 Canyon Rd., #103B	Boulder City	89005	Nov-15-2016	Jun-26-2018
Doc Mo's Kindred Spirits Animal Hospital	2437 E Cheyenne Ave	N Las Vegas	89030	Jun-26-2018	N/A

License History

License Category	License Status	Effective Date
Veterinarian	Active	Jan-01-2021
Veterinarian	Active	Jan-01-2020
Veterinarian	Active	Jan-01-2019
Veterinarian	Active	Jan-01-2018
Veterinarian	Active	Jan-01-2017
Veterinarian	Active	Jan-01-2016
Veterinarian	Active	Jan-01-2015
Veterinarian	Active	Jan-01-2014
Veterinarian	Active	Jun-03-2013
Veterinarian	Applicant	May-29-2013

PUBLIC LETTER OF REPRIMAND REGARDING:

SIRCY MOORE, D.V.M.
License #: 2174
Case # 6-2016DVM-19

The Nevada Board of Veterinary Medical Examiners filed a complaint against Sircy Moore, D.V.M. (Licensee) regarding his application for renewal of his license and his failure to prove completion of the requisite continuing education hours. After due investigation and consideration, the following facts regarding the complaint were discovered.

1) On or about December 29, 2015, Dr. Moore logged into the Board's website and renewed on-line. In his online renewal, Dr. Moore indicated that he had completed 22 hours of continuing education (CE) between January 1, 2015 and December 31, 2015.

2) On or about March 28, 2016, the Board's staff performed a continuing education audit, and Dr. Moore's application was randomly selected. The Board's staff sent Dr. Moore a letter requesting copies of Dr. Moore's continuing education certificates of attendance for the time period between January 1, 2015 and December 31, 2015.

3) On or about May 3, 2016, the Board's staff sent Dr. Moore an e-mail of a second notice to comply with the CE Audit. On June 9, 2016, the Board's staff sent Dr. Moore an additional e-mail in an attempt to reach and receive a response from Dr. Moore.

4) On or about May 20, 2016, June 9, 2016, and June 15, 2016, the Board's staff attempted to reach Dr. Moore by telephone at all of his telephone numbers known to the Board's staff, including telephone numbers for his employing veterinary facilities. Dr. Moore was no longer employed at any of the veterinary facilities of record.

5) On August 1, 2016 and September 13, 2016, the Board's staff attempted to contact Dr. Moore at a personal address the Board's staff had been supplied. The Board's staff also attempted to locate Dr. Moore through internet searches, to no avail.

6) In December 2016, after the Board's Executive Director called an employer of Dr. Moore's, Dr. Moore spoke with the Investigating Board Member. Though Dr. Moore claimed to have completed some hours of continuing education; however, as of the date of this Letter of Reprimand, Dr. Moore has not provided evidence or proof of completion of any of the requisite hours of continuing education.

The Nevada Board of Veterinary Medical Examiners finds this conduct to be in violation of applicable Nevada law and, pursuant to NAC 638.041(3), subject to disciplinary action. In particular, the Board finds that the above-described acts violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of a Board Regulation) and Nevada Administrative Code (NAC) 638.041(1) (Hours of CE for DVM) and NAC 638.0423(2) (Failure to Maintain Records of CE) in that Dr. Moore did not maintain or provide the records that would evidence completion any hours of continuing education for the period of January 1 through December 31, 2015. Dr. Moore could not document any hours of continuing education for the relevant time period.

Should the Letter of Reprimand be rejected by the Board it is agreed that presentation to and consideration by the Board of such proposed Letter of Reprimand or other documents or matters pertaining to the consideration of this Letter of Reprimand, shall not unfairly or illegally prejudice the Board, or any of its members, from further participation, consideration, adjudication, or resolution of these proceedings, and that no Board member shall be

disqualified or challenged for bias. If it is accepted by the Board, the Letter of Reprimand becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Through the signature of Licensee below, the Licensee agrees this conduct is a violation of the statutes and regulations detailed above. As a result of this admitted violation and by a majority vote of the members of the Board at its October 2016 meeting, this Public Letter of Reprimand is to be placed in the Licensee's licensing file. As a result of the above stated violation, the Licensee agrees to the following:

1) Dr. Moore shall pay attorney's fees, investigative costs, and Board costs of $300.00 and a fine of $350.00, for a total due of $650.00. Dr. Moore shall pay the entire amount due of $650.00 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the date of the Board's approval of this Letter of Reprimand.

2) Dr. Moore will provide to the Board's office written evidence of successful completion of 20 hours of continuing education within 60 days of the date of the Board's approval of this Letter of Reprimand. The 20 hours of continuing education in this paragraph may not be counted toward Dr. Moore' continuing education requirements for renewal of his license.

3) Dr. Moore's renewal applications shall be audited for the next three renewal periods to assure that he has properly satisfied the continuing education requirements for each of those renewal periods.

4) Failure by Dr. Moore to comply with any term or condition of this Letter of Reprimand shall result in additional disciplinary action, up to and potentially including suspension or revocation of Dr. Moore' license.

Dated this _____ day of December, 2016.

Sircy Moore, DVM 1/11/17
Sircy Moore, D.V.M.

Dated this 26 day of January, 2017.

Nevada State Board of Veterinary Medical Examiners

William Taylor DVM
William Taylor, D.V.M., President

STATE OF NEVADA

BOARD OF VETERINARY MEDICAL EXAMINERS
4600 KIETZKE LANE, BUILDING O-265
RENO, NEVADA 89502
PHONE 775 688-1788/FAX 775 688-1808
VETBDINFO@VETBOARD.NV.GOV
WWW.NVVETBOARD.US

PUBLIC LETTER OF REPRIMAND REGARDING:

SIRCY MOORE, D.V.M.
License #: 2174
Case # 05-2017DVM-34

The Nevada Board of Veterinary Medical Examiners filed a complaint against Sircy Moore, D.V.M. (Licensee) regarding his treatment of a 9-year-old female Labrador retriever named "Katie". After due investigation and consideration, the following facts regarding the complaint were discovered.

1) On June 29, 2017, the owner of a 9-year-old female Labrador retriever named "Katie" brought her to the Grateful Pet Animal Clinic (GPAC) to have her spayed as part of her participation in a neighborhood outreach program in which the owner was participating because of his straitened circumstances. Two days earlier, a veterinary assistant at GPAC had contacted the owner and given her instructions related to the pre-surgical care for Katie. The owner was an established client at GPAC through her ownership and treatment of another dog. As part of the community outreach program, GPAC had offered to perform the spay at no cost and had arranged to pick up and return Katie to the owner's home because the owner did not have a way to get Katie to GPAC.

2) On June 29, 2017, staff from GPAC (a veterinary assistant and the receptionist) visited the owner's home to pick up Katie for the spay surgery, and they presented authorization forms to the owner regarding the surgery. The owner signed the forms. The communication between GPAC's staff and the owner was apparently less than clear because the staff believed that the owner understood that if Katie was deemed a candidate for surgery, then the surgery would be performed without further communication with the owner whereas the owner understood that he would receive communication from GPAC prior to the performance of any surgery.

3) Prior to surgery, Dr. Moore physically examined Katie, including drawing blood that was tested pre-surgically. The blood test produced normal results except that the ALT was significantly elevated at 640 U/L where the normal range was 0-120 U/L. Dr. Moore did not communicate the elevated ALT level to the owner either prior to or after performing the spay surgery on Katie.

4) On June 29, 2017, Dr. Moore performed the spay surgery on Katie. Katie died at home approximately 12 hours after the surgery. Dr. Moore called the owner after learning of Katie's death and offered a post-mortem examination. A post-mortem examination was performed at GPAC, which showed that Katie had suffered post-surgical internal bleeding.

The Nevada Board of Veterinary Medical Examiners finds this conduct to be in

violation of applicable Nevada law and subject to disciplinary action. In particular, the Board finds that the above-described acts violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of a Board Regulation) and Nevada Administrative Code (NAC) 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and Principles of Veterinary Medical Ethics sections II(E) and VI(A) in that Dr. Moore did not communicate directly with the owner prior to performing the spay surgery on Katie and at no time communicated to the owner the elevated ALT level and how the elevated ALT level might affect Katie's health and treatment and the risk therein. While there is no definitive correlation to show that Katie's death was caused due to the high ALT levels in Katie's blood work, per the requirements of informed consent, Dr. Moore is required to share abnormal blood test results with the owner prior to surgery.

Should the Letter of Reprimand be rejected by the Board it is agreed that presentation to and consideration by the Board of such proposed Letter of Reprimand or other documents or matters pertaining to the consideration of this Letter of Reprimand, shall not unfairly or illegally prejudice the Board, or any of its members, from further participation, consideration, adjudication, or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias. If it is accepted by the Board, the Letter of Reprimand becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Through the signature of Licensee below, the Licensee agrees this conduct is a violation of the statutes and regulations detailed above. As a result of this admitted violation and by a majority vote of the members of the Board at its April 2018 meeting, this Public Letter of Reprimand is to be placed in the Licensee's licensing file. As a result of the above stated violation, the Licensee agrees to the following:

1) Dr. Moore shall pay attorney's fees, investigative costs, and Board costs of $782.50. Dr. Moore shall pay the entire amount due of $782.50 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the date of the Board's approval of this Letter of Reprimand.

2) Dr. Moore will provide to the Board's office written evidence of successful completion of 3 hours of continuing education related to veterinary ethics focused on improving his client communication skills.

3) Failure by Dr. Moore to comply with any term or condition of this Letter of Reprimand shall result in additional disciplinary action, up to and potentially including suspension or revocation of Dr. Moore' license.

Dated this 9 day of Oct, 2018.

Sircy Moore, D.V.M.

Dated this 18 day of October, 2018.

Nevada State Board of Veterinary Medical Examiners

Scott Bradley, D.V.M., President

STATE OF NEVADA

BOARD OF VETERINARY MEDICAL EXAMINERS
4600 KIETZKE LANE, BUILDING O-265
RENO, NEVADA 89502
PHONE 775 688-1788/FAX 775 688-1808
VETBDINFO@VETBOARD.NV.GOV
WWW.NVVETBOARD.US

PUBLIC LETTER OF REPRIMAND REGARDING:

SIRCY MOORE, D.V.M.
License #: 2174-A
Case #10-2019DVM-89

The Nevada Board of Veterinary Medical Examiners received a complaint against Sircy Moore, D.V.M. (Licensee) regarding Dr. Moore's treatment of 1½-year-old female miniature Poodle named Ellie. After investigation and consideration, the following facts regarding the complaint were discovered:

1) On September 13, 2019, the owner of a 1½-year-old female miniature Poodle named Ellie brought her to Dr. Mo's Kindred AH Spirits Animal Hospital (Kindred AH AH) with concerns about acute left hind leg lameness and pain. After an examination and obtaining radiographs, Dr. Moore diagnosed a left coxofemoral luxation. Dr. Moore sent Ellie home with pain medications and scheduled a surgery.

2) On September 16, 2019, Ellie was brought back to Kindred AH for surgery with Dr. Moore. Dr. Moore attempted to perform a left femoral head osteotomy via a dorsal approach. The surgery was unremarkable until after Dr. Moore transected the femoral head, at which time he could not remove it because, according to Dr. Moore, the femoral head had become lodged behind deeper tissue layers and he was unable to remove it. Rather than continue efforts to remove the femoral head, Dr. Moore stated he closed the incision, thus leaving the femoral head due to his concerns that a prolonged anesthesia could have resulted in complications for the patient. No anesthesia complications were recorded during the one hour anesthesia period.

3) Two days later, Ellie's owner became concerned when the incision became swollen and painful and attempted to take Ellie back to Kindred AH. However, Kindred AH was closed because Dr. Moore was out of town. Thereafter, on September 18 and 19, 2019, Ellie was taken to another veterinary hospital where it was noted that the incision site had swollen, so much so that by September 19, 2019, the swelling had progressed to a black coloration of the skin. The veterinarian at the second veterinary hospital recommended that Ellie be taken to a specialty hospital for a surgical consultation.

4) On September 19, 2019, Ellie was taken to a specialty hospital. At the specialty hospital, it was noted that Ellie had generalized weakness, hypotension, and incision site dehiscence with a large eschar and purulent exudate. Radiographs revealed

soft tissue swelling of the incision and a retained femoral head. The veterinarian at the specialty hospital diagnosed sepsis and began aggressive treatment to address the sepsis.

5) After two days at the specialty hospital, Ellie's condition had worsened and emergency surgery was recommended and Ellie's owner consented. The surgery involved removing the retained femoral head, obtaining a sample for aerobic culture, and amputation of the left hind leg.

6) Ellie suffered significant post-surgical complications for which she was at or taken to the specialty hospital on September 22-24, 25, 28, and 30 and October 1. On October 1, 2019, the owner opted for humane euthanasia which was performed without complication.

7) In the course of the Board's investigation of the instant matter, the Board's staff reviewed the medical records made by Dr. Moore at Kindred AH and determined that the records lacked documentation of surgery times, the types of anesthesia administered, and the doses of injectable medications administered.

The Nevada Board of Veterinary Medical Examiners finds this conduct to be in violation of applicable Nevada law. In particular, the Board finds that the above-described acts violated Nevada Revised Statutes (NRS) 638.140(5) (Incompetence), NRS 638.140(6) (Negligence) and NAC 638.045(2) (Negligence) and NAC 638.045(2) (Incompetence) where Dr. Moore knowingly did not remove the femoral head from Ellie's leg and closed the incision knowing that the femoral head remained in Ellie's body and did not establish a clear plan for prompt removal. Additionally, the Board finds this conduct to be in violation of NRS 638.140(1) (Violation of Board regulations) and NAC 639.0475 where Dr. Moore's records lacked documentation of surgery times, the types of anesthesia administered, and the doses of injectable medications administered.

Should the Letter of Reprimand be rejected by the Board it is agreed that presentation to and consideration by the Board of such proposed Letter of Reprimand or other documents or matters pertaining to the consideration of this Letter of Reprimand, shall not unfairly or illegally prejudice the Board, or any of its members, from further participation, consideration, adjudication, or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias. If it is accepted by the Board, the Letter of Reprimand becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Through the signature of Dr. Moore below, Dr. Moore admits this conduct is a violation of the statutes and regulations detailed above. As a result of this admitted violation and by a majority vote of the members of the Board at its July 2020 meeting, this Public Letter of Reprimand is to be placed in the Licensee's licensing file. As a result of the above stated violation, the Licensee agrees to the following:

1) Dr. Moore will pay the attorney fees, investigative costs, and Board costs of $880.00 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the date of the Board's approval of this Letter of Reprimand.

2) Dr. Moore will provide to the Board's office written evidence of successful completion of four hours of continuing education in orthopedic surgery in canines and two hours in medical recordkeeping within 60 days of the date of the Board's approval of this Letter of Reprimand. The six hours of continuing education in this paragraph may not be counted toward Dr. Moore's continuing education requirements for renewal of his license.

3) Failure by Dr. Moore to comply with any term or condition of this Letter of Reprimand shall result in additional disciplinary action, up to and potentially including suspension or revocation of Dr. Moore's license. Additionally, failure by Dr. Moore to comply with any term or condition of this Letter of Reprimand shall allow the Board's staff not to renew Dr. Moore's license until Dr. Moore remedies the failure to comply.

Dated this 20th day of July, 2020.

Sircy Moore, D.V.M.

Dated this 22 day of Oct, 2020.

Nevada State Board of Veterinary Medical Examiners

Steve Damonte, D.V.M., President

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
PHONE (775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

December 9, 2021

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: nu4cuss@yahoo.com

Sircy Moore, DVM
Doc Mo's Kindred Spirits Animal Hospital
2437 E. Cheyenne Avenue
Las Vegas, NV 89030

CEASE and DESIST: Unlicensed Dispensing in Nevada

Dear Dr. Moore:

The Nevada State Board of Pharmacy (Board) has determined that you are engaged in dispensing prescription drugs for animal patients without a valid registration. This constitutes a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.23505 and NAC 639.7423.

You are hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST dispensing any controlled substances or dangerous drugs for animal patients.

Please be aware that the forgoing does not preclude the filing of administrative charges. 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

13

13A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** *____*
Check box below for type of ownership and complete all required forms.
☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☒ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Northmark Pharmacy

Physical Address: 1945 CEI Drive

Mailing Address: (SAME)

City: Cincinnati State: OH Zip Code: 45242

Telephone: 513-569-3334 Fax: 513-569-3902

✓ Toll Free Number: 1-800-544-5133 (Required per NAC 639.708)

E-mail: dchachare@ Website: northmarkpharmacy.com

Managing Pharmacist: Deepali Chachare License Number: 22299 Temp

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: Mail Order	☒	☐ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☒	☐ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Deepali Chachare — 05/19/2024

Print Name of Authorized Person — Date

Board Use Only	Date Processed:	Amount: 500 check # 5071

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General ✓ Limited ____

Partnership Name: CEI Physicians, P.S.C., LLC

Mailing Address: 1945 CEI Drive

City: Cincinnati State: OH Zip Code: 45242

Telephone Number: 513-569-3334 Fax Number: 513-569-3902

Contact Person: Deepali Chachare

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
CEI Physicians, P.S.C, LLC	G	100%
Non-Licensed Nevada Physicians		

List names of 4 largest partners and percentage of ownership:

Name: N/A %: ____

Name: ____ %: ____

Name: ____ %: ____

Name: ____ %: ____

List any physician shareholders and percentage of ownership.

Name: N/A %: ____

Name: ____ %: ____

Name: ____ %: ____

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 4 pm Saturday 8 am 1 pm

Sunday Closed am ____ pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Deepali Chachare

Responsible Person of Northmark Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Deepali Chachare

Print Name of Authorized Person

05/19/2021

Date

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 02/01/2022
Amount:
License #: 22299

Deepali Y. Chachare

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:02/01/2022
Expires:08/01/2022

Deepali Y. Chachare

License #
22299
Temporary

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 #: 22299
Effective Date:02/01/2022

Expires: 08/01/2022
STATUS: Temporary

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Deepali Y. Chachare

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

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 March 31, 2023.

NORTHMARK PHARMACY

1945 CEI DRIVE

BLUE ASH, OH 45242

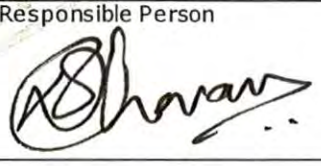
License Number: 022247900

Terminal - Pharmacy - Category 3

Expiration Date: March 31, 2023

CLASS: Terminal - Pharmacy - Category 3
BUSINESS TYPE: MD - Multi-Disciplinary Pharmacy

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
Deepali Chachare	

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

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 NORTHMARK PHARMACY LLC, an Ohio For Profit Limited Liability Company, Registration Number 2123465, was organized within the State of Ohio on July 20, 2012, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 25th day of January, A.D. 2022.

Ohio Secretary of State

Validation Number: 202202503340

1:5 398/525

NORTHMARK PHARMACY
1945 CEI DR
BLUE ASH, OH 45242-5664

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN3679745	10-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	09-07-2021

NORTHMARK PHARMACY
1945 CEI DR
BLUE ASH, OH 45242-5664

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
FN3679745	10-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	09-07-2021

NORTHMARK PHARMACY
1945 CEI DR
BLUE ASH, OH 45242-5664

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 menufacture, 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)

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 022247900

Northmark Pharmacy

1945 Cei Drive
Blue Ash, OH 45242
Hamilton County

Terminal - Pharmacy - Category 3

Compounding Inspection for Pharmacies

February 12, 2021

License 022247900 - Northmark Pharmacy

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 Elizabeth Bond
Start 2/8/2021 11:06 PM
End 2/12/2021 3:15 PM

Organization

Name
Northmark Pharmacy

License Type
Terminal - Pharmacy - Category 3

Category

License Number
022247900

Business Type
MD - Multi-Disciplinary Pharmacy

DEA Number
FN3679745

Responsible Person
Deepali Yogesh Chachare, RPH

Hours of Operation
M-F: 8AM-4:30PM; On Call Services 24/7

Contact

Address
1945 Cei Drive
Blue Ash, OH 45242
Hamilton County

Primary Number
(513) 569-3334

Fax Number

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Deepali Yogesh Chachare, RPH		Pharmacist	03230717	(513) 569-3334	dchachare@gmail.com

1) General Operations and Information

1) Multiple inspection reports were generated during this inspection. A full report will include the following information:

No

2) The pharmacy intends to use this inspection as part of the NABP Multistate Pharmacy Inspection Blueprint Program.

No

3) Ohio State Board of Pharmacy Personnel Present at Inspection Include:

Observation
Compliance Specialist Elizabeth Bond

4) Description of Business

Observation
This facility is a sterile compounding pharmacy located within Cincinnati Eye Institute (CVP) Corporate Office building. One pharmacist is employed full time, another pharmacist is available for consultation, two compounding technicians and two non-compounding technicians are also employed. The pharmacy dispenses about 1500-2000 prescriptions per week. About 60% of these are for Avastin syringes that are repackaged as patient specific doses. This pharmacy is licensed in multiple other states (see question 6 of this section for a list). All sterile compounding is low, medium, and hazardous drug compounding.

5) Is the license current and on-site available for viewing at the time of inspection?

Yes

Observation
Observed TDDD number: 022247900 Exp: 7/01/2021; RP- Deepali Chachare, RPh No issues noted.

6) The pharmacy is licensed in other states.

Yes

Observation
The site is licensed in the following states: Florida, Delaware, Illinois, Maine, Michigan, Indiana, Kentucky, Pennsylvania, Georgia, Wisconsin, Rhode Island, Missouri, Minnesota, New Jersey, Tennessee, Maryland, West Virginia, Washington, Virginia, North Carolina, New York, Wyoming, and Connecticut.

7) The pharmacy is registered with the FDA as a repackager or 503B outsourcer?

No

8) The pharmacy is licensed as a wholesaler/outsourcing classification by the Ohio State Board of Pharmacy?

No

9) At all times a pharmacist provides supervision and control of dangerous drugs.

Yes

10) Pharmacy staff are properly credentialed and performing duties within their scope of practice.

Yes

12) The pharmacy is appropriately staffed to conduct the practice of pharmacy in a safe and effective manner.

Yes

13) Additional observations regarding the pharmacy general operations and information include:

Observation
This inspection was requested by the licensee for out of state license renewal applications and not, as a result of, a complaint or area of concern. There are no areas of concern noted.

2) Security/Theft or Loss of Drugs

1) Is the security of the pharmacy drug stock adequate to detect and deter drug theft and diversion?

Yes

Observation
The building is secured with an alarm system, as well as, locks and cameras. The pharmacy is secured with a different keyed, deadbolt lock. There is only one key to the deadbolt and it is stored in a secure lockbox outside of the pharmacy. Only the pharmacist has the code to the lockbox. The doors are equipped with combination entry access available only to pharmacy employees. The floor and walls are solid and no windows are located within the pharmacy. The ceiling is caulked in place. No security issues were noted.

2) Dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A controlled substance order forms and records related to the practice of pharmacy are located inside the pharmacy barricade.

Yes

3) Are all records of accountability that are stored outside of the pharmacy barricade but within the same physical location secure and tamper evident?

Yes

Observation
All records of accountability stored at the licensed location are stored inside the pharmacy space.

4) Has the pharmacy experienced any drug thefts or losses in the last three (3) years?

No

5) Drug Theft or Loss Statement

Observation
Any theft or significant loss of drugs must be reported, by telephone, to the Board of Pharmacy and local law enforcement immediately upon discovery. If a controlled substance the DEA must be notified as well using a DEA-106 form.

3) Electronic Record Keeping Systems and Positive Identification

1) The pharmacy uses the following electronic record keeping system

Observation
Paper charts are utilized. Positive ID is achieved with pen and ink signatures.

2) Positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy is documented in accordance with OAC 4729-5-01.

Yes

Observation
Pen and ink signatures are utilized to achieve positive ID.

4) Controlled Substances

1) The facility maintains controlled substances on-site.

No

Observation
The facility does possess a DEA license. Observed license is current and on site upon inspection. DEA number: FN3679745 Exp: 10-31-2021 No issues noted.

2) The facility compounds using controlled substances.

Observation
The facility does not compound using controlled substances.

8) Controlled substances awaiting destruction are maintained with appropriate security and control.

No

Observation
No controlled substances on-site at this facility.

10) The facility conducts a complete and accurate inventory of all controlled substances on-hand annually.

Yes

Observation
Observed controlled substance inventories (stating no controlled substances on hand) dated January 2, 2020 and January 4, 2021. No issues noted.

11) An audit of controlled substances was conducted during the inspection:

Observation
No controlled substances on-site.

14) Additional Findings regarding controlled substances include:

Observation
The pharmacy has been granted exemption from reporting to OARRS.

5.3) General Non-Sterile Compounding Information

1) The pharmacy compounds patient-specific non-sterile compounds pursuant to a prescription.

No

Observation
The facility does not perform non-sterile compounding.

6.1.1) *General Sterile Compounded Product Information

1) *The licensee reports they compound the following risk levels for sterile products:

Low Risk
Medium Risk
Hazardous Drugs

2) *The licensee compounds the following types of sterile products.

Antibiotics
Hazardous Drugs/Chemotherapy
Opthalmic

4) *All CSP's are dispensed pursuant to a patient specific prescription?

Yes

8) Additional findings regarding general sterile compounded products includes:

Observation
Additional notes:
Pharmacy prepares Avastin syringes in batches greater than 25 syringes. Sterility testing is completed on all batches prior to release. Batch sterility samples are sent to an outside lab for testing (ARL). Product is not released until 14 day results have been returned. Pharmacy performs random potency testing on batches of antibiotic ophthalmic compounds by an outside lab. All new formulations or changes to the master formulation will be potency tested. Observed random results dated 1/19/2021 and 1/21/2021 with no issues noted.

6.1.2) Sterile Compounded Blood Products/Biologics/Sensitizing Agents

1) The licensee is performing compounding activities with blood-derived or biological material?

Yes

Observation
Observed Safety Protocols for Handling Blood and Body Fluids. No issues noted

6.1.4) Radiopharmaceuticals

1) Does the licensee prepare CSPs which are considered radiopharmaceutials?

No

6.1.5) Sterile Compounding for Animals

1) The pharmacy sterile compounds animal products.

No

6.2) *Compounding Policies and Procedures

1) *The facility has a policy and procedure manual for sterile product compounding.

Yes

Observation
The manual is paper and was purchased from PCCA. Observed documentation that policy review is occurring and documented. Policies were individualized. The manual was last updated throughout January of 2021. The updates are completed by RP, Deepali Chachare, RPh and signed with pen and ink signatures. No issues noted.

2) The policy and procedure manual contains written and properly approved SOPs designed to ensure the quality of the quality of the environment in which the CSP is prepared?

Yes

Observation
Reviewed Cleaning and Maintenance of the Clean Room Facility SOP Number 3.020, effective date of 8-5-15 and updated on 1-4-21. No issues noted.

3) Observation of facility adherence to policies and procedures:

Yes

Observation
Observed Gowning and Garbing adherence. No issues noted.

8) *The pharmacy has a plan in place to provide continued compounding services in the event the cleanroom fails environmental testing, as as a result must be closed for additional cleaning and re-certification.

Yes

Observation
No change since previous inspection. Jungle Jim's would assume the necessary compounding services required to maintain patient care.

6.3) *Sterile Compounding Training

1) *The training program includes the following essential elements to safely compound sterile products.

Yes

Observation
The site maintains excellent documentation of all aspects of staff training and competencies for sterile compounding. Northmark Pharmacy utilizes Compounder's International Analytical Laboratory and ARL Bio Pharma to perform an outside validation of aseptic technique for sterility, endotoxin, and potency. Observed records for DC dated 7-10-2020 and 7-22-20 and for SE dated 10-20-20, 10-29-20 and 10-30-20. This is a Best in Class practice.

2) *Compounding supervisors are adequately trained to supervise and/or verify staff training and compounding?

Yes

Observation
Observed all records for DC.

3) Relief personnel from outside agencies performing sterile compounding are appropriately trained.

No

Observation
The site does not utilize agency staff.

4) *There is documentation that compounding staff have completed and passed a didactic compounding review and exam prior to compounding and annually/semiannually thereafter.

Yes

Observation
Observed the following for DC (supervisor, RPh):

- Updates on USP Compounding Standards (11/6/2020)
- Innovative Approaches to Implementing USP Compounding Standards (11/6/2020)
- Rapid Sterility Strategies for Compounded Sterile Preparations (8/24/2020)
- Sterility Testing Requirements of USP 71 and 797 (4/30/2020)
- Sterilization by Filtration (4/28/2020)
- Low and Medium Risk Quiz (11-12-2020)
- High Risk Compounding Quiz (11-12-2020)
- Review of USP 800 Quiz (1-12-2021)

Observed the following for SE (tech):

- Hazardous Drug Management Essentials (1/25/2021)
- Low and Medium Risk Quiz (11-13-2020)
- High Risk Compounding Quiz (11-13-2020)
- Review of USP 800 Quiz (1-14-21)

6) *There is documentation that compounding personnel have passed an annual/semi-annual gowning procedure and gloved fingertip sampling test.

Yes

Observation
Observed records for DC dated 5/18/20 for Non-Hazardous and 5/7/20 for Hazardous compounding.
Observed records for SE for Non-Hazardous dated 11/3/2020 and for Hazardous compounding dated 11/6/2020.

7) *There is documentation that compounding personnel have passed a media fill test of appropriate breadth and depth prior to compounding and at least annually/semi-annually.

Yes

Observation
for DC: Non-Hazardous dated 5/18/20 and Hazardous dated 5/7/20
for SE: Non-Hazardous dated 11/4/2020 and Hazardous dated 11/6/20

9) *There is documentation that compounding personnel have passed an initial and annual/semi-annual observational compounding skills assessment.

Yes

Observation
For DC: Non-Hazardous dated 5/18/20 and Hazardous compounding dated 5/7/20
Observed records for SE for Non-Hazardous dated 11/3/2020 and for Hazardous compounding dated 11/6/2020.

10) *There is documentation that compounding personnel have received training on the operation of any equipment that may be used when preparing compounded sterile products.

Yes

6.4.1) *General Storage for Sterile Product Components

1) *Temperature monitoring of controlled room temperature drug storage areas is performed at least once daily.

Yes

Observation
Paper logs with pen and ink signatures are utilized. Current temperature is 68 degrees F. Observed logs with no issues noted.

2) *Temperature monitoring for refrigerated drug storage areas is performed at least once daily.

Yes

Observation
Temperatures in the drug storage area refrigerator are continuously and remotely monitored through a phone based system. Temperatures are recorded daily on log sheets. If a temperature is out of range, facility maintenance and the RP are notified. The issue is immediately resolved. Current temperature is 5 degrees F.

3) *Temperature monitoring for frozen drug storage areas is performed at least once daily.

Yes

Observation
Temperatures in the drug storage area freezer are continuously and remotely monitored through a phone based system. Temperatures are recorded daily on log sheets. If a temperature is out of range, facility maintenance and the RP are notified. The issue is immediately resolved. Paper logs with pen and ink signatures are utilized. Current temperature is -17 degrees C.

4) The pharmacy has an action plan in place for temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.

Yes

Observation
The facility/RP would relocate drugs to an alternate refrigerator or freezer in the event of an issue.

5) *Expired components for compounding are segregated from drug stock, and properly destroyed.

Yes

Observation
Expired drugs are removed from inventory and stored in a secure area near the purchasing department. The pharmacy staff audits the inventory for outdated compounded drugs on a daily basis and drug stock weekly basis. Paper records are maintained.

6.4.2) *Active pharmaceutical Ingredients used in Sterile Compounding

3) *The pharmacy compounds preparations using bulk powder active pharmaceutical ingredients (APIs).

No

6.4.3) Single and Multiple-Dose Vials used in Sterile Compounding

1) Single-dose vials used more than one (1) time after puncture follow USP 797 standards.

Yes

Observation
The site only enters SDV once and then discards the product.

2) Multiple-dose vials were observed stored outside of USP 797 and USP 51 standards.

Observation
All MDVs are given a 28 day expiration. The vial is stickered with the expiration date.

6.4.4) Sterile Compounded Stock Solutions

1) The pharmacy compounds stock solutions.

No

6.5) *Sterile Compounding Environmental Certification, Sampling and Monitoring

1) *Certification of primary engineering controls and ISO classified spaces has been conducted every 6 months, and whenever a device or room is moved, or major work is done to the space, by a CETA Certified vendor.

Observation
Northmark Pharmacy uses Steris to certify their PECs and ISO Rooms. Certifications were dated: November 16, 2020, May 18, 2020, November 20, 2019, and June 6, 2019 for HD areas and on November 2, 2020 and May 7, 2020, November 25, 2019, and May 14, 2019 for Non-HD areas. Steris is CETA certified.

2) *The certification report includes information about the equipment used for performing calibration testing.

Yes

3) Compounding supervisors are familiar with certification requirements and interpretation of results.

Yes

4) *ISO spaces meet or exceed the required air changes per hour (ACPH).

Observation
HD Anteroom (ISO 7): 40 ACPH
HD Prep: 48 ACPH
Non-HD Anteroom (ISO 8): 24 ACPH
Non-HD Prep: 146 ACPH

5) *Air pattern analysis using smoke studies was performed under dynamic conditions.

Yes

6) *Particle generating equipment located in ante and buffer areas are actively used during certification processes.

Yes

7) *Differential air pressures between rooms was measured and recorded during certification.

Observation
The differential pressure measured from the HD Anteroom to the HD Prep room was 0.029 water column positive pressure.

The differential pressure measured from the HD anteroom and all adjacent spaces was 0.056 water column positive pressure.
The differential pressure measured from the Non-HD Prep room to the Non-HD Anteroom was 0.034 water column positive pressure
The differential pressure measured from the Non-HD Anteroom to all adjacent spaces was 0.056 water column positive pressure.

Readings were taken when all doors were closed.

8) Air velocity from buffer rooms (or zones) to ante areas is at least 40 feet/minute.

Observation
Airflow velocities of the BSCs:
#1- 63 fpm average
Non-HD Areas:
92 fpm
LAFW: 92 fpm average

9) *Certification included the measurement of particle counts 0.5um and larger under dynamic conditions.

Observation
HD Anteroom: 12,980- 22,040
HD Prep: 3,000- 7,800
BSC #1- zero
Non-HD Anteroom: 3400- 92,500
Non-HD Prep room: 620-2,760
LAFW: zero

10) *HEPA filters were leak tested.

Yes

Observation
No issues noted.

11) *Viable air sampling has been conducted no less than every 6 months in each PEC, in all compounding rooms, and whenever a device or room is relocated or altered, or if major service to the facility was performed.

Observation
No issues noted. Observed results from 11-16-20 and 5-18-20 for HD areas and 11-2-20 and 5-7-20 for Non-HD areas.

12) *Viable air samples were collected in appropriate locations, on appropriate growth media, and incubated for an appropriate interval.

Yes

13) *Viable air samples did not exceed USP action levels.

14) *Surface sampling has been conducted periodically according to the pharmacy surface sampling plan.

Observation
No issues noted. Observed results from 11-16-20 and 5-18-20 and 11-2-20 and 5-7-20 for Non-HD areas.
In addition to the sampling performed at certifications, the RP is conducting in-house surface sampling on a monthly basis. Observed documentation of results with no growth noted for ISO 5 hood surfaces and BSC surfaces for the years of 2018, 2019, 2020, and 2021.

15) *Surface samples did not exceed USP action levels.

Yes

16) *Compounding operations are suspended if mold, yeast, coagulase positive staphylococcus or gram negative rods are detected in the PEC.

Yes

17) Document CAI or CACI manufacturers provided the licensee with written documentation based on validated environmental testing that any components of personal protective equipment or cleansing is not required during compounding.

Observation
The site does not utilize isolators.

19) Additional findings regarding the sterile compounding environmental certification include:

Observation
Observed certification report for one Ductless Fume Hood completed on May 4, 2020 with no issues noted. Completed by Steris.

6.6) Sterile Compounding Equipment Certification and Calibration

1) Appropriate equipment and utensils are available, clean, and in good working order.

Yes

2) *Types of equipment/compounding devices utilized include:

Incubators

Balances

Observation
Maintenance for incubators includes confirmation of correct functioning, including control of gas levels, temperature mapping of empty and simulated load chambers and alarm functioning.

Balance maintenance includes internal calibration per manufacturer instructions. Performance check after auto-calibration. Weigh known weights individually, shall be within 0.1% of actual mass value of the individual weight. Drift test uses one weight weighted 10 times (sometimes over several days) variation of observed weights from the mean shall not exceed +/- 0.2mg. Calibrate daily, after any maintenance, and after relocation of or failure of balance.

3) *The pharmacy maintains documentation of calibration and maintenance of equipment/compounding devices?

Yes

Observation
Observed records of independent calibration verification for the balance dated October 30, 2020 with no issues noted.

4) *Environmental monitoring equipment and gauges are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines, and calibration is documented.

Yes

Observation
Calibrations are verified and documented on the semi-annual room and PEC recertifications.

6.7.1) *General Sterile Environment

1) *Sterile Compounding is performed in a separate and distinct compounding area.

Yes

2) *Surfaces of sterile product compounding area are resistant to disinfectants, non-permeable, and low particulate generating.

Yes

3) *Walls are painted with epoxy based paint or other impermeable surface, and are seamless or have sealed seams.

Yes

4) *Ceiling tiles and light fixtures are impervious, smooth, mounted flush and sealed.

Yes

5) *Floors are overlaid with wide sheet flooring with seamless or heat welded seams and coving.

Yes

6) *Compounding areas do not contain dust collecting overhangs.

Yes

8) *ISO room which are completely enclosed are equipped with monitors/gauges to measure differential pressure.

Yes

9) *Pressures are continuously monitored and a plan is in place to detect and react to pressure differentials outside acceptable limits.

Yes

Observation
Observed paper pressure monitoring logs with pen and ink signatures without issue. The HD compounding areas are equipped with a continuous electronic monitoring system. The system is continuously monitored via maintenance. Maintenance telephones the RP in the event of an excursion. All PECs are equipped with audible alarms.

11) *Temperatures of the compounding areas are controlled by a thermostat, with appropriate air-conditioning systems in place.

Yes

Observation
Paper temperature logs with pen and ink signatures are utilized by the site. Current temperature is 68 degrees F.

12) Temperature monitoring of the compounding is in place to detect any excursions.

Yes

13) Humidity of the compounding area is maintained to provide humidity within the specified ranges.

Yes

Observation
Current humidity is 20%.

6.7.2) *Sterile Compounding Ante-Area

1) *A working sink 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 PECs.

Yes

6.7.3) *Cleanrooms for Sterile Compounding

1) *The licensee maintains the following primary engineering control devices.

Biological Safety Cabinets (BSC)
Laminar Air Flow Hoods (LAFW)

2) *The buffer/clean room (ISO 7) space does not contain sinks or drains.

Yes

3) Primary engineering controls are located out of traffic flow and avoid disruption from the HVAC system.

Yes

4) *Only appropriate furniture, equipment, supplies and other material required for compounding is located in the clean room.

Yes

5) *Clean room provides adequate windows/observational space for compounding supervision.

Yes

6.7.4) *Isolators for Sterile Compounding

8) Additional findings regarding isolators used for sterile compounding include:

Observation
The site does not utilize isolators for sterile compounding.

6.8) *Sterile Compounding Environment Cleaning

1) *Personnel cleaning compounding areas follow proper garbing procedures.

Yes

3) Cleaning equipment and solutions are appropriate and labeled to prevent inappropriate use.

Yes

Observation
The following products are used for cleaning the classified rooms and PECs:

- Safetec 2 step product called Surface Safe- detergent and hydrogen peroxide components
- Cavicide
- Spor-Klenz RTU by Steris (Hydrogen Peroxide and Peroxyacetic Acid)
- 2% bleach solution
- Sterile water
- Sterile Alcohol

5) *Cleaning agents effective for bacteria, viruses, fungi and spores are used in the appropriate order and for the appropriate dwell times.

Yes

6) *All ISO 5 PECs are cleaned at the beginning of each shift, between compounding activities, and at least every 30 minutes while compounding, and after spills or suspected surface contamination.

No

Observation
Observed cleaning logs from January 2021 with no issues noted. Logs are paper with pen and ink signatures.

7) *The pharmacy has documentation that counters, easily cleanable work surfaces, and floors are cleaned and disinfected daily.

Yes

Observation
Observed paper logs with pen and ink signatures dated January 2021 with no issues noted.

9) *Monthly cleaning includes cleaning and disinfecting of walls, ceilings and shelving in the buffer/clean room and in the ante-room.

Yes

Observation
Observed paper logs with pen and ink signatures dated January 2021 with no issues noted.

6.9.1) General Requirements of Compounding Personnel- observed

1) Entry to compounding areas is limited to authorized staff only.

Yes

2) Compounding personnel were observed free of rashes, burns, sunburn, weeping sores, conjunctivitis or active respiratory infections.

Yes

3) Compounding personnel were observed free of personal outer garments, cosmetics, visible jewelry and artificial nails/nail polish.

Yes

4) *No food, drink or inappropriate materials were observed in ante-areas, buffer areas, or segregated compounding areas.

Yes

6.9.2) *Sterile Environment Ante-Room Observation

1) *There is a clear line of demarcation between the dirty and clean side of the ante-room.

Yes

3) *Compounding personnel were observed donning all required personal protective equipment, in the correct order and replacing personal protective equipment when appropriate.

Personal items such as sweaters, coats, hats etc. were removed prior to entering the ante-area.

Head and facial hair covers and masks were donned prior to crossing the line of demarcation

Shoe covers were donned while crossing the line of demarcation, and the dedicated shoe cover never touched the dirty side of the line of demarcation.

Face masks and eye shields were donned after crossing the line of demarcation

Hand cleansing procedures were performed

Hands and forearms were dried using a lint-free disposable towel or an electronic hand dryer

A nonshedding gown with sleeves that fit snugly around the wrist and enclosed at the neck was donned.

4) *Personnel do not enter the ante-room and cross the line of demarcation without donning shoe covers or dedicated shoes.

Yes

6.9.3) *Sterile Environment Cleanroom Observation

1) *Personnel enter the clean room properly garbed from the ante room and immediately complete aseptic hand cleansing using alcohol-based surgical hand scrubs with persistent activity.

Yes

2) *Sterile gloves are donned after personnel complete aseptic hand sanitizing.

Yes

3) *Disinfection of contaminated gloved hands is accomplished by wiping/rubbing sterile 70% isopropyl alcohol to all contact surfaces and letting the gloved hands dry thoroughly.

Yes

8) Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing.

Yes

12) Additional findings regarding the cleanroom include:

Observation
Sterile compounding was not observed while on-site due to the time of the inspection and workflow. Interviewed lead technician (SE) regarding gowning and garbing procedures with no issues noted.

6.10.7) Sterility Testing

8) Additional findings regarding sterility testing include:

Observation
Observed Sterility Test results for Avastin (lot 01202021@2) dated 01/21/2021 and (lot 01182021@3) dated 1/19/2021 with no issues noted by ARL Labs.

6.10.8) Endotoxin Testing

4) Endotoxin testing is performed by:

Outside laboratory

Observation
ARL Bio Pharma performs the testing.

6) Additional findings regarding endotoxin testing include:

Observation
Observed endotoxin results for Avastin (lot 01182021@3) dated 1/21/2021 and (lot 01202021@2) dated 1/25/2021 with no issues noted.

7.1) Hazardous sterile compounding policies and procedures.

1) The licensee has specific Standard Policies and procedures regarding the transport and handling of hazardous drugs?

Yes

7.2) Training for Hazardous Sterile Drug Compounding

2) Is the compounding staff appropriately trained in the storage, handling and disposal of hazardous drugs?

Yes

Observation
Excellent documentation of training and competencies.

4) Have compounding personnel verified in writing they understand the risk associated with compounding hazardous drugs, or compounding with hazardous chemicals?

Yes

Observation
Observed documentation for DC and for SE including the Workers Right-To-Know Sign-Off Sheet and Acknowledgment of Hazardous Drug Risk.

6) Additional findings regarding personnel training for hazardous drug compounding include:

Observation
Observed records of the following training/competencies in the BSC for hazardous compounding for DC (RPh) dated May 7, 2020:

- Gowning and Garbing
- Cleaning & Disinfection
- Media Fill Test (Both low and medium risk level testing)
- Gloved Fingertip Sampling
- Aseptic Technique Assessment
- Didactic Training (1/2/20 and 1/12/21)

Observed records of the following training/competencies in the BSC for hazardous compounding for SE (tech) dated

- Gowning and Garbing
- Cleaning & Disinfection
- Media Fill Test (Both low and medium risk level testing)
- Gloved Fingertip Sampling
- Aseptic Technique Assessment
- Didactic Training (1/12/20 and 1/25/2021)

7.3) Hazardous Drug Compounding

1) *Does the licensee prepare hazardous drugs as CSPs?

Yes

Observation
Mitomycin, methotrexate, and autologous eye drops (blood product) are the primary products compounded in the hazardous compounding suite.

2) *Does the licensee have a negative pressure room?

Yes

5) *The hazardous drug PEC was observed located in a physically separate space from other preparation areas.

Yes

6) Staff wears chemotherapy gloves while handling hazardous drugs during the following:

Receiving
Distributing
Stocking
Inventorying
Preparation for administration
Disposal

7) Does the licensee staff don the appropriate personal protective equipment when compounding in a BSC or CACI?

Yes

8) Does the licensee have an appropriate area for storage of hazardous drugs?

Yes

Observation
The facility has a neutral pressure hazardous receiving area and stores hazardous drugs within the negative pressure room.

9) The storage area for hazardous drugs has at least 12 air changes per hour (ACPH)

Yes

Observation
HD are stored inside the negative pressure buffer room.

11) Safety Data Sheets are available to personnel for drugs and chemicals used in the pharmacy.

Yes

Observation
These are paper and are stored in the hazardous drug prep room.

12) *Hazardous drug CSPs are compounded in an ISO Class 5 environment with an appropriate primary engineering control?

Yes

Observation
A BSC is used for HD compounding.

13) *The hazardous drug primary engineering control is located in an ISO Class 7 environment.

Yes

14) The ante-room adjacent to the ISO 7 negative pressure sterile compounding room is certified ISO 7.

Yes

15) *Negative pressure rooms and primary engineering controls are equip with pressure indicators.

Yes

16) *The pressure indicator was observed to have not less than 0.01-inch water column negative pressure to adjecent positive pressure ISO Class 7 or better ante-areas.

Yes

Observation
Current differential pressure is -0.03 inch water column.

17) * The pressure indicator reading is documented daily by the licensee.

Yes

18) Observed Closed System Transfer Devices utilized in the compounding of hazardous CSPs.

Yes

Observation
The facility uses the OnGuard System by Baxter as their CSTD.

19) Does facility staff have access to hazardous drug spill kits?

When asked, staff members could quickly locate spill kits stored. Observation
Spill kits are stored in areas where hazardous drugs are administered.

8) *Record Keeping For Compounding

1) The pharmacy maintains a record of all drugs purchased.

Yes

2) Records are readily retrievable within a seventy-two hour period.

Yes

3) The pharmacy maintains a record of all compounds dispensed.

Yes

5) *The pharmacy maintains records of all drugs compounded.

Yes

6) Records provide accountability to ensure patients do not receive more drugs than intended by the prescriber.

Yes

18) Records Request

1) Requested Records

Observation
For Information Purposes:
The pharmacy is to produce, within three (3) business days (in a mutually acceptable format), any records of accountability or dispensing, to the Board of Pharmacy upon request.

(C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released, upon request, to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

(1) Prescription identification number; or, if an order for medication, the name of the patient;
(2) The drugs prescribed or ordered;
(3) Quantity of drugs prescribed, dispensed, administered or personally furnished;
(4) Name of the prescriber;
(5) Date, name of agency, and signature of person removing the records.

20) Inspection Affirmation

1) Inspection Affirmation

Observation
As the on-duty pharmacist, at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent, and understand its content. If this inspection report requires a written response of corrective action, the response shall be provided to the Ohio State Board of Pharmacy within 30 days of this inspection. I understand that if I am not the Responsible Person documented on this site's Ohio TDDD license, I will ensure the Responsible Person is notified of this inspection report and any corrective actions required. Responses can be emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or they may be mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Deepali Yogesh Chachare, RPH

(signature)

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 Northmark Pharmacy LLC

Physical Address 1945 CEI Drive

City Cincinnati State OH Zip 45242

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 513-569-3334 Website www.northmarkpharmacy.com

Licensing Company Email _____

Section 2: Personal Information

First Deepali Middle Yogesh Last Chachare

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

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

Mailing Address [redacted] Man O War Lane

City Mason State OH Zip 45040

Telephone _____ Email dchachare@cvphealth.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 DC

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)	
Insitute of Pharmaceutical Education and Research		06/00-12/01	
Address	**City**	**State**	**Zip**
Boregaon-Meghe,WardhaMaharashtra, India.	Wardha	MH	4120701
Diploma/Degree obtained, if any			
Masters in Quality Assuarance			
School Name		**From - To (MM/YY – MM/YY)**	
S.G.R.S College of Pharmacy			
Address	**City**	**State**	**Zip**
Saswad, Pune Maharashtra, India	Pune	MH	412301
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			

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
05/13-02/22	[redacted]Man O War Lane	Mason	OH	45040
09/10-05/13	8616 Arrowwood Dr	Mason	OH	45040
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 DC

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)
Northmark Pharmacy LLC			01/13-01/22
Business Address	**City**	**State**	**Zip**
1945 CEI Dr	Cincinnati	OH	45242
Phone	**Title**		**Number of Employed Hours**
513-569-3334	Pharmacit-in- charge		40
Description of Duties			
Sterile Compounding as per USP 797 and USP 800 guidelines. Maintaing compliance requiremnets for all licensed states.Filling and checking prescriptions. Performing DUR.			

Business Name			From - To (MM/YY – MM/YY)
Healthwarehouse.com			06/10-01/13
Business Address	**City**	**State**	**Zip**
7107 Industrial Rd,	Florence	KY	41042
Phone	**Title**		**Number of Employed Hours**
(800) 748-7001	Pharmacist		40
Description of Duties			
Patient counseling and discussing the requirements of treatment. Filling and checking prescriptions. Performing DUR.			

Business Name			From - To (MM/YY – MM/YY)
Healthwarehouse.com			
Business Address	**City**	**State**	**Zip**
7107 Industrial Rd	Florence	KY	41042
Phone	**Title**		**Number of Employed Hours**
800) 748-7001	Pharmacist-intern		40
Description of Duties			
Performing duties and training under the supervision of the 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			

Continue on next page if additional space is needed.

Applicant's initials DC

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

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

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

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

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

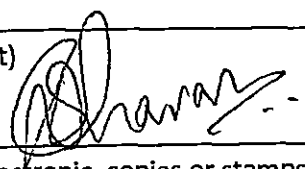
Applicant's initials DC

I, Deepali Yogesh Chachare, **certify that as the designated representative for** Northmark Pharmacy 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

Deepali Chachare
Print Name (First, Last)



Original Signature (electronic, copies or stamps not accepted)

02/01/2022
Date

Applicant's initials DC

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.

Deepali Chachare

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/01/2022

Date

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

State of Ohio, ss. County of Hamilton

I, Deepali Chachare, 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

2/1/2022

Date

Subscribed and Sworn to before me this 1st day of February 2022

Notary Public Signature

LORETTA HACKEL, NOTARY PUBLIC
COMM. EXP. 10/04/2026
STATE OF OHIO
(Seal)

Applicant's initials DC

13B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Sofie Co

Physical Address: 5900-B Obata Way

Mailing Address: Same as physical address

City: Gilroy State: CA Zip Code: 95020

Telephone: (408) 842-0520 Fax: (408) 842-0220

Toll Free Number: (866) 607-6650 (Required per NAC 639.708)

E-mail: michael.levy@sofie.com Website: www.sofie.com

Managing Pharmacist Rima Othman License Number: 12057

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☒	☐ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☒	☐ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☐	☒ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☐	☒ Other: n/a	☒	☐ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: n/a

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Hai Vu, Facility Manager
Print Name of Authorized Person

16 June 2021
Date

Board Use Only Date Processed: 6/29/2021 Amount: $500 Mail ✓ R210066171271

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: VA

Parent Company if any: GRD US Pet Operations, Inc.

Mailing Address: 21000 Atlantic Blvd, Suite 730

City: Dulles State: VA Zip: 20166

Telephone: (703) 787-7900 Fax: (571) 434-0330

Contact Person: Michael Levy

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) GRD US Pet Operations, Inc. 21000 Atlantic Blvd, Suite 730, Dulles, VA 20166
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 2,000,000 series A, 4,000,000 series B, 1,850,000 series C

3) What was the price paid per share? A - 0.10/share B - 0.10/share C - $10.00/share

4) What date did the corporation actually receive the cash assets? September 17, 2017

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: n/a %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 3 am 3 pm Saturday 3 am 12 pm

Sunday closed am _____ pm 24 Hours n/a

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: n/a

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Hai Vu

Responsible Person of Sofie Co

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Hai Vu

Print Name of Authorized Person

16 June 2021

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
Santa Clara) ss.
COUNTY)

I, Hai Vu, 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 Facility Manager / Pharmacist-in-Charge (PIC) for Sofie Co (the 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 sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product 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 AFFIANT SAYETH NOT.

I, Hai Vu, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Hai Vu
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
21st day of June, 2021.

Damacia P. Garcia
NOTARY PUBLIC

DAMACIA P. GARCIA
Notary Public - California
Santa Clara County
Commission # 2354570
My Comm. Expires Apr 16, 2025

Nevada State Board Of Pharmacy

THIS STUB IS YOUR RECEIPT
Rima Othman

Date: 10/07/2021
Amount:
License #: 12057

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Expires:10/31/2023

Rima Othman

License #
12057
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 #: 12057

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Rima Othman

NONTRANSFERABLE
POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That SOFIE Co. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on December 8, 1995;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

December 14, 2021

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2021121416675577

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Retail Pharmacy Permit

Renewal Certificate

LICENSE NO. PHY 55786
RECEIPT NO. 11762059

VALID UNTIL SEPTEMBER 01, 202

SOFIE CO
5900-B OBATA WAY
GILROY CA 95020

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.

08/25/21
08/25/21 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM #PHPHY (09/30/19)

BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Sterile Compounding License

Renewal Certificate

LICENSE NO. LSC 101112
RECEIPT NO. 00174185

VALID UNTIL SEPTEMBER 01, 202

SOFIE CO
5900 B OBATA WAY
GILROY CA 95020-7065

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.

08/03/21
08/03/21 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

WPHLSC (09/30)

SOFIE
From start to clinic

FACILITY NAME: SOFIE CO DBA SOFIE

ADDRESS: 5900-B OBATA WAY, GILROY, CA 95020

PHONE: (408) 842-0520

FAX: (408) 842-0220

TOLL FREE: (866) 607-6650

Sofie Co. dba Sofie does not handle any controlled substances in the practice of pharmacy so therefore the pharmacy does not have a DEA permit.

SOFIE
From start to clinic

SOFIE OFFICER LISTING

NAME	BUSINESS ADDRESS	TITLE
PATRICK PHELPS	21000 ATLANTIC BLVD SUITE 730 DULLES, VA 20166	PRESIDENT, CEO, & DIRECTOR
PHILIPP CZERNIN		CRO & DIRECTOR

SOFIE Co.

Common Stock Ledger

Stock Cert. No.	Name of Shareholder	Number of Shares	Date Acquired	Transferred From (or Original Issue)	Transferred To	Date of Transfer	Stock Balance
100	Unknown, but cancelled	Unknown	Unknown	Unknown	Unknown	Unknown, but cancelled	0
101	Unknown, but cancelled	Unknown	Unknown	Unknown	Unknown	Unknown, but cancelled	0
102	Unknown, but cancelled	Unknown	Unknown	Unknown	Unknown	Unknown, but cancelled	0
103	Unknown, but cancelled	Unknown	Unknown	Unknown	Unknown	Unknown, but cancelled	0
104*	GRD US Pet Operations, Inc.	2 million	4/2/2012	Original	N/A	N/A	2 million
105**	GRD US Pet Operations, Inc.	4 million	4/2/2012	Original	N/A	N/A	4 million
106***	GRD US Pet Operations, Inc.	1.85 million	4/2/2012	Original	N/A	N/A	1.85 million

* Series A common stock, par value $0.10 per share

** Series B common stock, par value $0.10 per share

*** Series C common stock, par value $10.00 per share

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 Sofie Co.

Physical Address 5900 B Obata Way

City Gilroy State CA Zip 95020

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 408-842-0520 Website www.Sofie.com

Licensing Company Email Kunj.Patel@Sofie.com

Personal Information

First Mark Middle Anthony Last Juarez

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

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

Mailing Address [redacted] River Haven Dr.

City Mariposa State CA Zip 95338

Telephone [redacted] Email mark.juarez@Sofie.com

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

Section 2: Military Service (NRS 622.420)	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 3: Statutory Mandated Requirement (NRS 425.540, 425.5401, 425.5402)	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 MJ

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

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.

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)	
Armona Union Academy		08/1979 – 06/1983	
Address	City	State	Zip
14435 Locust street	Armona	CA	93202
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Fresno state University		09/1984 – 06/1988	
Address	City	State	Zip
1620 E. Bulldog Ln	Fresno	CA	93710
Diploma/Degree obtained, if any			
Pre Pharmacy / Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
University of The Pacific		08/1988 – 07/1992	
Address	City	State	Zip
3601 Pacific Ave	Stockton	CA	95211
Diploma/Degree obtained, if any			
Doctor 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			

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
11/20 – Present	[redacted] River Haven Dr	Mariposa	CA	95338
08/16 – 11/20	[redacted] Mansfield Rd	Hollister	CA	95023
2010 – 2016	[redacted] Moonglow Rd	Prunedale	CA	93907

Applicant's initials MJ

Section 7: A designated representative must provide proof that he or she has been employed for at least 8,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.3935) 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)
Sofie Co.		01/2005 – 12/21
Business Address	**City**	**State / Zip**
5900 B Obata Way	Gilroy	CA 95020
Phone	**Title**	**Number of Employed Hours**
408-842-0520	Regional Director operations	33,280 hrs

Description of Duties: Dispensing and distribution of prescription Radiopharmaceuticals, labeling & packaging, compounding of radio pharmaceuticals.

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

Description of Duties

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

Description of Duties

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

Description 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:

NA

MV 15 Dec 21

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials MV

I, Mark Juarez, **certify that as the designated representative for** Safe Co., **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

Mark Juarez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/15/21
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 Juarez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/15/21
Date

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

State of California, ss. County of Santa Clara

I, Mark Juarez, 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

12/15/21
Date

Subscribed and Sworn to before me this 15 day of Dec 2021.

Notary Public Signature

MITAN M. GANDHI
Notary Public - California
Santa Clara County
Commission # 2377635
My Comm. Expires Oct 19, 2025

(Seal)

Applicant's initials MG

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: 7/7/2020 Inspector: Mayta Vu

Firm: SOFIE CO Phone: (408) 842-0520

Address: 5900 B OBATA WAY City: GILROY Zip: 950207065

Ownership: CORPORATION

Permit #: LSC101112 PHY55786 Permit Exp: 9/1/2020 DEA#: DEA Exp:

Date of Self Assessment Form: 5/23/2019 Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 0000 to 1800 Hours Saturday 0000 to 0900 Hours Sunday: On-Call

PIC HAI M VU RPH55234 Administrator

RPH Consultant

Staff	RPH Name:	License #:	Staff Name:	License #:
	MARK A JUAREZ	RPH45793	ARTHUR S HERNANDEZ JR	TCH128729
	JAMES W KLAG	RPH81844	CYNDI COVARRUBIAS	TCH139386
			EFREN S PASAO	TCH85269
			EXEQUIEL B LOPEZ JR	TCH158642
			JOEL M SIMON	TCH108313
			LONG TRAC - QUALITY	MANAGER

Inspector Remarks:

Sterile Compounding Renewal Inspection
Assisted by PIC Vu, RPh Juarez, and QA Specialist Long Trac
Closed door nuclear pharmacy servicing a 600-mile radius geographical area (from Temecula to Chico).
Pharmacy and Compounding Self-Assessments - available
Sterile compounding: Sterile to sterile, radiopharmaceuticals only – examples include: fluorodeoxyglucose (FDG)-F18 and florbetaben, sodium fluoride-F18, Ga-68 Dotatate and PSMA
Average number of CSPs compounded daily: approximately 200 preparations

STERILE COMPOUNDING AREA
The compounding suite consists of an ISO 8 ante room and an ISO 7 non-hazardous buffer room. There is a handwashing room prior to entry into the ante room. The ante room has a line of demarcation, a small bench and a shelving unit with garbing supplies. The buffer room has one ISO S Pinestar 797 MT Dosing hood, one ISO 5 Germfree BBF-3 Class II Type A1 hood, and TEMA hot cells. The buffer room also has several workstations and three pass-throughs.

Last certification completed on March 10, 2020 by ENV Services
Dynamic testing, HEPA filter leak testing, Non-viable air sampling
Air changes – ante room at 32 acph and buffer room at 41 acph
Pressure differentials – ante room to gowning room at 0.080" w.c., buffer room to ante room at 0.056" w.c.
Smoke studies – available, viewed during inspection

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Cleaning agents
Germicidal detergent: Steri-Perox, Decon-Quat
Disinfectant: Sterile 70% Isopropyl Alcohol
Sporicidal: Hypo-chlor 0.52%
Cleaning of walls and ceilings: done monthly

POLICIES AND PROCEDURES – spot checked prior to inspection
Annual review of Policies and Procedures by PIC. Last review performed
Aseptic Technique, Hand hygiene and garbing, Conduct in an ISO environment - available
Facility cleaning and disinfecting - available
QA program/policy and procedure: end-product testing, recalls
Environmental sampling: action levels for CFUs and actions to be taken when CFUs have been exceeded - available
Compounding, filling, and labeling; BUDs; storage of compounded preparations - available
Reference materials: readily available

LABELING REQUIREMENTS
Compounded by pharmacy – prints on label
Generic names of principal ingredients, BUD
Route of administration

RECORDKEEPING – maintain for 3 years
Master formulas/ Patient specific compounding records
- Viewed for: Ga-68 Dotatate 5.00mCi and Ga-68 PSMA-R2 7.00mCi

Refrigerator/ freezer/ incubator / room temperature logs – electronically monitored, viewed for 6/23/20 to 6/28/20
Pressure logs (rooms, TEMA hot cells, Laminar flow hood) – viewed for June 2020
Cleaning logs for room, PECs, pass-throughs – viewed for June 2020
Equipment maintenance documents for: Thermocoupler, Triple-Display Timer, and TLC Scanner

PROTECTIVE CLOTHING
Sterile gloves and **persistent** hand scrub – Avagard available
Low shedding coverall/gown, head, face and shoe covers, masks

TRAINING – viewed for both PIC Vu and TCH Covarrubias; maintain for 3 years
Media fill testing, viable sampling report - written documentation and process review by qualified pharmacy personnel
Didactic, QA, cleaning, hand hygiene and garbing, GMP training, Radiation Safety Training, ALARA training, DOT transporting and shipping of radiopharmaceuticals

QUALITY ASSURANCE / PROCESS EVALUATION
Quality control testing in accordance with radiopharmaceutical guidelines.
ITLC (Instant thin layer chromatography) performed on all preparations
- Viewed for: Ga-68 Dotatate 5.00mCi and Ga-68 PSMA-R2 7.00mCi

Environmental sampling: Both viable air and surface sampling done in house on a daily basis.

PHARMACY WAIVERS
Waiver implemented at this facility includes:
- USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8) – policy available

Discussion:
1.

. ease submit all requested items within 14 days, not later than July 21, 2020 to Inspector Mayta Vu by email: mayta.vu@dca.ca.gov

Mayta Vu, Inspector

California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Phone: (559) 753-1446
Fax: (559) 291-1013
Email: mayta.vu@dca.ca.gov

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Mark Juarez

Inspector (sign) _____

Inspector (print) Mayta Vu

Owner(sign) Hai Vu

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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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

ORDER OF CORRECTION

Date: 7/7/2020 Permit #: LSC101112

Time of Day: 8:34 AM

Name as shown on permit: **SOFIE CO**

Address: 5900 B OBATA WAY City: GILROY

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. **BPC 4126.84126.8**	United States Pharmacopeia-National Formulary. The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.
	As it relates to CCR 1751.4(j), in that at the time of inspection, viable air and surface sampling in the ISO 8 ante room was not available for review.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) Mayta vu Print Name Hai Vu

Date July 7, 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.

SOFIE
From start to clinic

10 Jul 2020

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Attention: Mayta Vu, Pharm.D.

Subject: SOFIE Co. dba SOFIE
5900 B Obata Way, Gilroy CA 95020
Pharmacy Permit No. LSC101112/PHY55786
FEI number 3006246010
Inspection Date: 07 Jul 2020

Dear Dr. Vu,

SOFIE is committed to compliance to ensure product quality and patient safety. SOFIE acknowledges the non-compliant finding and is fully committed to correcting issues and making continuous improvements. This letter will serve as the plan for corrective action resultant to the Orders of Correction received on the 07th of July 2020 at the SOFIE facility in Gilroy, CA.

Item BPC 4126.84126.8: *United States Pharmacopeia-National Formulary. The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.* As it relates to CCR 1751.4(j), in that at the time of inspection, viable air and surface sampling in the ISO 8 ante room was not available for review.

Our SOP for Environmental Monitoring of Pharmacy Classified Areas has just been updated to include ISO 8 ante room. Namely, microbial air sampling and non-viable particle counts are to be performed within the clean side of the demarcation at least every 6 months while surface sampling will occur monthly. The latest version of this SOP (PH.0005, rev. D) is included here for your review.

During the visit, you mentioned that our prescription labels do not specify routes of administration. This problem has been corrected. A sample of today's prescription label is included.

SOFIE
From start to clinic

SOFIE strives to provide superior products that are both safe and effective and appreciates the feedback which helps us continuously improve. We believe that the changes committed to following this routine inspection help to achieve that goal.

Thank you for your consideration of the above. If any additional information is needed, please do not hesitate to contact me.

Sincerely,

Hai Vu, Pharm.D, Ph.D.
Facility Manager and Pharmacist in Charge, Gilroy, CA
SOFIE
5900-B Obata Way
Gilroy, CA 95020
Tel: +1 408-842-0520
hai.vu@sofie.com
www.sofie.com

Please find enclosed the following supporting documents:

1) PH.0005, rev. D: Environmental Monitoring of Pharmacy Classified Areas.
2) A copy of today's prescription label.

SOFIE From start to clinic	Environmental Monitoring of Pharmacy Classified Areas PH.0005	Page 1 of 8 Revision D	TRUE COPY

Purpose / Scope: This document describes the procedure for performing environmental monitoring (EM) in pharmacy classified areas certified as ISO 5, ISO 7, and ISO 8. For ISO 5 areas, this procedure applies to environmental monitoring (EM) of pharmacy ISO 5 enclosures that are dedicated for pharmacy use or used to compound pharmacy products regulated by USP compounding regulations. If manufacturing and dispensing activities are performed in the same ISO 5 enclosure on the same day, environmental monitoring during the dispensing of compounded radiopharmaceuticals will be performed per QC.0064, *Environmental Monitoring in ISO 5 Areas During Manufacturing* or equivalent SOP.

Compounding/dispensing can be performed by the operator by hand or by using the manipulator arms within the isolator-type dispensing hot cells. If these activities occur by hand, contact plate sampling of the operator's gloves is required. If they occur in an isolator cell, the glove contact plate sample should be taken using the manipulator finger to give a more accurate representation of the surface contacting the dose syringes.

Responsible: The Pharmacist in Charge (PIC) is responsible for the overall organization and completion of the environmental monitoring program described in this procedure. The pharmacy staff (pharmacists and/or pharmacy technicians) compounding or dispensing in ISO Class 5 conditions have the responsibility to execute the sampling associated with this environmental monitoring. Incubation, reading, and recording of results are the responsibility of QC technicians or designee.

Note: If this SOP is not compliant, or required, for the specific state in which the drug product is being compounded, Corporate Pharmacist – in – Charge must be contacted and must approve compliance with those State regulations pursuant to the practice of pharmacy.

Schedule: Environmental monitoring (EM) of ISO 5 enclosures during pharmacy compounding of final drug products using surface contact plates and glove/manipulator check plates is performed daily when in use and after the first compounded batch. Environmental monitoring of dedicated Pharmacy ISO 5 Enclosures during dispensing using surface contact plates and glove/manipulator check plates is performed after completion of all dispensing activities for that day and prior to cleaning. Microbial air sampling and non-viable particle counts are performed in the applicable ISO 5 Enclosures and ISO 8 areas (within the clean side of demarcation) at least every 6 months. Surface sampling of all classified areas (DHCs, ISO 7, and ISO 8 areas) will occur monthly.

Increased environmental monitoring is required:

- In conjunction with the certification of new facilities and equipment
- After any modification of facilities or equipment
- In response to identified trends (e.g., EM excursions or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)
- In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved)

Table 1: Sampling Locations and Frequency

Sampling Locations	Sample Code	Daily	Monthly	Biannually
Glove samples	PH-GR / PH-GL	X		
Manipulator arm	PH-ML / PH-MR	X		
ISO 5 work surface	PH-CP1	X		
ISO 5 air sampling	PH-AS1			X
ISO 5 particle counts	PH-PC1			X
Pass Box In particle counts	PBI-PC1 / PBO-PC2			X
ISO 5 pre-chamber surface	PH-PC		X	
Pass Box In surface	PH-PBI		X	
Pass Box Out surface	PH-PBO		X	
ISO 8 Air Sampling	AR-AS1 (AS2,AS3)			X
ISO 8 Surface Sampling	AR-CP1		X	
Cleanroom Pass Throughs	PH-PT1 (PT2, PT3)		X	

Equipment / Materials:

Equipment		
ISO Class 5 Enclosure (LAFH, BSC, DHC, etc.)		
Active Air Sampler		
Non-Viable Sampler		
Incubator, 20-25 C, with calibrated temperature monitoring/recording device		
Incubator, 30-35 C, with calibrated temperature monitoring/recording device		
Materials	**QTY**	**SP or SBM#**
90 mm TSA Plates	0-2	0077
Contact Plates	1-3	0078
Decon-Ahol	QS	0125
Sterile Alcohol Spray Bottle (Formulated with Purified Water)	QS	0070
Steri-Perox	QS	0124
Sterile Wipes	QS	0126

Definitions:

Viable Particulates	A viable particle is a particle that contains one or more living microorganisms. These can affect the sterility of the pharmaceutical product and generally range from ~0.2µm to ~30µm in size.
Non-Viable Airborne Particulates	A non-viable particle is a particle that does not contain a living microorganism but acts as transportation for viable particles.
IPA	Isopropyl Alcohol (Decon-Ahol)
Dynamic Operating Conditions	Conditions in the classified area in which operating personnel are present and performing actual or simulated activities.

Procedure:

A. Viable Microbiological Monitoring in the ISO 5 Area

1. Viable microbial monitoring is performed on a routine basis and required for each day compounding occurs.
   a. If more than one batch is compounded on a given calendar day, EM should be taken after the first compounded batch of the day, before cleaning, and the plates from the batch should be taped, bagged, or otherwise kept together.
2. The microbiological monitoring of the ISO Class 5 areas will be performed using 3 different techniques to provide analysis of the microbiological status of the sampled areas.
   a. Glove Samples
      i. LAFH
         1. Glove monitoring should be performed by following the steps in **Figure 1** below. First: imprint index, middle, ring and little finger. Second: imprint thumb. Use the "rolling" technique described in QA.0008, *Aseptic Technique*.

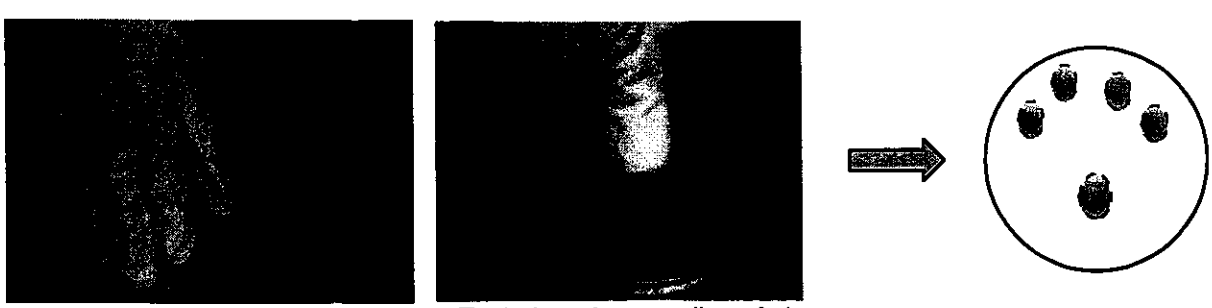


Figure 1: Technique for sampling of gloves

2. Repeat above steps to monitor the 2nd glove.

3. Label each plate with the operator's initials, date, and PH-GL (left glove) or PH-GR (right glove) to identify the location of sampling.
4. If contact plate sampling (section A.1.b., below) is performed immediately following glove sampling, the same gloves may be worn, proceed to step A.1.b.
5. Incubate as described in Incubation (section F below).
6. Record Results in Attachment 1: *Environmental Monitoring of Dedicated Pharmacy ISO 5 Enclosures and ISO 5 Enclosures for Compounded Drug Products*

ii. Isolator-type dispensing hot cells

Note: This section is only required for ISO 5 enclosures dedicated pharmacy dispensing only

1. At the end of dispensing each day, perform EM sampling of the manipulator finger pads as follows. Due to radiation safety concerns, this EM sampling may take place multiple hours after operations have ceased but must occur prior to cleaning the DHC for the next day's dispensing.
2. Carefully remove the lid from the contact plate without touching the media.
3. Imagine a line dividing the contact plate evenly in half; press one half of the contact plate media to the pad of the top manipulator finger pad, similarly to a glove touch sample, see **Figure 2**.
4. Press the other half of the contact plate media to the bottom manipulator finger pad.
5. Repeat steps 2 through 4 on the second manipulator arm.
6. Following sampling, carefully and thoroughly disinfect the manipulator finger pads with Steri-Perox or other higher-level disinfectant (70% sterile IPA may be used after to remove residue). Visually inspect the finger pads and replace prior to next use if deterioration is detected.
7. Label each plate with the operator's initials, date, and PH-ML (left manipulator finger) or PH-MR (right manipulator finger) to identify the location of sampling.
8. The contact plates will be secured (e.g. tape together or parafilm) with the accompanying EM plates and incubated according to Section F.

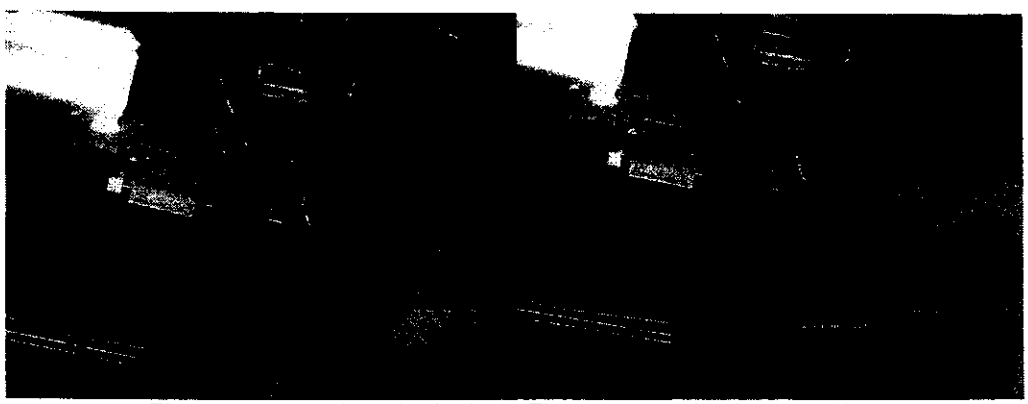


Figure 2: Sampling Manipulator Finger pads with Contact Plate

b. Contact Plates:
   i. Sanitize gloves prior to taking contact plate samples.
   ii. Carefully remove the lid of the contact plate and gently press the agar to the center of the work surface to be sampled using a rolling method.
   iii. Label the plate with the operator's initials, date, and PH-CP1 to identify the location of sampling.
   iv. Clean and wipe sampled surface with a sterile wipe wetted with IPA immediately after sampling.
   v. Incubate as described in Incubation (section F below).
   vi. Record Results in Attachment 1: *Environmental Monitoring of Dedicated Pharmacy ISO 5 Enclosures and ISO 5 Enclosures for Compounded Drug Products*.
c. Active Microbiological Air Sampling
   i. Active microbiological air sampling is required to be performed no less than every 6 months while compounding.
   ii. Sanitize gloves with IPA prior to sampling.
   iii. Sanitize the head of the air sampler with IPA. Allow to dry. Place a 90mm settling plate in the air sampler according to the instructions for the sampler.
   iv. Wipe the air sampler with IPA prior to introducing it to the ISO 5 enclosure.

v. Sample 1 m^3 (1000L). Ensure that the air sampling unit is set to the proper volume and flow rate necessary to sample 1 m^3. Refer to QC.0017, *Operation and Maintenance of the Lighthouse Microbiological Air Sampler*, for instructions on setting sampling parameters, if needed.
vi. Label the plate with the operator's initials, date, and PH-AS1 to identify the location of sampling.
vii. Incubate as described in Incubation (section F below).
viii. Record Results in Attachment 2: *Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring of Dedicated Pharmacy ISO Class 5 Enclosures.*
ix. Document Sampling in Attachment 5: *Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing Log.*

B. Non-Viable Monitoring of ISO 5 Areas

1. Non-Viable particle counts are required to be performed no less than every 6 months while compounding in the ISO 5 area.
2. Set the sampling volume to 1ft^3. Follow the SOP appropriate to your model of particle counter (e. g. OP.0063, Procedure for Operation of the Climet CI 154 Particle Counter) to sample 1 ft^3.
3. Connect the particle counter to the sampling probe or dedicated sampling tubing, if present.
4. Sanitize the sampling probe with IPA and position it in the ISO 5 enclosure.
5. For pharmacy dedicated dispensing hot cells (DHC), the pass box in and pass box out, if present, will be sampled no less than every 6 months.
6. Record Results in Attachment 2: *Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing in an ISO Class 5 Enclosure.*
7. Document Sampling in Attachment 5: *Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding Log.*

C. Non-Viable and Viable Microbiological Monitoring of Cleanroom

1. Follow QC.0036, *Environmental Monitoring is ISO 7 Areas*
2. No additional monitoring is required as the sampling frequency required per QC.0036 exceeds regulatory requirements.

D. Viable Microbiological Monitoring in ISO 8 Areas

1. Environmental monitoring includes active air sampling and surface sampling using contact plates (see Section E).
2. Non-Viable particle sampling is completed during the certification process (biannually) of the cleanroom suite and additional sampling is not necessary.
3. Environmental monitoring will be performed in the clean side of the anteroom every 6 months.
4. Sampling Locations and Schedule
   a. Air sample and contact plate sampling locations shall be identified by each site.
      Note: contact sampling will occur monthly (see Section E).
   b. Number of air sampling locations will be determined by each site. (see 7. Active Air Sampling).
   c. Contact sample location will be determined by the site taking into consideration the most frequently touched surfaces.
5. A diagram showing the exact sampling locations and the justification for the locations shall be available in the ISO Class 8 area using Attachment 7, *ISO 8 Sample Locations.*
   a. An example of a precise sampling location could be, "contact plate sample of the lid used for the 7.5 size sterile gloves" or "contact plate sample the clean side of the gowning bench"
   b. The diagram and written justification of the sampling locations must be approved by Site QA/QAS and Director, Sterility Assurance or Microbiologist.
   c. The sampling diagram must be revised with each revision of this SOP.
6. All personnel performing sampling of the ISO 8 room along with all site QA personnel must train on the approved sampling diagram. After understanding the sampling diagram said personnel must sign the approved diagram to attest that they have reviewed and understand the precise sampling locations.
7. Active Air Sampling
   a. The number of samples required will be determined by calculating the area of the clean zone in meters.
      i. Calculate the number of samples to be taken in the clean zone by using the following equation:

$$N \text{ (number of samples)} = \sqrt{A} \text{ (area in meters)}$$

Example: The area of the clean zone of the anteroom in Romeoville (IL1) was measured to be 3.058 meters. The number of viable air samples the site will take every 6 months under dynamic conditions are 2.

b. Sanitize gloves with IPA prior to sampling.
c. Sanitize the head of the air sampler with IPA. Allow to dry. Place a 90mm settling plate in the air sampler according to the instructions for the sampler.
d. Sample 1 m3 (1000L). Ensure that the air sampling unit is set to the proper volume and flow rate necessary to sample 1 m3. Refer to QC.0017 for instructions on setting sampling parameters, if needed.
e. Label the plate with the operator's initials, date, and the location of sampling.
f. Repeat b – e for additional sampling locations.
g. Incubate plates as described in Incubation (section F).
h. Record results in Attachment 3: *Bi-Annual Environmental Monitoring of ISO 8 Areas.*
i. Document sampling in Attachment 6: *Log for Biannual ISO 8 Air Sampling and Monthly Surface Sampling.*

E. Surface Sampling of Classified Areas

1. Surface sampling must occur monthly using contact plates after use and before cleaning. Surface areas included in this sampling include all DHC (TEMA, Comecer, Von Gahlen, and Radiation Shielding) pre-chambers (PH-PC) and pass boxes (PH-PBI / PH-PBO), cleanroom pass throughs (PH-PT1, PH-PT2, PH-PT3), and the location designated by each site in the ISO 8 area (AR-CP1).
2. Sanitize gloves with IPA prior to taking contact plate samples.
3. Carefully remove the lid of the contact plate and gently press the agar to the center of the work surface to be sampled using a rolling method.
4. Label the plate with the operator's initials, date, and sample location code to identify the location of sampling.
5. Wipe the sampled area using a sterile wipe wetted with IPA.
6. Incubate as described in Incubation (section F below).
7. Record Results in Attachment 4: *Monthly Surface Sampling of Classified Areas.*
   Note: For PH-PBI and PH-PBO (Pass box in and pass box out) of dispensing hot cells, the limit will be determined by ISO classification determined for the pass box (ISO 7 or ISO 8) at the facility.
8. Document sampling in Attachment 6: *Log for Biannual ISO 8 Air Sampling and Monthly Surface Sampling.*

F. Incubation

1. After plates have been sampled, secure together each set of samples (with tape or parafilm) and incubate to allow possible microbiological contamination to grow.
2. Plates must be incubated in an inverted position (i.e. sitting on the closed lid of the plate).
3. Incubate plates:
   a. Not Less Than (NLT) 48 hours (max 4 days or 96 hours) at 30°C to 35°C, followed by
   b. NLT 120 hours (max 7 days or 168 hours) at 20°C to 25°C.

   Note: Plates should be moved as soon as possible to obtain results and the upper bounds should only be used for extenuating circumstances (weekends, holidays, etc.). Additionally, plates must be moved immediately following a holiday/long weekend/weather event in which the facility was not operational and thus plates could not be moved. A deviation is not required for plates exceeding the maximum incubation timeframe if the plates could not be moved due to the facility not being operational (e.g., holiday, weather event, etc.) and the plates were moved the first operational day following the extended shut-down.
   c. Time of incubation will be documented in days and hours after the minimum number of hours of incubation have been met.
      i. Ensure the max number of days/hours for incubation has not been exceeded.
      ii. For example, plates were incubated on 14 May 20 at 07:00 and removed from incubation on 17 May 20 at 13:00 then total incubation time would be documented as 3 days 6 hours.
4. The plates must be removed, analyzed by laboratory personnel, and any recovered CFU recorded on the appropriate attachment after the initial incubation (30°C-35°C) and after the final incubation (20°C-25°C) period. Record results on appropriate attachment.
5. If a plate shows growth (either passing or failing results) after initial incubation, move plates to the second incubator to continue the incubation process. If growth is observed, alert site QA/QAS and PIC.
6. If a temperature excursion occurs per OP.0017, *Records of Temperature*, initiate a deviation per QA.0003, *Deviation Procedure*, and assess the impact to the plates.

G. Results

1. The QC technician, or designee will visually inspect all sample plates to establish if any microbiological growth has occurred by holding plates up to a light source
2. Growth media is to be visually verified and reviewed by QA/QAS prior to disposal or shipment of plates.
3. Colony forming units (CFU) are counted and recorded for each plate after initial incubation and final incubation.
   a. A CFU is defined as individual colonies of bacteria, yeast or mold. A colony of bacteria or yeast refers to a mass of individual cells of the same organism, growing together. Colonies may be distinguished by visual traits such as color, texture, margin, elevation, form, and opacity.
   b. Overlapping or split colonies with clearly distinguishable morphologies must be counted as individual CFU.
   c. Spreading colonies of the same morphology should be identified and counted as a single CFU.
   d. Plates in which there are too many CFU to practically count may be considered "too numerous to count" by the individual reading the plate. Record "TNTC" for the amount of CFU on the EM results form.
4. Any viable count (CFU) found in the ISO 5 area shall be identified to genus and species. Plate(s) must be sent to a contract test laboratory per QA.0022, *Shipment of Microbiological Samples*.
5. All plates used to sample ISO 8 areas (anteroom and pass throughs) containing suspected molds must be shipped for identification per QA.0022.
   a. Sequencing to genus and species must be ordered for all morphologies suspected of being molds.
   b. Molds appear on agar as filamentous, fuzzy, cottony, powdery, spreading and/or thread-like. When in doubt, treat growths as if they are mold.
6. An investigation per QA.0058, *Environmental Monitoring Review, Remediation, and Excursion Investigation* must be initiated for samples with results that exceed the acceptance criteria limits as specified in Table 1 and samples with organism identification results as specified in Table 2.
   a. An assessment may need to be performed to determine if additional corrective action is necessary.
7. **Remediation**
   a. If the ISO 5 results exhibit growth, the area must be cleaned with a sporicidal agent, such as Spor-Klenz, Hypo-Chlor or a sporicidal agent, as specified in QA.0058.
      i. This cleaning must be performed within 3 business days upon confirmation of the growth. The cleaning must be documented on the area's cleaning log.
      ii. Required cleanings must be communicated to the designated technician(s). The communication may be done verbally or in writing.
   b. Upon recovery of any growth appearing to be mold, growth exceeding the action limit, growth identified as an objectionable organism, and/or spore former in the ISO 8 area the entire cleanroom suite area must be cleaned following the monthly cleaning regime in QA.0027, *Cleaning and Disinfection of ISO 7 Classified Rooms*, with a sporicidal agent, such as Spor-Klenz or Hypo-Chlor as specified in QC.0054.
      i. This cleaning must be performed as soon as possible, no more than 3 calendar days upon confirmation of the non-conformity, visual identification of the mold, or receipt of identification report. The cleaning must be documented on the area's cleaning log.
      ii. Required cleanings must be communicated to the designated technician(s). The communication may be done verbally or in writing.
   c. In some states the Board of Pharmacy (BOP) requires notification of EM recoveries or non-viable excursions. In this instance, if regulatory notification is required to the state BOP if any growth or excursions are observed, record this observation in the EM form. The facility Pharmacist in Charge (PIC) (or corporate PIC as applicable) should be consulted to determine if this requirement applies to the specific SOFIE location.
      Note: EM data after remediation may be required by state Board of Pharmacy.
      i. If notification is required, document the date the notification was sent.
      ii. N/A the section if this section is not applicable to the site.
   d. Increased EM may be required under the following conditions and will be captured in QA.0058, change controls, or CAPAs. Director, Sterility Assurance will be consulted as necessary.
      i. In conjunction with the certification of new facilities and equipment.
      ii. After any modification of facilities or equipment (significant repairs).
      iii. In response to identified trends (e.g., repeat EM excursions or trends, failed media fails involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination).
      iv. In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved).
   e. Ensure EM is trended quarterly per QC.0083, *Trending and Reporting Environmental Data*.

Table 2: Acceptance Criteria

ISO Class	Non – Viable Particles (ft^3)	Microbial Active Air Sampling (cfu/m^3)	Microbiological Surface Sampling[1] (cfu/plate)
ISO 5	≤ 100	≤ 1	≤ 3
ISO 7	N/A[2]	N/A[2]	≤ 5[4] (pass boxes, if applicable)
ISO 8	N/A[3]	≤ 100	≤ 50

[1]Includes glove and telemanipulator sampling
[2]See QC.0036
[3]Performed during biannual certification of classified area
[4] Floors are ≤ 10 CFU

Table 3: Alert Organisms

Gram-Negative Rods
Coagulase Positive Staphylococcus
Fungal Organisms (Molds and Yeasts)

Attachments:

Attachment 1: Environmental Monitoring of Dedicated Pharmacy ISO 5 Enclosures and ISO 5 Enclosures for Compounded Drug Products
Attachment 2: Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing in an ISO Class 5 Enclosure
Attachment 3: Environmental Monitoring of ISO 8 Areas
Attachment 4: Environmental Monitoring of Cleanroom Pass boxes
Attachment 5: Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing Log
Attachment 6: Log for Biannual ISO 8 Air Sampling and Monthly Surface Sampling
Attachment 7: ISO 8 Sample Locations

Document Control History:

References:

OP.0017 *Records of Temperature*
QA.0003 *Deviation Procedure*
QA.0008 *Aseptic Techniques Procedures*
QA.0022 *Shipment of Microbiological Samples*
QA.0027 *Cleaning and Disinfection of ISO 7 Classified Rooms*
QA.0058 *Environmental Monitoring Review, Remediation, and Excursion Investigation*
QC.0017 *Operation and Maintenance of the Lighthouse Microbiological Air Sampler*
QC.0036 *Environmental Monitoring is ISO 7 Areas*
QC.0064 *Environmental Monitoring in ISO 5 Areas During Manufacturing*
QC.0083 *Trending and Reporting Environmental Data*

Associated Documents:

- USP <797> Pharmaceutical Compounding – Sterile Preparations
- USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging (informational)

Document Originator & Reviewer Approval Signatures:

Approval	Name	Title	Signature	Date
Originator	Kunj Patel	Corporate Pharmacist – in – Charge / HIPAA Compliance Officer / RCM Associate	Kunj Patel (Jul 6, 2020 12:49 CDT)	Jul 6, 2020
Reviewer	Analisa Fuller	Quality Assurance Specialist (QAS)	Analisa Fuller (Jul 6, 2020 15:09 EDT)	Jul 6, 2020

Reviewer	Laura Crandall - Carney	Regional Manager, QA	Laura Crandall-Carney (Jul 6, 2020 15:33 EDT)	Jul 6, 2020
Reviewer	Lynn Chwojdak	Facility Manager/Pharmacist – in – Charge (PIC)	Lynn Chwojdak (Jul 7, 2020 11:04 EDT)	Jul 7, 2020
Approver	Hilary Lee	Associate Director, QA		Jul 7, 2020

Revision History:

Revision	Issue Date	Reference #	Details of Change
A	28 Jun 2016	N/A	Initial release.
B	28 Jul 2017	DC-ZEV-2017-026	Updated to Pharmacist in Charge in responsibilities section for Pharmacy SOP. Added statement to comply with specific State regulations pursuant to the practice of pharmacy over this SOP when applicable.
C	30 Apr 19	DC-2019-009	Reformatted to QA.0001-00C format and streamlined EM forms. Revised to allow for manipulator fingers to be sampled in dispensing hot cells (the surface being sampled must be thoroughly wiped clean after sampling). Added more clarity for review of EM plates. Require remediation of any CFU isolates to align with changes to QA.0058. Added more detailed instructions for glove touch sampling. Renamed glove contact plate names to PH-GR/GL to align with the QC.0064 naming format.
D	09 Jul 20	CC-2019-048 CC-2019-048-A1	Updated the incubation scheme to reflect current guidance and pending USP <825> release. Added that number of CFU recovered must be documented after initial and final incubation. Attachments were updated to allow this documentation. Added the requirement for ISO 8 environmental monitoring and surface sampling requirement of classified areas. Added ISO 7 environmental section that directs operator to appropriate procedure. Changed EM requirement during compounding from after each batch to daily. Added stipulations for when increased monitoring is required. Added additional acceptance criteria due to new EM requirements and additional attachments. Added remediation steps for ISO 8 areas.

SOFIE From start to clinic	Environmental Monitoring of Dedicated Pharmacy ISO 5 Enclosures and ISO 5 Enclosures for Compounded Drug Products PH.0005 Attachment 1	Page 1 of 1 Revision D

Date: _____ **Batch:** _____ ☐ Compounding ☐ Dispensing

Equipment	Serial Number/EQP#	Cal. Exp.Date
ISO Class 5 Enclosure (LAFH, BSC, DHC)		

Material	SP	Lot #/MTN	Expiration
90mm TSA Settling Plates	0077		
Contact Plates	0078		

Equipment	EQP #	Calibration Expiration
Incubator (30-35°C):		
Data Logger:		
Incubator (20-25°C):		
Data Logger:		

Incubation @ 30°C -35°C (48 hrs. – 4 days or 96 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (days/hrs):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

30°C – 35°C Results (Performed during transfer)

Sample Code	Limit	Initial Results (CFU):	Pass/Fail
PH-CP1	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-GR (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-GL (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-MR (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-ML (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail

Incubation @ 20°C -25°C (120 hrs. – 7 days or 168 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (days/hrs):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

20°C – 25°C Results (Final)

Sample Code	Limit	Final Results (CFU)	Pass/Fail
PH-CP1	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-GR (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-GL (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-MR (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-ML (☐ N/A)	≤ 3 CFU/plate		☐ Pass ☐ Fail

[redacted] ☐ Yes; date notification occurred: _____ ☐ N/A

Comments:

Results Read by:		Date:	
Reviewed by:		Date:	

SOFIE From start to clinic	Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing in an ISO Class 5 Enclosure PH.0005 Attachment 2	Page 1 of 2 Revision D

Date: _____ ☐ Compounding ☐ Dispensing

Non-Viable Particle Counts Sampling			
Equipment:			
Particle Counter EQP #:		Calibration Expiration:	
ISO Class 5 Enclosure EQP #:		Calibration Expiration:	
Sampling:			
Performed by:		Date:	

Results (Attach, Sign & Date Results. Use reverse, if necessary):

Sample Location	Sample Reference	Result (Particles 2 0.5µm)	Acceptance Criteria (Particles 2 0.5µm)	Pass/Fail	Initials
Zero Count	ZERO COUNT	_____ / ft³	≤ 10	☐ Pass ☐ Fail	
[illegible]	[illegible]	_____ / ft³	≤ 100	☐ Pass ☐ Fail	
Dispensing Pollution Control (PBI) and Pass Box Out (PBO)					
Pass Box In (PBI) (☐ N/A)	PBI-PC1	_____ / ft³	≤ 10,000 / ft³ (ISO 7)	☐ Pass ☐ Fail	
Pass Box Out (PBO) (☐ N/A)	PBO-PC1	_____ / ft³	≤ 10,000 / ft³ (ISO 7)	☐ Pass ☐ Fail	
Regulatory reporting required:		☐ Yes; date notification occurred: _____		☐ N/A	
Reviewed by:			Date:		

SOFIE From start to clinic	Bi-Annual Viable and Non-Viable Air Sampling Environmental Monitoring During Compounding and Dispensing in an ISO Class 5 Enclosure PH.0005 Attachment 2	Page 2 of 2 Revision D

Date: _____ ☐ Compounding ☐ Dispensing

Viable Particulates

Equipment:

Air Sampler EQP #:		Calibration Expiration:	
ISO Class 5 Enclosure EQP #:		Calibration Expiration:	

Materials:

90mm TSA Plates	SP.0077	MTN:		Expiry:	

Viable Sampling:

Performed by:		Date	

Incubation

Equipment	EQP #	Calibration Expiration
Incubator (30-35°C):		
Data Logger:		
Incubator (20-25°C):		
Data Logger:		

Incubation @ 30°C -35°C (48 hrs. – 4 days or 96 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

30°C – 35°C Results (Performed during transfer)

Sample Code	Limit (CFU/m^3)	Initial Results (CFU/m^3)	Pass/Fail
PH-AS1	≤ 1 CFU/plate		☐ Pass ☐ Fail

Incubation @ 20°C -25°C (120 hrs. – 7 days or 168 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

20°C – 25°C Results (Final)

Sample Code	Limit (CFU/m^3)	Final Results (CFU/m^3)	Pass/Fail
PH-AS1	≤ 1 CFU/plate		☐ Pass ☐ Fail

Action Limits Exceeded? See Section 8.0 of QA.0002 and Attachment 2 of QA.0002

Regulatory reporting required?	☐ Yes; date notification occurred: _____	☐ N/A

Comments:

Performed by:		Date:	
Reviewed by:		Date:	

SOFIE From start to clinic	Bi-Annual Environmental Monitoring of ISO 8 Areas PH.0005 Attachment 3	Page 1 of 1 Revision D

Date: _____ **Next Due Date:** _____

Equipment:			
Air Sampler EQP #:		Calibration Expiration:	

Materials:					
90mm TSA Plates	SP.0077	MTN:		Expiry:	
Contact Plates	SP.0078	MTN:		Expiry:	

Viable Sampling			
Performed by:		Date	

Incubation		
Equipment Type	**EQP #**	**Calibration Expiration**
Incubator (30-35°C):		
Data Logger:		
Incubator (20-25°C):		
Data Logger:		

Incubation @ 30°C - 35°C (48 hrs. – 4 days or 96 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr.)	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

30°C - 35°C Results (Performed during transfer)

Sample Code	Limit (CFU/m³)	Initial Results (CFU/m³)	Pass/Fail
AR-AS1	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS2 or ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS3 or ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS4 ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail

Incubation @ 20°C - 25°C (120 hrs. – 7 days or 168 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr.):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

20°C - 25°C Results (Final)

Sample Code	Limit (CFU/m³)	Final Results (CFU/m³)	Pass/Fail
AR-AS1	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS2 or ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS3 or ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail
AR-AS4 ☐ N/A	≤ 100 CFU/plate		☐ Pass ☐ Fail

Notification to Client Required for Excursion of ≤ 20% and Immediate Corrective Action	
Notification Required?	☐ Yes; date notification occurred: _____ ☐ N/A

Comments:

Performed by:		Date:	
Reviewed by:		Date:	

SOFIE From start to clinic	Monthly Surface Sampling of Classified Areas PH.0005 Attachment 4	Page 1 of 1 Revision D

Date: _____ **Next Due Date:** _____

Materials:					
Contact Plates	SP.0078	MTN:		Expiry:	

Performed by:		Date	

Equipment Type	EQP #	Calibration Expiration
Incubator (30-35°C):		
Data Logger:		
Incubator (20-25°C):		
Data Logger:		

Incubation @ 30°C - 35°C (48 hrs. – 4 days or 96 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr)	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

30°C - 35°C Results (Performed during trainee)

Sample Code	Limit	Initial Results (CFU)	Pass/Fail
PH-PC or ☐ N/A	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-PBI or ☐ N/A	≤ 5 CFU/plate or ≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PBO or ☐ N/A	≤ 5 CFU/plate or ≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT1	≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT2	≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT3 or ☐ N/A	≤ 50 CFU/plate		☐ Pass ☐ Fail
AR-CP1	≤ 50 CFU/plate		☐ Pass ☐ Fail

Incubation @ 20°C - 25°C (120 hrs. – 7 days or 168 hours)

Incubated by (initials):	Start Temp. °C:	Start Date & Time:	End Date & Time:	Incubation Duration (day/hr):	Removed by Initials:
	_____	_____ @ _____	_____ @ _____	_____	

20°C - 25°C Results (Final)

Sample Code	Limit	Final Results (CFU)	Pass/Fail
PH-PC or ☐ N/A	≤ 3 CFU/plate		☐ Pass ☐ Fail
PH-PBI or ☐ N/A	≤ 5 CFU/plate or ≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PBO or ☐ N/A	≤ 5 CFU/plate or ≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT1	≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT2	≤ 50 CFU/plate		☐ Pass ☐ Fail
PH-PT3 or ☐ N/A	≤ 50 CFU/plate		☐ Pass ☐ Fail
AR-CP1	≤ 50 CFU/plate		☐ Pass ☐ Fail

	☐ Yes; date notification occurred: _____ ☐ N/A

Comments:

Performed by:		Date:	
Reviewed by:		Date:	

SOFIE From start to clinic	Bi-Annual Viable Environmental Monitoring in ISO 5 Areas PH.0005 Attachment 5	Page 1 of 1 Revision D

☐ Compounding ☐ Dispensing

Equipment	Serial Number/EQP#
ISO Class 5 Enclosure	

Date performed	Samples Performed:	Next Due:	Performed By Initials/Date:	QA/QAS Initials/Date:
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			
	☐ PH – PC1 ☐ PH – AS1			

Reviewed by:_____ Date:_____

SOFIE From start to clinic	Log for Biannual ISO 8 Air Sampling and Monthly Surface Sampling PH.0005 Attachment 6	Page 1 of 1 Revision D

Type of Sampling	Samples Performed:	Next Due:	Performed By Initials/Date:	QA/QAS Initials/Date:
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			
☐ Biannual ☐ Monthly	☐ Attachment 3 ☐ Attachment 4			

Reviewed by:_____ Date:_____

SOFIE From start to clinic	ISO 8 Sample Locations PH.0005 Attachment 7	Page 1 of 2 Revision D

Environmental Monitoring Sampling Locations in ISO 8 Areas at [Site]

Insert or draw a diagram of the ISO 8 anteroom with sampling locations clearly depicted.

Viable	
Location ID	**Location Description**
AR-AS1	
AR-AS2	
AR-AS3	
AR-CP1	

N (number of samples) = √A (area in meters)

Area in meters = meters

Number of samples =

Justification for sampling locations:

Provide a written justification for the selection of the sampling locations here.

Prepared By

Name	Title	Signature	Date
	QA/QAS		

Approved By

Name	Title	Signature	Date
	Choose an item.		

SOFIE From start to clinic	ISO 8 Sample Locations PH.0005 Attachment 7	Page 1 of 2 Revision D

By signing below, each operator attests that they have reviewed the approved sampling diagram, have asked any clarifying questions, and understand the required sampling locations, sampling frequency, and the associated acceptance criteria for each location.

Name	Title	Signature	Date

Signature: Kunj Patel
Kunj Patel (Jul 6, 2020 12:49 CDT)

Email: kunj.patel@sofie.com

Title: Corporate Pharmacist - in - Charge / HIPAA Com|

Signature: Laura Crandall-Carney
Laura Crandall-Carney (Jul 6, 2020 15:33 EDT)

Email: laura.crandall-carney@sofie.com

Title: Regional Manager, QA

Signature:

Email: hilary.lee@sofie.com

Title: Associate Director, QA

Signature: Analisa Fuller
Analisa Fuller (Jul 6, 2020 15:09 EDT)

Email: analisa.fuller@sofie.com

Title: QA Specialist

Signature:
Lynn Chwojdak (Jul 7, 2020 11:04 EDT)

Email: lynn.chwojdak@sofie.com

Title: Facility Manager/Pharmacist-in-Charge

Signature:
Chantele Clark (Jul 9, 2020 07:58 EDT)

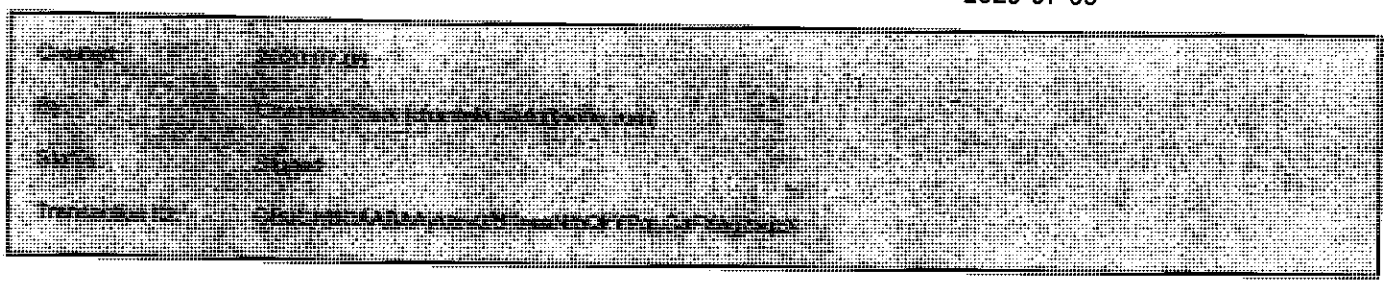
Email: chantele.clark@sofie.com

Title: Document Specialist Administrative Assistant

PH.0005-00D Environmental Monitoring of Pharmacy Classified Areas

Final Audit Report

2020-07-09



"PH.0005-00D Environmental Monitoring of Pharmacy Classified Areas" History

Document created by Chantele Clark (chantele.clark@sofie.com)
2020-07-06 - 5:44:35 PM GMT- IP address: 38.103.108.221

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Signature Date: 2020-07-06 - 5:49:17 PM GMT - Time Source: server- IP address: 104.176.64.97

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2020-07-06 - 7:10:34 PM GMT- IP address: 38.103.108.221

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Signature Date: 2020-07-06 - 7:33:37 PM GMT - Time Source: server- IP address: 38.103.108.221

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2020-07-06 - 7:33:39 PM GMT

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2020-07-07 - 3:02:03 PM GMT- IP address: 104.47.55.126

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Signature Date: 2020-07-07 - 3:34:12 PM GMT - Time Source: server- IP address: 68.33.22.105

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Signature Date: 2020-07-09 - 11:58:39 AM GMT - Time Source: server- IP address: 38.103.108.221

Signed document emailed to Kunj Patel (kunj.patel@sofie.com), Chantele Clark (chantele.clark@sofie.com), Laura Crandall-Carney (laura.crandall-carney@sofie.com), Lynn Chwojdak (lynn.chwojdak@sofie.com), and 2 more
2020-07-09 - 11:58:39 AM GMT

GA-68 Dotatate

Stanford Medical
Center Main
Hospital
Fri, 07-10-20 08:00
REPRINT

3.22ml 7-10-20@11:00 [redacted] Rx#621408

GA-68 Dotatate
GA-68 Dotatate
07-10-20 11:00

Stanford Medical Center Main Hospital
Rx#621408 3.22ml GA-68 Dotatate
5.00mCi 07-10-20@11:00

CAUTION RADIOACTIVE MATERIAL

Rx#621408 408-842-0520
ORD UNIVERSITY MED CENTER-MAIN HOSPITAL
Doctor : George Labban
Proc : GA-68 Dotatate [redacted]
GA-68 Dotatate GADCA12007100
SOFIE Co. dba SOFIE 5900-B Obata Way, Gilroy, California 95020-7065
5.00mCi 07-10-20@11:00 3.22ml

SOFIE Co. dba SOFIE
5900-B Obata Way, Gilroy, California 95020-7065
408-842-0520

Rx#621408 Run: [#8 07-10-20 08:00]

Customer: Stanford Medical Center Main Hospita
Doctor : George Labban
Patient : [redacted]
Proc : GA-68 Dotatate
Rad.Phar: GA-68 Dotatate
Chem Name: GA-68
Inv/Lot#: 6716/GADCA120071001

Cal Act : 5.00mCi 07-10-20@11:00
Cal Time: 07-10-20 11:00
Manuf : In House Prep
Assay : 1.55 mCi/ml
Use By Date : 07-10-20 12:34
Vol/Qty : 3.22ml

For IV use as directed/Do not use if cloudy or particulate
Rph : HMV

Compounded by Sofie Co

PO# : 35787586

REPRINT

NEW DRUG LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY

SOFIE Co. dba SOFIE
5900-B Obata Way, Gilroy, California 95020-7065
408-842-0520

Rx#621408 Run: [#8 07-10-20 08:00]

Customer: Stanford Medical Center Main Hospita
Doctor : George Labban
Patient : [redacted]
Proc : GA-68 Dotatate
Rad.Phar: GA-68 Dotatate
Chem Name: GA-68
Inv/Lot#: 6716/GADCA120071001

Cal Act : 5.00mCi 07-10-20@11:00
Cal Time: 07-10-20 11:00
Manuf : In House Prep
Assay : 1.55 mCi/ml
Use By Date : 07-10-20 12:34
Vol/Qty : 3.22ml

For IV use as directed/Do not use if cloudy or particulate
Rph : HMV

Compounded by Sofie Co

PO# : 35787586

REPRINT

NEW DRUG LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY

Ship To : **STANFORD UNIVERSITY MED CENTER-MAIN**
Addr 1: 300 Pasteur Dr
City: Stanford
State: Ca Zip Code: 94305

Pharm Name : SOFIE Co. dba SOFIE

Rx#621408
Customer: Stanford Medical Center Main Hospital
Doctor : George Labban
Patient : [redacted]
Proc : GA-68 Dotatate
Rad.Phar: GA-68 Dotatate
Inv/Lot#: 6716/GADCA120071001

Cal Act : 5.00mCi 07-10-20@11:00
Cal Time: 07-10-20 11:00

Vol/Qty : 3.22ml

Use By Date : 07-10-20 12:34
Rph : HMV

14

14A

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 1915 Hurd Drive

City: Irving State: TX Zip: 75038

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (224) 667-5417 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Christine.Limbaugh@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

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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: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (224) 667-5417 Email: Christine.Limbaugh@abbott.com
Contact Person Name: Christine Limbaugh

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____
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 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 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**	✓			
• **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.

Christine Limbaugh

Print Name of Authorized Person Submitting Application

Christine Limbaugh

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ processed 1/20/22

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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John

- Funck, Jr., Robert
- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian
- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

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LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
CERTIFICATE OF GOOD STANDING

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2299

ABBOTT LABORATORIES / ATTN NICOLETTE CANNELLA
1921 HURD DR
IRVING TX 75038

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ABBOTT LABORATORIES

1915 HURD DR
IRVING, TX 75038

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1002546
Expires: March 2, 2022

NON-TRANSFERABLE

Commissioner

510310

File Number 5972-555-6

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 I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT LABORATORIES INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON DECEMBER 19, 1997, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801582 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

Authentication: 203983224

Date: 08-23-21

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

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Abbott Laboratories Inc.
Date Filed:	12/19/1997
File Number:	87902
Minnesota Statutes, Chapter:	303
Home Jurisdiction:	Delaware
This certificate has been issued on:	09/20/2021

Steve Simon
Secretary of State
State of Minnesota

Beiheng Zhang
Mingge Zhang
Yucheng Zhao
Anita Zvaigzne

ALI Irving 2 Facility 1915 Hurd Drive

The workers at the ALI Irving 2 facility are as follows:

Oyemayowa Abioye
Konjit Admassu
Alaa Al Hasseun
Zaid Al-Ali
Aymen Alani
Blanca Aleman
Ade Alibaloye
Sean Alizadeh
Nasreen Amana
Derek Amedee
Dasia Amedee
Ara Amen
Subbu Ananthanarayanan
Maria Andrade
Leslie Andrews
Moazzam Arastu
Jesse Arenas
Jacob Armstrong
Zaid Arrefayine
Shailes Aryal
Cathy Austin
Onome Ayegba
Zachary Bailey
Harold Balatbat
Jacinto Baldobino
Piroska Bathory
Gordana Begic
Danik Bellows
Ilham Benfdil
Lorianne Bitshi
Jeremiah Bondurant
Kara Brooks
Bryant Brown
Garret Brown
Lane Brunkhorst
Gregory Bryant
Amanda Bui
Nicolette Cannella
Michael Cano
Kelly Caraway
Neal Carner
Janet Carroll
Jose Castellon
Otis Cheatham
Shanshan Chen
Jonathan Chenot
Man Chieh
Pharo Choun
Arman Chowdhury
Anwar Chowdhury
Charles Christopher
Geroalyn Clark
Carla Coffie
Xavier Colbert
Erin Coleman
Adriana Corral
Ashley Cousin
Corey Crenshaw
Debra Curry
Johnson Dang
Dedric Davis
Ramon Delgado
Barnabas Demeke
Abeselom Demisse
Kewakbt Dimberu
Shane Doherty
Leighton Doolittle
Nelson Dorta
Rodolfo Dosal
Lisa Dougherty
Deandra Dsouza
Brenda Dubay
Terry Dufek
Jennifer Dunstan
Trinh Duong
Chikheang Eak
Xavier Edwards
Jarvis Edwards
Hassan Eid
Samantha El Hefni
Patrick Elizarraraz

Philip Elmore
Adel Farag
Deyanira Feliciano
Kelly Fitzpatrick
Andrew Flores
Latifah Franklin
Louis Garza
Baldo Garza
Ivy George
Sujan Ghimire
Christopher Giang
Helina Girma
Siomara Gonzales
Carlos Gonzalez
Brigitte Gonzalez
David Gonzalez
Hilario Gonzalez
Donte Green
Norman Greer
Kimberley Gulyas
Ruth Hailessellasse
Daniel Handy
Pamela Harthcock
James Hawkins
Jason Haynes
Olvin Heredia Rivera
Eddie Hernandez
Jose-Rene Herras
Christopher Herricks
Steven Hickey
Cody Hill
Carolyn Hix
Larry Hoover
Antonio Hubbard
Jordan Hughes
Van Huynh
Cyril Isip
Chyna Jackson
Sylvia Jackson
Carmen Jackson
Dezorah Jackson
Paul Jeannet
Marty Jimenez
Vaughn Johns
Latoya Jones
Lonnie Jones
Muhammad Junaid
Radhika Kaimal
Miriam Kebaya
Emily Kemins
Nyla Kennard
Vanda Khoury
Ji Kim
Brandon Kittle
Karen Kostov
John Kostro
Jess Lackey
Karen Lazzaro
Bobby Ledbetter
Don Lenear
Monique Lewis
Amanda Lilley
Frederick Lipsey
Jeannette Lopez
Jared Love
Andrew Machungo
Keshia Mack
Wilfried Mackita
Mohammed Zeeshan Malik
Lisa Marshall
Vanessa Martin
Raphael Martin
Ruby Martinez
Michael Mcclanahan
Connally Mccullough
Sharla Mcgee
Sean Mckee
Darian Mcknight-Gaut
Eduardo Mendoza
Alex Mishork
Cyprian Mogunde
Sharifa Mohamed Zain
Stephen Moreland
Andrew Murillo
Ravi Hriday Narayanam
Zeena Nartker
Jalpa Nathwani
Deenar Nayani
Roderick Neal
Ai Nguyen
Si Nguyen
Nam Nguyen
Tam Nguyen
Maria Nguyen
Uyen Nguyen
Thanh Nguyen
Daniel Nieman
Karen Nowaski
Phillip Ochieng

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020 — Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14B

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 1921 Hurd Drive,

City: Irving State: TX Zip: 75038

Mailing Address (if different from physical address): Risa Baldy, 100 Abbott Park Road; Dept T4M1 Bldg AP8A-1

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 668-3605 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Risa.Baldy@Abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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: Blood/Plasma Donation Centers;Blood Banks	☐ Others:

Section 2: History of Company Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 668-3605 Email: Risa.Baldy@abbott.com

Contact Person Name: Risa Baldy

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____

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 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 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**	✓			
• **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.

Risa Baldy

Print Name of Authorized Person Submitting Application

Risa Baldy

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Processed 1/20/22

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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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)?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert

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- Frels, John
- Funck, Jr., Robert
- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian
- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

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LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A

CERTIFICATE OF GOOD STANDING

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ABBOTT LABORATORIES
1921 HURD DR
IRVING TX 75038

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ABBOTT LABORATORIES

1921 HURD DR
IRVING, TX 75038

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1000203
Expires: October 16, 2023

NON-TRANSFERABLE

Commissioner

511815

File Number 5972-555-6

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 I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT LABORATORIES INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON DECEMBER 19, 1997, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801582 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

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

Authentication: 203983224

Date: 08-23-21

ALI Irving 1 Facility

The workers at the ALI Irving 1 facility are as follows:

Saleha Abdulla
Sheikh Abdullah
Muhammad Abdurrahim
Kamal Abusalah
Radreena Adair
Sabal Adhikari
Ronald Adley
Birkayehu Afessa
Thelma Agidee
Prince Agrawal
Filiberto Aguilar Mata
Carlos Aguilera
Roshani Ahir
Shahina Ahmed
Syeda Ahmed
Kristine Ajpek
Patricia Akamnonu
Neeha Alam
Vicky Alcorn
Jennifer Alhadad
Saima Ali
Martha Allen
Timothy Alligrant
Pedro Almaguer
Christian Alonso Hernandez
Domingo Alonzo
Muqdad Alsalman
Yasmeen Alshara
Adrena Alvarado
Bushra Amarneh

Carina Amaya
Jessica Amaya
Rejitha Anand
Enid Anderson
Charles Andrews
Christina Andrews
Okezie Anude
Johnny Appiah
Richard Appiah
Diana Arellano
Gbenga Aremu
Ruben Arenas
Simon Arenas
Shiva Argula
Sabina Armaselu
Norman Armstrong
Bello Arukarawei
Tammie Ates
Rasmi Atluri
Benjamin Ayegba
Mahnaz Ayoubi
Sangita B K
Yocam Baccam
Jeremy Bailey
Lisa Bakajza
Christopher Baker
Jordan Baker
Rajesh Balakrishnan
Thelva Balkus
Abhishek Bansal

Marcus Barbee
Joann Barber
Corban Barnet
Philicia Barney
Guillermo Barrera
Mario Barrientos
Fauzia Basharat
Uzma Basheer
Sage Bauer
John Baum
Michael Baylis
Eva Baylon
Haydee Bearden
Jason Beasley
Nicholle Bechtel
Mark Beischer
Charles Bell
James Bell
Alex Beltran
Will Benedict
Scott Bennett
Sarah Benson
Kyle Berlin
Ricarte Bernal
Joseph Berry
Francisco Betancourt
Nelson Bethel
Rose Beunier
Daniel Beyer
Aparna Bhaskar

Sudiksha Bhattarai
Omar Bibi
Anil Bidary
Paul Bieniek
Paul Biggers
Michael Billings
Charles Birden Jr
Robert Birmley
Luca Birolini
Caeley Black
Gregory Blackwell
Edwin Bland
Jessica Blaylock
Richard Blazek
Brandon Blond
William Boettcher
Kevin Bonilla
Jeremy Boomer
Abarna Boopesh
Kevin Booze
Abraham Borjon
Elizabeth Bouchard
Debra Bowers
Jacob Boyer
Anthony Bradford
Noé Brambila
Travis Branch
Reilly Brandt
Craig Bray
Scott Breeding
Laurie Brewer
William Brewster
Albert Brideau
Cintia Briones-Diaz
Brandon Brooks
Collin Brown
Rodquavian Brown
Stephen Brown
John Browning
Gerald Brundage
Mark Bryant
Ronney Bryant
Hung Bui
Lien Bui
Federico Bulnes
Jennifer Burgin
Kenneth Burk
Judith Burley
Kiera Burnham
Patricia Burns
Richard Button
Montrelle Calhoun
Monica Camp
Christopher Cannon
Regina Carl
Damir Carlo
Jennifer Caro-Barnes
Jack Carolan
Ronita Carter
Marita Cason
Luis Castillo Quinonez
Maribel Castro
Roseann Caudle
Ernestina Cazares
Maria Cazares
Tatiana Cervera
Virginia Chaidez
Jagannadha Reddy Challa
Che Ho Chan
Siva Chandaluri
Michael Chase
Esha Chatterjee
Maegan Chavez
Suzanne Cheang
Bonnie Chen
Li Chen
Renee Cheng
Jana Chevier
Christopher Childers
Demario Childs
Demontrel Childs
Thandiwe Chirunga
Jaya Choudhury
Timothy Chumley
Vincent Ciriello
George Cislo
Rigoberto Cisneros Jr.
Emily Clary
Adair Claycomb
Asha Cleveland
Savan Cleveland
Catherine Click
Eric Cluff
Alexis Coates
Michael Cobert
Trevor Coffman
Katerina Colladej
Clare Collins
Natalie Compres

Reginna Conda
Scott Cook
Andre Cooper
Kelley Cooper
Cassandra Coor
Daniel Copeland
Payal Copling
Salvador Cordero
Michael Cornett
Luis Corral
Leslie Cortez
Randale Crain
Robert Crain
Thomas Creel
Alin Cruz
Daisy Cruz
Yuan Cuanchiohong
Brian Cummins
David Curran
Jedrick Currie
Ann Cychosz
Andrew Dalrymple
Austin Daneman
David Dang
Andre Daniels
Bryant Daniels
Oluwaseun Dare Lawal
Stephen Darrouzet
Tony Dates
Jehron Davis
Joshua Davis
Kary Davis
Markeith Davis
Tina Davis
Margarita De Jesus
Kris Dearden
Jerry Dechert
Jenna Dede
Andrea Defrance
Daniel Deleon
Jennifer Demartin
Justin Dempsey
Davis Denny Iv
Daniel Devereux
Ashim Dhingra
Hussein Diab
Brittany Diaz
Marilu Diaz
Phuong Diep
Trinh Diep
Beverly Din
Alberto Dismuke
Byron Dixon
Kristina Dixon
James Do
Thuc Do
Steven Doering
Daniel Dominguez
David Dominguez
Carrie Dopona
Daniel Droll
Karthikeyan Duraiswamy
Stephen Dweh-Chenneh
Laura Eads
Renni Eappen
Danielle Edwards
Hali Egnatchik
Victoria Ehlers
Sandra Eichman
William Eiland
Mutaz Elatta
Denissa Elizabeth Babu
Royce Eller
Paula Elliott
Kathryn Ensminger
Gloria Escobar
Abdollah Eskandari
Mary Esparza
Raul Estevez
Nestor Estrada
Gary Evans
Jose Evaro
Timothy Ewing
Zaman Fabela
Irena Fajdetic
Anthony Fallon
David Fancher
Charlie Fang
David Favors
Shan Feldpaush
Corinne Fenton
Elise Fermier
Roland Fernandez
Anthony Figliola
Stephanie Filar
Martin Filipowicz
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Andrew Fischer
Dora Flores

Angela Flynn
Jedidiah Fojtasek
Brent Foshee
Matthew Foster
Meredith Foster
Lana Fountain
Stephanie Fowler
Aaron Fox
Demarcus Francis
Shelley Franco
Benjamin Franklin
Gregory Franklin
Diane Frasure
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Stephanie Fryar
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Jose Fuentes
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Douglas Fuller
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Terry Gailbreath
Ray Gaines Jr
Consuelo Galindo
Amanda Galvan
Kiran Ganji
Martin Garcia
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Norma Garcia-Perez
Gregory Gardner
Rebecca Gardner
Michael Garn
Alejandro Garza
Carolina Garza
Jose Garza
Teresa Gates
Yemisirach Gebeto
Alesia George
Glenn George
Helen Geter
Sharvari Ghayal
Siavash Gheshmi
Sudeep Ghimire
Cheri Giller
Richard Gocher-Bell
Alexander Godfrey
Boris Goldstein
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Cordell Gomm
Amanda Gonzalez
Araceli Gonzalez
Ilse Gonzalez
Maria Gonzalez
Martin Gonzalez
Raul Gonzalez
Ray Gonzalez
Shannon Goode
Erick Gordon
Ramahn Gordon
Iris Gorman
Megha Gowda
Kelvin Graham
Megan Grandone
Connie Graston
Christopher Gray
Elizabeth Gray
Laura Greaves
Ewing Green
Russel Green
Nicole Gregorich
Tony Griffin
Kwakena Groce
Lashadrick Groce
Zachary Grubbs
James Grubert
Katherine Guevara
Moran Guo
Claudia Gutierrez
Michael Guzzi
Maheswararao Gypuri
Ranen Habib
Kjartan Haga
David Hague
Saad Haik
Austin Hain
Jean Hakizimana
Yeraldi Hall
Oday Hameed
Lawrence Hamilton
Jamie Hansen
Scott Hansen
David Harding
Jason Harris
Cheavon Harrison
Brenda Hart
James Hart
Edward Harvey
Salman Hasanuddin

Natasha Hawes
Gina Hawthorne
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Nikeale Haynes
Kelsey Hays
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Charles Hecht
Zakariah Hegab
Mouhib Helou
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Guillermo Hernandez
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Germaine Hunter
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Vicki Huse
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Ross Hynek
Avegail Ibad
Realyn Ibad
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Clara Immanuel
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Zeeshan Iqbal
Sneha Ganesh Iyer
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Ralph Jansen
Katelin Jara
John Jarmush
Joe Jasso
Billy Jenkins
Blake Jenkins
Johnnie Jenkins
Tian Jiang
Joel Jimenez
Austin Jinks
Emil Jivan
Ansu John
Manju John
Priscilla John
Alvin Johnson
Diane Johnson
Doretha Johnson
Kelvin Johnson
Kerry Johnson
Nicholas Johnson
Nicole Johnson
Paulisa Johnson
Ronda Johnson
Shelbi Johnson
Veronda Johnson
William Johnson
Rakesh Johny
Brittany Jones
Jared Jones
Patrick Jones
Sarah Jones
Kyshawn Joplin
Som Joseph
Eudor Juarez
Sabrina Juarez
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Atout Kamgaing
Namrata Karki
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Farrukh Kasbati
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Dayo Kazeem
Ashmita Kc
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Ronnie Lewis
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Zixiao Li
Qing Liao
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Jingsheng Lu
Ling Bin Lu
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Jorge Lucio
Jonathan Luckie
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Jessica Luoma
Robert Luoma
Yuan Ma
David Macdonald
Scott Mackler
Christine Macklin
Kiana Magnuson
Richard Mahoney
Sunil Mainali
Christine Mains
Trindell Major
Andrew Makarich
Surjit Makkar
Sinu Maliyil
Anupama Malleshappa

Nicole Maly
Jordan Mammen
Benequis Manoy
John Marino
Cynthia Markbreiter
David Marshall
Keith Marshall
Levi Martin
Nakeia Martin
Wendy Martin
Martha Martinez
Michelle Martinez
Monique Martinez
Valerie Martinez
Rida Maryam
Christian Masterson
Jobby Mathai
Shaji Mathew
Kiké Maung
Kristy Mayo
Nadine Mbala
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Vinson Mccants
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Zhu Mei
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Susan Milholland
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Justice Miller
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Adrian Murray
Mohamed Musa
Muhammad Naeem
Bhavya Nair
Barbara Nance
Ahmad Naseri
Muhammad Nassef
Karime Navarro
Wanda Ndimbie
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Truman Neeley
David Negron
Brendan Nelson
Chun Ng
John Ngo Sy
Dan Nguyen
Dat Nguyen
Hai Nguyen
Khanh Nguyen
Phuc Nguyen
Quang Nguyen
Steven Nguyen
Tam Nguyen
Thanh Nguyen
Thuan Nguyen
Toan Nguyen
Tom Nguyen
Tomathao Nguyen
Deniece Nielson
Denise Nix
Trenton Nix
Tyler Nix
James Nolan

Toni Norman
Trevon Norman
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Kelly Nottingham
Boladji Nougbedo
Kyle Novak
Matthew O'Hara
Brian Ochranek
Donald O'Connell
Nathaniel Odenweller
James Odom
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Vivian Ojeda
Solomon Okunseri
Ibukun Oni
Dora Ordonez
Andrew O'Reilly
Noe Ortiz
Owusu Osei
Nicholas Owen
Kelly Owens
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Paul Padilla
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Margaret Page
Lea Pagkaliwangan
Ian Paramo
Rudolph Paramo
Doseo Park
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Mary Parker
Janet Parkinson
Harpreet Parmar
Vinay Kumar Patchipulusu
Anish Patel
Dhaval Patel
Pratikkumar Patel
Ripal Patel
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Keeli Patterson
Kristen Patterson
Rossi Paul
Corey Pawlichuk
Tracy Pedretti
Brent Pelletier
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Pamela Perlick
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Leroy Petteway
Diana Petty
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Huy Pham
Minh Pham
Nhuhuong Pham
Tuan Pham
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Quan Phan
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Kathryn Porter
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Leslie Posey
John Pospichal
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Edna Prieto-Ballengee
Barry Prince
Ahmad Pryor
Boyd Pryor
Esteban Puente
Steven Pulcher
Jason Puzniak
Daud Qasemi
Lei Qiao
Orville Raggio
Mohammad Rahman
Bima Rai
Razvan Raicu
Raamvishnuraja Rajendra Raja
Shan Ramasubramanian
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Pramit Rana
Phyllis Randell
Eddie Randon
Patricia Ravalico
Traci Redmer
Kevin Reed
Daniel Rehberg

Katherine Reinhardt
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Jorge Rezende
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Adam Risley
Daniel Rist
Nathan Risteen
Kathryn Ritchie
Santos Rivera
Diane Roberson
Tara Roberson
Kara Roberts
Jeff Robeson
Wanda Robinson
Larissa Robles
Ana Rodas
Brandon Rodgers
Edgar Rodriguez
Josue Rodriguez
Louis Rodriguez
Maribel Rodriguez
Patricia Rodriguez
Victoria Rodriguez
Angel Rojas Rebollar
Brandon Rosemeyer
Bruce Ross
Bryan Ross
Brian Roth
Farzana Rouf
Ranjan Rout
Donna Rowell
Daniel Rowold
Gregory Rumeser
Kimberly Runnels
Robin Rutherford
Charles Ryan
Wajeeh Saadi
Artur Sabanskyy
Carole Sadate-Onguene
Amreek Saini
Mabin Sainju
Nazmus Sakib
Brigido Salgado
Supraja Salla
Teniola Salvador
Vivek Salyankar
Edward Sanchez
Rafael Sanchez
Alyson Sanders
Jorge Santana
Norberto Santana
Harish Santhanam
Harold Santiago Ramos
Deryl Sapp
David Sarine
Michael Satterfield
Sagun Satyal
Swetha Satyanarayana Reddi
Iman Sazmand
Phyllis Schrantz
Oscar Schwartz
Tobias Schwarz
Desiree Scudder
Jim Searles
Nidhi Shah
Sandeep Shah
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Majid Shaik
Aasta Shakya
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Yong Sheng
Taurus Shepard
Vincent Shepherd
Chris Sherrod
Jay Shoberg
Stephen Sholden
Elisha Shomefun
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Shelista Shrestha
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Melissa Simpson
William Simpson
Gurjit Singh
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Scott Slater
Natalie Small
Dennis Smiter
Angela Smith
Bradley Smith
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Florence Smith
Gail Smith
Jeremy Smith
Letha Smith
Mikayla Smith
Nathan Smith
Yolonda Smith
Alex Smittie
Emilie Snelson
Christopher Solomon
April Solorzano
Rahul Sonwalkar
Jorge Soto
Craig Spangler
Rupa Spencer
Sara Speyerer
Camelia Spiridon
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Heidi Stair
Brian Starkey
Michael Stasaski
Christopher Steidle
Randall Stem
John-Paul Stephens
Cynthia Stevenson
Sandra Stonebraker
Kathleen Streich
Guodong Su
Po-Jung Su
Hooriya Sulaiman
Adegboyega Sule
Naureen Suteria
Caroline Swafford
Henry Swalla
Richard Sweeney
Michael Szapiel
Mehrzad Taherzadehboroujeni
Vinita Talgaonkar
Kevin Talley
Raghuvamshi Taneti
Wilson Tanjaya
Balogun Taofik
Ali Taqi
Ronald Taylor
Nicole Teague
Dmitriy Terekhov
Marty Terry
Rebecca Terry
Jyotsana Thapa
Orvil Thapa
Ruthie Thillen-Chennault
Auresa Thomas
Jokutty Thomas
Lewisorentha Thomas
Monisha Thomas
Sibin Thomas
Veneeta Thomas
Vinita Thomas
William Thomasson
Grace Thompson
Keith Thompson
Murray Thompson
James Thomson
Powell Thoppil
Austin Thorn
Elizabeth Thottakara
Myka Tibbets
Adrian Tijerina
David Tipotsch
Tanya Titus
Keerti Tiwari
Dorra Tlili
Sovann Toch
Matthew Todd
Eberhard Todtenhoefer
Hedrick Tolliver
Charles Tonkon
Telma Toral Agreda
Andrea Tornatore
Cherisse Torrence
Jacob Torrez
Claire Tran
Cynthia Tran
Peter Tran
Valerie Travers
Casimiro Trevino
Tram Trinh
Zach Trotter
Austin Tucker
Everett Tucker

Tammy Turner
Vickie Turner
Gregory Tyber
Mason Tyler
Nawal Ulhaq
Jagadish Ulloor
Alyssia Urquieta
Christopher Utke
Luis Uzarraga
Faustino Valdez
Evelyn Valerio-Rivera
Nadene Vanpelt
Ruby Vansickle
Angelica Vargas
Babu Varmah
Melissa Vaughan
Nalini Ved
Arunteja Veermalla
Inocencio Velazquez
Clemente Velazquez Munoz
Karina Velez
Pranitha Veliverthi
David Venegoni
Kara Venegoni
Daniel Verona
Leandra Victor
Rajsree Vijayan
Andri Villalba
Jose Villarreal
William Visoski
Christopher Vu
John Vuittonet
John Vuong
Billy Wade
Bryan Waid
Alex Waldhauser
Angus Walker
Jay Walker
Mary Walker
Michele Walker
Shawntae Walker
Danna Walters
Maria Warren
Darrell Watson
Merrik Watson
Donavon Watts
Christopher Weaver
Nancy Weiland
Jerry Weitzel
James Welch
Susan Werner
Bradley Weston
Avery Wheeler
Catherine Whitaker
John White
Sylvia White
Sathren Whitfield
Michele Whitlock
Chasity Whitmer
Neil Whitney
James Whitt
Kevin Whytus
Glorianna Wiebelhaus
Alan Williams
Antonio Williams
David Williams
Don Williams
Elijah Williams
Kathleen Williams
Lynvol Williams
Philip Williams
Sidney Williams
William Williams
John Wilson
Timothy Wilson
Jalen Winborn
Alexander Wirtz
Michael Wisdom
Kenneth Wong
Pamela Wood
Jonathan Woody
Amare Worku
Solomon Worku
Tianbing Xia
Jagriti Yadav
Johnathan Yager
Dror Yahalom
Morgan Yakich
Hua Yang
Zehua Yang
Lyle Yarnell
Aaron Yee
Sharl Youkhana
Joshua Young
Hadi Zadeh
Gerald Zapata
Veronica Zapiain Aguayo
Lisa Zavala
Julio Zelaya

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020 — Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14C

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 3158 Martin Luther King Jr. Drive

City: North Chicago State: IL Zip: 60064

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (224) 667-5417 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Christine.Limbaugh@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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 Inc.
Address: 100 Abbott Park Road City: Abbott Park State: IL Zip: 60064

Name: Alere San Diego Inc.
Address: 829 Towne Center Drive City: Pomona State: CA Zip: 91767

Name: Sekisui Diagnostics P.E.I. Inc. ; 70 Watts Avenue Prince Edward Island C1E 2B9
Address: See in parentheses above line. City: Charlottetown, Canada State: - Zip: -

Name: SENTINEL CH. S.p.A.
Address: Via Robert Koch, 2 City: Milano, Italy 20152 State: - Zip: -

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (224) 667-5417 Email: Christine.Limbaugh@abbott.com
Contact Person Name: Christine Limbaugh

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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:
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 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 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**	✓			
• **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.

Christine Limbaugh

Print Name of Authorized Person Submitting Application

Christine Limbaugh

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 CC Processed 4/20/21

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John
- Funck, Jr., Robert
- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian

- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

EXHIBIT A
CERTIFICATE OF GOOD STANDING

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

April Veoukas
Director, Regulatory Affairs
Strategic Regulatory Affairs
Abbott Quality & Regulatory

Abbott
D-03Q4, AP52
200 Abbott Park Road
North Chicago, IL 60064
T: +1 224 667 8197
april.veoukas@abbott.com

Confidential and Proprietary – Not for Public Disclosure

Via Email (m.herrera@pharmacy.nv.gov & pharmacy@pharmacy.nv.gov)

December 16, 2021

Dear Maria Herrera,

In response to your December 7 email, enclosed please find the home state licenses in support of our 12 Nevada State Board of Pharmacy Wholesaler Applications for the wholesalers and facility locations identified in the table.

Wholesaler	Facility Location	Home State License
1. Abbott Laboratories Inc.	3158 Martin Luther King Jr. Drive, North Chicago, IL 60064	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10
2. Abbott Laboratories Inc.	1921 Hurd Drive, Irving, TX 75038	See attachment A
3. Abbott Laboratories Inc.	1915 Hurd drive, Irving, TX 75038	See attachment B
4. Abbott Laboratories Inc.	15900 Valley View Court, Sylmar, CA 91342	See attachment C License Number: 115222 Certificate is in the mail after confirmation from the renewal process.
5. Abbott Laboratories Inc.	6901 Preston Road Plano, TX 75024	See attachment D
6. Abbott Laboratories Inc.	2305 Walnut Street, Roseville, MN 55113	Minnesota State does not license medical device distributors.[2] Minn. Stat. § 151.01
7. Abbott Laboratories Inc.	42301 Zevo Drive, Suite #F, Temecula, CA 92590	See attachment E
8. Abbott Molecular Inc.	1300 East Touhy Avenue, Des Plaines, IL 60018	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10

[1] The Illinois Dept. of Financial and Professional Regulation states that no licensing is required in order to warehouse and/or distribute such product in or out of the State of Illinois. The requirements of licensure and practice are provided by the Act and Rules in Administrative Code, 68 Ill. Adm. Code 1510.10. Definitions of "wholesale distribution" and "prescription drug" do not include medical devices.
[2] Minnesota state does not license medical device distributors by the office of Minnesota Statues, Minn. Stat. § 151.01. Definitions of "prescription drug", and "manufacturing" do not include medical devices.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

Authentication: 203983224

Date: 08-23-21

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

File Number 5972-555-6

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 I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT LABORATORIES INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON DECEMBER 19, 1997, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801582 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

LIST OF WORKERS ABBOTT WHOLESALER FACILITIES
EXHIBIT C

ALI North Chicago Facility

The workers at the ALI North Chicago facility are as follows:

Andrew Adaman
Bianca Alderin
Paul Allen
Moises Alvarez
Elssie Andino
Glenda Andino
Esai Arenas
Catherine Arenas
Allen Austin
Sesilia Banales Garibay
Patricia Banda
Jennifer Barber
Harold Barbour
Alonzo Barnes
Lesley Barrera
Stephan Bartley
Sean Berger
Vijay Bhagat
Fred Brown
Timothy Cairo
Maria Castaneda
Luis Castellanos
Andre Chen Young
Evan Cielek
James Cole Jr
Ryan Connelly
Joseph Conver
Miya Cook
Erick Cooper
Omar Cortes
Andrea Covarrubias Lizardo
Joseph Crane
Victor Delgado
Joel Delgado
Andrew Desanto
Jorge Diaz
Su Diekfuss
Kassandra Dominguez
Mark Dulaney
Charles Duncan
Kevin Dunk
Michelle Dussault
Jonathan Edmondson
Reggee Elazegui
Liliana Enriquez
Pedro Enriquez
Gerardo Figueroa
Lisel Forbes
Matthew Fredricks
Bernetta Friar
Alicia Friar-Taylor
Humberto Gallego
Florencio Garcia
Juan Garcia
Daniel Gifford
Rodolfo Gonzalez
Cristopher Gonzalez Navas
Jeff Goodwin
Rasheeda Greene-Woods
Kenneth Griffin
Leon Griffin
Deborah Haflinger
Aaron Hankins
John Herrera
Michele Hines
Robert Hogan
Ben Hornickle
Haoyun Huang
Ljiljana Jelaca
Tyrone Jenkins
Michael Johnson
Kristen Johnson
Breanna Johnson
Douglas Jones
Arhonda Jones
Holly Kammer
Destinee Kammer
Michael Knodel
Peter Kreilinger
Joseph Laky
Catherine Laky
Brittany Lamb
John Landis
Jacob Lange

Carmen Lanza
Zachary Lawler
Joshua Lawler
David Lewsader
Susan Limberg
Rashand Lindo
Tiffany Lyles
Gabriel Magnani
Roy Major, Jr
Dani Mani
Demetrios Markoutsis
Christopher Marshall
Jerry Marshall
Priscilla Martinez
Brandon Medina
Antonio Mejia
Carlos Mendoza
Tai-Lynne Moreno
Kimberly Morris
Antionette Morrison
Luke Naidicz
Katherine Nevel
Ian Neville
Glenn Olson Ii
James Oswalt
Jose Otero
Julia Pacini
Noreen Patlan
Gary Pawelak
Marcelo Perez
Larry Phan
Glenn Pikalek
Addir Pineda
Sean Pschirrer
Ramil Pureza
Ryan Rafeldt
Shibani Raje
Alejandra Ramirez-Merida
David Rauch
Margaret Repp
Francisco Reyes
Abel Reyes
Consuelo Rivera
Jaime Rodriguez
Cesar Ruffolo
Callie Rusch
Hugo Saenz Ocampo
Linda Salminen
Daniel Santillanes
Marina Sarkisian-Dye
Michelle Sarver
Chasity Sawyers
David Scherer
Debra Schlichting
Sandra Skogen
Kyle Spradlin
Logan Stoneking
Trashaun Taylor
Anthony Tinzly
Elias Trujillo Cabrera
Tess Tuquilar
Brandon Turner
Berenice Valle Ayala
Trevor Vaughan
Jannet Villarreal
Scott Vrabel
Sonia Watson
Thomas Weiland
Jenna Willie
Ray Ynosencio
Zachary Ynosencio
Earl Young
Israel Zarate

14D

NEVADA STATE BOARD OF PHARMACY

98S Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 6901 Preston Road

City: Plano State: TX Zip: 75024

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (217) 530-5766 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Katherine.Douglas@Abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (217) 530-5766 Email: katherine.douglas@abbott.com

Contact Person Name: Katherine Douglas

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____

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 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 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**	✓			
• **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.

Katherine Douglas

Print Name of Authorized Person Submitting Application

Katherine Douglas

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 CC

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

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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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John
- Funck, Jr., Robert

- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian
- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

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LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
CERTIFICATE OF GOOD STANDING

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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

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

Authentication: 203983224

Date: 08-23-21

TEXAS
Health and Human Services

Texas Department of State Health Services

John Hellerstedt, M.D.
Commissioner

December 7, 2021

Abbott
Attn: Britany Osterman
100 Abbott Park Rd.
North Chicago, IL 60064

CFN: 0029552
Lic.: 0029552
Type: 2503
File: 1406

Re: License Verification

Dear Ms. Osterman:

This letter shall serve as a verification of licensure for the following firm:

Advanced Neuromodulation Systems Inc., an Abbott Company
6901 Preston Road
Plano, TX 75024

License No.	0029552
Type of license:	Device Manufacturer
Status of license:	Current
Date license issued:	01-24-2020
Date license expires:	02-20-2022
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me or Mr. Justin Arnold at 512-834-6755, via fax at (512) 834-6759, or email me at Karen.Tannert@dshs.texas.gov.

Sincerely,

Karen Tannert, R.Ph., M.P.H.
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Karen Tannert
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

File Number 5972-555-6

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 I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT LABORATORIES INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON DECEMBER 19, 1997, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801582 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

Bei Ning Zhang
David Zhang
Min Zhang
Bryan Zilar
Donna Zimmerman

ALI Plano Facility

The workers at the ALI Plano facility are as follows:

Amir Abdollahi
Seble Abebaw
Senait Abebe
Olusegun Famubode Abimbola
Ralph Ablorh-Quarcoo
Eddie Abshire
Rommel Acosta
Jason Adams
Aderonke Adejare
Christina Aguilar
Nicandro Aguilar
Rosalinda Aguinaga
Nighat Akhtar
Swetha Akula
Myron Albert
Matthew Aldridge
Mekdes Alemu
Ted Alfonso
Sarah Alhamad
Tekeste Alimaw
Jemymah Allen
Christopher Allison
Mwamvua Amalile
Aimee Amburgey
Alkaben Amin
Anshul Anand
Sahana Ananth
Tanya Anderson
Asif Aniyathakundu
Naga Vardhani Annapureddy
Charlotte Anthony
Lashanda Armstrong
Lauren Armstrong
Achol Atem
Manan Atit
Farah Awadat
Genet Ayele
Sean Babalola
Khadija Baddaz
Timothy Baggett
Eric Baidya
Zakiul Bakshi
Binesh Balasingh
Loi Bao
Syed Askari Baqar
Emmanuel Barajas Cortes
Matthew Baris
Ricky Basher
Debbie Bassett
Ambika Bastola
Kevin Bauckman
William Baumgart
John-Paul Bedinger
Jeremy Beer
Woinshet Belachew
Helena Benavides
Matthew Bentle
Lauren Berglund
Ethiopia Beshah
Margaux Best
Aashish Bhakta
Pallavi Bharoliya
Ramamurthy Bhat
Sudeep Bhat
Linda Binon
Alexander Blessing
Marc Bogdan
Kevin Boland
Assunta Boldit
Steven Boor
Matthew Botello
Monica Botero
Bryce Bouaphavong
Brittany Boudreau
Dana Boutelle
Orion Bowers
Brian Boyd
Laura Bracken
Curtis Bradford
Joshua Bradford
Matthew Bradley

Nilesh Brahme
Sara Brandt
Shayna Brewer
Cory Brinkman
Jordan Brock
Mattie Brooks
Amber Brown
Jay Brown
Rashad Brown
Vanessa Brown
Zachary Brown
Doug Bryan
Julia Bryant
Diep Bui
Van Bui
Emebet Bulcha
Ricardo Bulla
Jennifer Burkholder
Bryan Burnett
John Burns
Paul Burns
Precy Cabato
Robert Cabrera
Courtney Cadieux
Leo Calderon
Michael Campbell
Kari Campon
Dale Canovali
Tommy Cao
Suzanne Carbone
Juan Cardona
Rose Marie Carranza
Wei Carrigan
Annett Carter
Delisa Cash
Michelle Castaneda
Maria Castillo
Ramazan Cavdar
Gloria Cervantes
Tammy Chan
Shannon Chancelor
Ayush Chandrakiran
Rajesh Chandran
Thomas Changsuk
Rajwinder Chatrath
Pooja Chatterjee
Manoj Chauhan
Hunn Chhoeuy
Peter Chhun
Shirisha Chiluka
Ameya Chilwar
Kyuwan Choi
Evelyn Chong
Sesha Sai Srikar Pavan Kumar Chongala
Sreenivas Chowdiah
Heather Claytor
Cherith-Eden Clements
Daniel Cobb
Kerri Coduti
Mainor Coello
Christopher Coffman
Landon Cohorn
Isela Collins
Gary Combs
Eden Conanan
Mark Conrad
Jessica Coogan
Nicholas Cooper
Francine Costantino
Nicholas Couturier
Brian Cox
Curtis Cox Ii
Jessica Cramp
Bobby Crawford
Chris Crawford
Christopher Crawford
Gregory Creek
Alexis Crespo-Laboy
Victor Cuevas Ii
Navin Dabhi
Arash Dabir
Phuong Dam
Diem Dang
Satiesha Daniel
Kathy Dao
Yen Kim Dao
Tina Darabadey
Jeremiah Darden
Amitabh Das
Rajasree Das
John Dascanio Ii
Apurva Dave
Sanchali Deb
Scott Debates
Alison Deere
Elezabet Degfa
Andrea Morrison Deitz
Kathryn Dellamonica
Dianne Denlar

Keith Denton
Balwant Deol
Vidhi Desai
Daran Deshazo
Madeline Devega
Ayanna Devese
Raj Dhesikan
Dorin Diaconescu
Alpha Diallo
Mamadou Diallo
Armando Diaz
Ricardo Diaz Diaz
Chany Dickerson
Xin Ding
Kim Dinh
Nga Dinh
Matthew Dion
Shanmukh Divakarla
Thomas Dixon
Nguyen Do
Tri Doan
David Donaldson
Indranie Doobay
Joshua Dornback
Alka Doshi
Kevin Doucet
Pamela Dravitz
Robert Dreffs
Jodi Dubuclet
Sean Duffy
Victoria Dukes
Deana Dunbar
Nyanwuor Duop

Almaz Ebsa
Kimberly Eddleman
Jacob Edwards
James Efurd
Robert Egemo
Keesha Eguia
Jonathan Eipper
Paul Eisen
Michael Elder
Robert Elliott
Suzanne Elliott
Fauziah Embi
Bradley Epperson
Rickey Epps Jr.
Steve Escamilla
Michael Eubank
Ellen Evans
John Evans
Buyeh Faal
Cody Faisst
Ousman Fatty
Justin Faughn
Shane Fechner
Armando Fernandez
Victor Fernandez Nieto
Patrick Fey
Thomas Fimiani
John Finn
Patrice Fisher
Eric Fogel
Robert Font
Jacquelyn Ford
Kelly Fortado

Michael Fortner
Cory Frank
Michael Frassica
Stacy Fruge
Masahiro Fujimoto
Hemalatha Gadwal
Christopher Gallivan
Diego Gallo
Felita Ganaden
Dhruvin Gandhi
Ronak Gandhi
Vikram Gaonkar
Lisa Gaouette
Celsa Garcia
Melissa Garcia
D'Aquanita Garner-Hunter
Robert Garza
Tesfahun Gemechu
Lincy George
Sagith George
Mary Gerber-Soukup
Louis Gianni
Aretha Gibson
Eric Gibson
Manoj Gidda
Daniel Gilbert
Saad Girgis
Sri Godey
Sager Goel
Aditya Gokhale
Gabriel Gonzalez
John Gonzalez
Kimberly Goode

Patrick Gorman
Venkat Goruganti
Jacqueline Gorzelic
Abeselom Goshu
Douglas Goss
Anitha Govindarajan
Mason Graff
Ian Graham
James Graham
Cindy Grant
Jonathan Grant
Steve Gray
Michael Green
Shirley Green
Bryan Gregg
Erica Grego
Danea Grimes
Stacey Grisham
Elizabeth Grohmann
Arthur Groome
Nanitha Gubendra Gunabalan
Jose Guerra Sanchez
Linda Guice
Srichandan Gutta
Jorge Guzman
Lejla Hadzidedic
Maria Hamlin
Caroline Hammer
Mohamed Hamouda
Jill Hampton
Paul Hankins
Donald Hanson
Jordan Hanson
Kira Hanson
Nicole Harbert
Nikesha Harrington
Clinton Harris
Mohammad Hasan
Eileen Haselhorst
Nicole Hatt
Ronald Haverkamp
Jackial Heckard
Kellee Heffner
Kevin Helm
Josephine Henderson
Mark Hendrick
Sophia Herdzik
Geronimo Hernandez
Lyndahl Himes
Jose Hinojosa
Ahuva Hirschberg
Trang Hoang
Edward Hogan
Marcia Hogan
Edward Hook
Mary Hor-Lao
Kande Horne Kara
Lakshmi Hothur
Isabel Hoverman
Liza Howlader
Waley Hua
Michelle Hughes-Moore
Richard Hughey
Anh-Nguyet Huynh
Chan Huynh
Tuyen Huynh
Peter Ifft
Regina Ingram
Rochelle Inscho
Sandya Iqbal
Jacqueline Ishmeal
Nazia Islam
Mehran Jaberzadeh
Sonie Jackson
Omar Jamal
Devin Jaqua
Sahar Javed
Clarissa Johansen
Mary John
Philip John
Betty Johns
Darryl Johnson
Holly Johnson
Laura Johnson
Laura Johnson
Melissa Johnson
Michael Johnson
Felicia Jones
Jacklyn Jones
Jamie Jones
Kasandra Jones
Robert Jones
Jenner Joseph
John Jung
Aravind K Kallahally
Nagabhushan Kaliyur Sathyanarayana Murthy
Sokanna Kan
Uma Mahesh Kanchumarthi
Ming Yao Kao

Shashidhara Kappagal Matt
Makarand Karvekar
Natasha Kashyap
Mustafa Melih Kasti
Bunna Katt
Sharath Reddy Katta
Kathyayini Kattamanchi
Kamaljit Kaur
Sharnjit Kaur
Sukhvinder Kaur
Majida Kawar
Dana Kayode
Michael Kellen
Robert Kelley
Chadwick Kennedy
Abdul Khan
Mirza Khan
Naseem Khozein
Raymond Koons
Nisha Koshy
Tyler Kramer
Diane Krebbs
Chelsey Krutch
Katelyn Kuehnhold
Nicole Kuksuk
Vivek Kulkarni
Santhana Krishnan Kumarasami
Hua Ching Kuo
Tsion Kurfa
Anahita Kyani
Katie Labra
Ryan Lakin
Asunta Lako
Melanie Lang
Rahul Lanka
Kevin Lapolt
Patricia Lapolt
Douglas Lautner
Joyce Lawrence
Justina Lay
Dien Le
Lien Huong Le
Maria Le
Phuongtham Le
Viet Le
Khoeun Leang
Michel Lebel
May Ledermann
Jun Lee
Kwangdeok Lee
Raymond Lee
Mulatu Letabo
Nancy Lewis
Yimin Li
Lindsay Liechty
Lisa Lim
Sue Linder-Linsley
Ellen Lipes
Gustavo Litovsky
Grace Liu
Min Liu
Wanzhan Liu
Natasha Lohray
Christopher Longpre
Roberto Lopez
Victor Lopezdenava
Hang Louth
Austin Lu
Phoebe Lu
Charles Luevano
Dil Luitel
Bibin Lukose
Edward Lundberg
Thinh Luu
Tuong Ly
Yongting Ma
Kent Magnuson
Melissa Maguire
Yogish Mahadevaiah
Sivaganesh Maharajan
Kim Mai
Carol Majanga
Shikha Malik
Carlo Malkoun
Garrett Malone
Sravan Mamidi
Gopinath Mani
Shelly Mannion
Sangeeta Mantripragada
Cedric Marionneaux
Yanira Marquez Rodriquez
Wendy Martin
Audrey Martinez
David Martinez
Brad Maruca
Rubina Masal
Richard Mascarenhas
Forest Massey
Abraham Mathews

Betty Mathews
Josh Mathews
Kusumam Mathews
Raman Matiana
Thet Matthews
Ken'Drea Mayes
Ogechi Mba
Cindy Mcbride
Hailey Mccurry
Lauren Mcdonald
Ronnie Mckan
Rosaria Mclemore
Cameron Mcpherson
Casey Mcquaide
Daniel Mcquaide
Scott Mcreynolds
Carole Meade
Anissa Meche
Gerardo Medina
Aneri Mehta
Vrunjal Mehta
Janine Meinhardt
Hanna Melese
Yang Meng
Kelli Merk
Martin Meyerhardt
Nigest Mheretie
Chinhyuinh Miao
Otis Michaud
Keenan Middleton
Diva Milians
Neidi Miller
Gary Mink

Jake Mireles
Yatish Mistry
Swathi Modem
Abhay Modi
Netsanet Moges
Iliyas Ali Mohammad
Arif Mohiuddin
Jennifer Mon
Susan Moncy Tharakan
Daniel Moore
Tonja Moore
Linda Morgan
Sovannary Moung
Rashmi Moza
Romesh Moza
Namish Mpeti
Hetal Mukesh Gandhi
Swetha Mulgae
Gert Muller
Mohammad Munawar
Mahamadrafik Munshi
Anthony Murphy
Dan Murphy
Michael Murphy
Karlene Murray
Prashanth Muthuram
Shameka Myers
Purna Nallamothu
Ameya Nanivadekar
Sadia Naz
Toni Neal
Amelwork Negash
Avery Nelson

Steven Newcomb
Monica Ng
Alex Nguyen
Anna Nguyen
Baothuy Nguyen
Dennis Nguyen
Karen Nguyen
Mai Nguyen
Mary Nguyen
Selena Nguyen
Zoan Nguyen
Lisa Nitzschke
Veronica Nix
Robert Nobles
Ernest Nolan
Vikki Nordeen
Alliance Nshamamba
Scott Obrien
Jeffrey Obumseli
Jane Odom
James Oesterling
Ozioma Okeke
Alexandra Oliveros-Villalba
Cody Olson
Janai Onguti
Melanie Oprea
Richard Ornelaz
Denis Ortleb
Lindsey Ostrander
Stella Osuji
Anna Ovalle
Kishore Padmanabha Rao
Marco Paez

David Page
Luisa Palomino
Hemanth Pancha
Wesley Pao
Hyun-Joo Park
Angela Parker
Barbara Parker
Shirley Parker
Christopher Partee
Bhanu Patel
Dipika Patel
Hirenkumar Patel
Jyoti Patel
Niki Patel
Saurin Patel
Seema Patel
Yagna Pathak
Ajinkya Patil
Lisa Patty
Manoj Paul
Steven Peck
Vineela Reddy Peddamallu
Venkat Penaganti
Samuel Perdomo
Adriana Perez
Precious Perkins
Roger Perrier
George Peters
Kristin Peters
Noah Peterson
Dao Pham
Thuha Pham
Dianna Phan
Hoan Phan
Lan Phan
Narin Phan
Thuy Phan
Tom Phan
Tram-Huong Phan
Marinna Run Phann
Drew Phillips
Nida Phillips
Rath Pin
Susmitha Pingali
Rodney Poche
Crystal Pomeroy
Matthew Portman
Pinakin Potdar
Jason Pounds
Timothy Powell
Rin Prak
Kevin Propst
Cherise Pruitt
Kyle Pulley
Asish Punnoose
Timothy Quillin
Gavin Rade
Elnaz Rahman
Aaron Raines
Shammarre Rajigadoo
Lee Ramirez
Jenish Rana
Kanchan Rana
Harkinder Rangi
Tom Ratenski
Himanshu Arun Raut
Steven Ravenscraft
Manaswini Ravisankar
Moe Rawshdeh
Thomas Rea
Manasi Reardon
Govardhan Reddy
Sherry Rice
Patricia Richard
Amanda Richardson
Gina Rickard
Graham Ridgard
Gabriel Rivera
Hermes Rivera
Syed Haider Imam Rizvi
Frances Roberts
Irene Robertson
Sarah Robeson
Asia Robinson
Ricardo Robledo
Boris Rodionov
Aurora Rodriguez
Blanca Rodriguez
Daniel Rodriguez
Luis Rodriguez-Lopez
Barry Rogers
Erika Ross
Richard Rousseau
Jenna Roycraft
Erika Rubalcava
Allison Ruebsamen
Brandon Ruebsamen
Yvonne Rueter
Kathlena Ruiz

Rodrigo Ruiz
Vanessa Rutledge
Dana Saeed
Puja Saha
Mohit Sahay
Sudhanshu Sahoo
Mike Salehi
Claudia Salgado
Dena Salsman
Irene Sanchez
Jorge Sandoval
Orlando Sandoval
Jannie Sanford
Sokhom Sann
Sonia Santimano
Nabraj Sapkota
Towanda Sasser
Macie Schmitt
Jeremy Schwark
Dorothy Scott
Kriss Scott
Markeisth Scott
Sherry Scott
Vince Scott
Martha Sekum
Taing Sengheu
Luis Sepulveda
Eisa Shafek
Tricia Shafer
Jagatkumar Shah
Ronnie Shalev
Jim Shanahan
Ilango Shanmugavelu
Rudresh Shantamurthy
Palka Sharma
Taruna Sharma
Jennifer Shepard
Yanwei Shi
Lester Shreffler
Ami Shrestha
Ruth Siddiqi
Daniel Silion
Priscilla Sim
Wogayehu Sima
Yetimwork Sima
Garnetta Simons
Anjali Singh
Parminder Singh
Joe Sipper
Manjunath Sirigiri
Simon Skariah
Prachi Slominski
Linda Smallwood
Brenda Smith
Lonnie Smith
Luke Snow
Ren Sode
Debra Soule
Paige Sovern
Brian Sparks
Cory Spence
Andrew Sprick
Jessica Stafford
Joe Standridge
Mark Steer
Kharyl Stephens
Angel Stevenson
Todd Stirman
John Stockton Ii
Carla Stokes
Annie Stovall
Shelley Stracener
David Strickland
Sean Strobel
Magesh Subbarao Rengabashyam
Selima Sultana
Li Sun
Swetha Sunil Kumar
Tim Swinehart
Jennifer Swittens
Heidi Syndergaard
Nabila Tabassum
Muluwork Tadesse
Zil Talati
William Talton
Elias Tarsinos
Vitalis Tasi
Brian Taylor
Naytasha Taylor
Said Tbaini
Melese Teklu
Amy Templeton
Hana Terefe
Aberham Tezera
Sandhya Thakur
Sreetharan Thankathuraipandian
Ronak Thawani
Shradha Thokala

David Thomas
Joyce Thomas
Edward Thompson
John Thompson
Lisa Thornhill
Menbere Tiba
James Tidwell
Nam Tieu
Kent Tillman
Ralph Ting
Sharath Chandra Tipparthi
Hanna Tiruneh
Martha Tobias
Tucker Tomlinson
Merle Torres
Vibol Touch
Carol Tovan
Xuan Tram
Dung Tran
Gina Tran
Vinnie Tran
Stephen Trieu
Ann Trinh
Janja Trtanj
Walter Truitt
Anitra Tucker
Nasir Uddin
Jeffrey Urbanski
Makyori Urbina Mink
Cecilio Uribe
Jose Valdez
Kausik Valeti
Abbey Van Booven
Abraham Vargees
Alice Varghese
Philip Varughese
Phanindra Vasireddy
Edward Velasquez
Rosemary Velasquez
Ruben Javier Velez
Helen Veneziale
Nishant Verma
Shelby Via
Jose Viana
Gagan Vijay
Roland Villania
Mireya Villegas
Hoang Vo
Shirley Vo
Jordan Vogel
Binh Vu
Dung Vu
Mirjana Vukich
My-Lien Vuong
Dalton Wachel
Wayne Waite
Don Walden
Janet Walker-Rust
Nicolette Wallaert
Curt Wallgren
Jenifer Walsh
Xiaochen Wang
Yun Wang
Zhichao Wang
Amanda Ward
Andrew Washington
Brittini Washington
Felecia Washington
Alexander Weaver
Patrick Weeks
Catherine Wehland
Kai Weitekamper
Bruce Weldum
Stephen Wheeler
Lauran White
Craig Whitfield
Marilyn Whitlock
Heather Whittington
Andrea Wilcox
Rebecca Wilkins
Dallas Wilkison
Brian Williams
Kegan Williams
Wesley Winfrey
Adam Winkle
William Winstrom
Elhum Wood
Stephen Wood
Scott Wright
Li Wu
Shu Wu
James Wucher
Zhentian Xie
Bing Xu
Ying Xu
Dong Xue
Tao Yan
Abdulia Yankson
Verda Yates

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020 — Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14E

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 2305 Walnut St.

City: Roseville State: MN Zip: 55113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (925) 734-4071 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Lucy.Tan@Abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (925) 734-4071 Email: Lucy.Tan@abbott.com
Contact Person Name: Lucy Tan

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____
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 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 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**	✓			
• **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.

Lucy Tan

Print Name of Authorized Person Submitting Application

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Processed 1/20/22

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

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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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John
- Funck, Jr., Robert

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- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian
- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

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LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A

CERTIFICATE OF GOOD STANDING

April Veoukas
Director, Regulatory Affairs
Strategic Regulatory Affairs
Abbott Quality & Regulatory

Abbott
D-03Q4, AP52
200 Abbott Park Road
North Chicago, IL 60064
T: +1 224 667 8197
april.veoukas@abbott.com

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Via Email (m.herrera@pharmacy.nv.gov & pharmacy@pharmacy.nv.gov)

December 16, 2021

Dear Maria Herrera,

In response to your December 7 email, enclosed please find the home state licenses in support of our 12 Nevada State Board of Pharmacy Wholesaler Applications for the wholesalers and facility locations identified in the table.

Wholesaler	Facility Location	Home State License
1. Abbott Laboratories Inc.	3158 Martin Luther King Jr. Drive, North Chicago, IL 60064	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10
2. Abbott Laboratories Inc.	1921 Hurd Drive, Irving, TX 75038	See attachment A
3. Abbott Laboratories Inc.	1915 Hurd drive, Irving, TX 75038	See attachment B
4. Abbott Laboratories Inc.	15900 Valley View Court, Sylmar, CA 91342	See attachment C License Number: 115222 Certificate is in the mail after confirmation from the renewal process.
5. Abbott Laboratories Inc.	6901 Preston Road Plano, TX 75024	See attachment D
6. Abbott Laboratories Inc.	2305 Walnut Street, Roseville, MN 55113	Minnesota State does not license medical device distributors.[2] Minn. Stat. § 151.01
7. Abbott Laboratories Inc.	42301 Zevo Drive, Suite #F, Temecula, CA 92590	See attachment E
8. Abbott Molecular Inc.	1300 East Touhy Avenue, Des Plaines, IL 60018	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10

[1] The Illinois Dept. of Financial and Professional Regulation states that no licensing is required in order to warehouse and/or distribute such product in or out of the State of Illinois. The requirements of licensure and practice are provided by the Act and Rules in Administrative Code, 68 Ill. Adm. Code 1510.10. Definitions of "wholesale distribution" and "prescription drug" do not include medical devices.

[2] Minnesota state does not license medical device distributors by the office of Minnesota Statues, Minn. Stat. § 151.01. Definitions of "prescription drug", and "manufacturing" do not include medical devices.

File Number 5972-555-6

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 I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT LABORATORIES INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON DECEMBER 19, 1997, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801582 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White
SECRETARY OF STATE

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

Authentication: 203983224

Date: 08-23-21

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

Steven Yauch	Laizu Zaman	Jiajun Zhang
Jammie Yaw	Pawneez Zamani	Mingming Zhang
Woineshet Yimer	Fan Zhang	Wenhao Zhang
Tewabech Yirgu	Guoshuai Zhang	Muhammad Zia

ALI Roseville Facility

The workers at the ALI Roseville facility are as follows:

Abdifatah Abdullahi	Corey Cerveny Cermak	Hel Mu
Abdifatah Ahmed Mohamed	Craig Tommeraasen	Herman Liundaunda
Abdifitah H Adam	Daniel Alan Anderson	Hue Vue
Abdirazaq Mohamed	Daniel Amtataw	Ian James Macmillen
Abdullahi Khadar	Daniel Perez	James J King
Abigail Turner	Darrell X Peterson	James Travis Hocker
Adam Roy Fried	Darryl Barber	Jeff Wehner
Adenike X Kazeem	Daud Farah	Jeremy Garner
Ahmed Ibrahim	David Needom	Jeremy Mccawley
Alison Hagen	David Tran	Jerrica Donald
Amin Ali	David Wade	Jess Smith
Andray E Jones	Divine L Bilbro	Jethro Vang
Angel M Mora	Dylan Charles Hopkins	Jim Kauffmann
Anthony J Moe	Edward Nanabanyin Lewis	Joe Twohy
Ashley E Morris	Edwin Jeffery	John Dai
Asia Washington	Elvis Cid	Johnny Solangkoun Lee
Baird Matthew Cuppy	Elvis N Moua	Jon Bodin
Benjamin D Hahn	Emily A Chipman	Jon Douville
Beth Coverdale	Emmanuel Gutierrez	Jordan Schulte
Blake M Timm	Erik Alexander Vold	Josilyn Smith
Bradley G Sackey	Francine Marie Christiansen	Juan Duran
Brian Marlon Starks	Fred Douglas Collins	Juan Osborne
Carlos Hernandez	Gopal Chuwan	Julius Momo
Chao X Yang	Hatim Mohamed	Keen Thao
Christopher N Baden	Heidi Miranda-Pino	Keith L Tell

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 15900 Valley View Court

City: Sylmar State: CA Zip: 91342

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (818) 493-3884 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Tina.Romo@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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. Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

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SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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: Refer to addendum for responses.
Address: City: State: Zip:

Name: Refer to addendum for responses.
Address: City: State: Zip:

Name: Refer to addendum for responses.
Address: City: State: Zip:

Name: Refer to addendum for responses.
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (818) 493-3884 Email: Tina.Romo@abbott.com
Contact Person Name: Tina Romo

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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:
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 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 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**	✓			
• **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.

Tina Romo

Print Name of Authorized Person Submitting Application

Tina Romo

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc Paid 1/20/17

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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John
- Funck, Jr., Robert

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- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian
- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

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LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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Colleen Canan
Abbott Medical - 115222
DBA: Abbott Medical, St. Jude Medical Cardiac Rhythm Management.
15900 Valley View Court
Sylmar, CA 91342

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Abbott Medical
DBA: Abbott Medical, St. Jude Medical Cardiac Rhythm Management.
15900 Valley View Court
Sylmar, CA 91342

LICENSE NUMBER: 115222
EXPIRATION DATE: 12/9/2023

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.

From: Rodriguez, Albert@CDPH <Albert.Rodriguez@cdph.ca.gov>
Sent: Monday, December 13, 2021 1:51 PM
To: Canan, Colleen <colleen.canan@abbott.com>
Subject: RE: Your application for a Medical Device Manufacturing license for the Sylmar facility

EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.

Hello Colleen,

Thank you for submitting the amended application. I have recommended your firm's license for renewal. Please allow 2-4 weeks to receive the license certificate in the mail. In the meantime it can be considered that your firm has license number 115222.

Thank you,

Albert Rodriguez
Drug and Medical Device Specialist
California Department of Public Health
Drug and Medical Device Compliance and Enforcement
2 MacArthur Pl., Suite 100
Santa Ana Ca. 92707
714-957-6909

EXHIBIT A

CERTIFICATE OF GOOD STANDING

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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

Authentication: 203983224

Date: 08-23-21

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

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	ABBOTT LABORATORIES INC. WHICH WILL DO BUSINESS IN CALIFORNIA AS ABBOTT SALES, MARKETING & DISTRIBUTION CO.
File Number:	C2062341
Registration Date:	12/08/1997
Entity Type:	FOREIGN STOCK CORPORATION
Jurisdiction:	DELAWARE
Status:	ACTIVE (GOOD STANDING)

As of September 19, 2021 (Certification Date), the entity is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect 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 September 20, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: Z12KEEY

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at *bebizfile.sos.ca.gov/certification/index*.

Kepha Ogato
Mark Oglesby
Anthony Onubogu
Jesse Oyervides
Swetha Paritala
Jerred Parkhurst
Martin Parra
Nayan Patel
Trusha Patel
Andrew Patin
Nguyen Pham
Marvin Phillips
Derrick Phillips
Kimberley Pierce
David Pitts
Tremeka Player
Christopher Porter
Martin Posada
Malinda Powell
Fredrick Prather
Doletta Prowell
Komal Puranik
Marco Quiroz Vargas
Divyapriya Raghavan
Kamini Rao
Tariq Rehman
Joe Reyes
Timbresha Reynolds
Hazel Riley
Marcello Robinson
Shawn Rodney
Luis Rosas
Perla Ross
Mohammed Saaid
Rawan Sadiq
Jessie Samaniego
Mandel Sanders
Osayd Sawalha
Amna Shamim
Edward Sheriff
Bimal Shrestha
Molly Silvers
William Silvers
Dexter Simmons
Kynnedee Skillern
Rodney Smith
Latoya Smith
Nathan Smith
Paul Smith
Michele Smith-Waheed
David Solis
Paul Sonthavong
Antonio De Jesus Soto-Gomez
Leslie Stamper
Theresa Stephens
Lillie Steward
Mayor Talabi
Dalyn Talavera Roman
Bryant Tate
Marcus Thomas
Arthur Thompson
Hoang Tran
Gloria Turner
Emmanuel Ugochukwu
Michael Umunnakwe
Juan Vasquez
Vincent Vinh
Lan Vu
Tesfaye Waktola
Pamela Walker
Keith Walker
Michael Warne
Antaishia Welch
Karen Wells
Richard Welter
Jonathan Whiteley
Charlene Williams
Earl Williams
John Wilson
Derrick Wilson
Christopher Yarnell
Frederick Yeboah
Michael Zavosky
Shadi Zumut

ALI Sylmar Facility

The workers at the ALI Sylmar facility are as follows:

Adnan Abbasi
Taraneh Abdollahi-Fard
Sherinay Abdukerim

Kristin Abele
Abraham Abrahan
Andrew Acosta
Juan Adames
Mary Adams
Lilia Adatan
Lisa Adlhoch
Kopal Agrawal
Noel Agredano
Jennifer Aguero
Claudio Aguilar
Jose Aguilar
Cindy Aguinaga
Renalyn Agustin
John Ahearn
Amir Ahmadi
Kazi Ahmed
Carole Akins
Akshay Akkineni
Bharat Reddy Akunapuram
Jose Alabat
Nadia Alam
Abdullah Alasfar
Oscar Alba
Michelle Aldana
Lionel Ali
Saman Ali
Wesley Alleman
Michelle Almanza
Omar Almousilli
Boris Alonzo
Jaime Altamirano
Daniel Alvarado
Samantha Alvarado
Jorge Alvarez
Arafat Amat
Jorge Amely-Velez
Marlena Amirkhanyan
Godfrey Anandan
Alfred Andres
Lilian Angeles
Manisha Annam
Jose Luis Aparicio
Mariela Aponte
Leonard Apontti
Christopher Arabia
Sonali Arangil
Beatriz Araujo
Jana Arbogast
Vishnu Prasad Arcot Ethirajan
Abdul Arghandehwal
Penelope Arguello
Mohammed Arif
Andrew Arp
Zachary Arteaga
Fnu Arushi
Shoorideh Asgari
Mehdi Asgharzadeh
Suhanya Ashok
Pratibha Ashok Kumar
Lakshmi Attaluri
Diane Austin
Jess Austin
Rodolfo Avalos
Rozio Avalos
Cassandra Avila
Gerardo Avila
Robert Avila
Ashley Axelrood
Mario Ayala
Melissa Ayala
Madhavi Ayyalasomayajula
Boris Ayzen
Arash Azarmi
Elias Azzam
Derek Baba
Vashtie Bachan
Johanna Baena-Rivero
Michael Baffoni
Benjamin Bailey
Adrian Baima
Noreen Bajwa
Lisa Bakoo
Karthik Balakrishnan
Samuel Balaskas
Jamal Balkhi
Arnab Banerjee
Trung Banh
Monika Bararia
Chirag Barchha
Bonnie Barnes
Brian Barnes
Grant Barnes
Brian Barr
Ramon Barraza
Santiago Barrera
Ma-Paz Barrientos
Kristin Bass
Abhinaba Basu

Elizabeth Bautista-Cisneros
Robin Beasley
John Becker
Joel Bedoya
Himansu Behera
Negin Behzadian
Prerna Belani
Carmelino Beleno
Jack Belshé
Beatriz Beltran
Emily Benedict
Homer Benitez
Simone Benjamin
Christina Bentello
John Bereziuk
Luis Bernal
Glenn Bersabe
Gregory Bevan
Deivid Beytayoub
Rupinder Bharmi
Avi Bilu
Pulkit Bisen
Arya Biswas
Alyssa Blacker
Brian Blazer
Robert Blunt
Madhusudhan Bodapati
Craig Boggs
Shadi Bohlool Kheibari
Maribel Bonilla
Walter Bonilla
Daniel Booth
Jasmine Borbon
Samira Bordji
Arielle Borisov
Alexander Bornzin
Gene Bornzin
Swaralipy Bose
Alicia Botham
Donald Bowman
Serguei Bozin
Jason Brader
Rhoneil Bragasin
Maria Bravo
Atiba Brereton
Donovan Brill
Nicholas Brodsky
Robin Brosman
Erik Brown
Tiffany Brown
Wesley Brown
Sarah Brown-Gallardo
Kyle Browning
Paul Buckley
Carl Buice
Laura Burckhardt
Kristina Burkwald
Ajith Burra
Silvia Buskett
Jaydrath Butala
Belinda Cabrera
Cesar Cabrera
Hector Cabrera
Luis Cabrera
Orlando Cabrera
Lisa Caffee
Gia Cai
Bruce Cain
Todd Callahan
Anna Calleja
Raul Campos
Colleen Canan
Altheos Canares
Liliana Cancino-Zepeda
Nancy Canizalez
Diming Cao
Hai Cao
Mai Cao
Armando Cappa
Percival Carino
Maribel Carlos
Drew Carlson
Ricardo Carrillo
Scott Carroll
Maria Castillo
Richard Castillo
Michael Castroverde
Arthur Cayabyab
Martha Ceballos
Sylvia Ceballos
Atenea Ceniceros
Leslie Centeno
Scott Centurion
Elsie Cervantes
Loreto Cervantes
Osma Chacon
Mrunalini Chaduruppa
Seshank Harsha Chaganti
Marisa Chaides

Cynthia Chan
Wendy Chan
Brian Chang
Kunal Chaniary
Steve Chantasirivisal
Vishnu Charan
Katrina Charitonuk
Puja Chaudhry
Dolores Chavez
Princesa Chavez
Rachel Chavez
Ramona Chavez
Sylvia Chavez
Nitika Chellappa
Darren Chen
Eric Chen
Felix Chen
Jonathan Chen
Xi Lin Chen
Xiangqun Chen
Xiaofeng Chen
Billy Chhoet
Nathan Chiang
Shichan Chiang
Theodore Chiang
Rohithkumar Chilagani
Michael Childers
Ellen Cho
Han Cho
Jorge Chong
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Santosh Chopade
Chirawat Chotikasupaseranee
Timothy Chou
Brett Christensen
Charlene Chua
Martha Clark
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Juan Cobieya
Lesa Conemac
Joseph Connell
Maria Contreras
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Nicole Cooper
Brooke Cormane
Michael Corner
Chris Corral
Cecilia Cortez
Daniel Cortez
Edna Cortez
Martha Cortez
Sarai Cortez
Veronica Covarrubias
Jesus Cristerna
Maria Cruz
Michael Cruz
Monica Cruz
Francis Cunningham
Anmol Dabra
Asghar Dadashian
Naveen Daggumalli
Nirav Dalal
John Dale
Ariel Dalisay
Emily Dalsgaard
Dro Darbidian
Arindam Das
Puviarasu Dasarathan
Geoffrey Daush
Kelly Dauven
Cristina David
William Davies Jr
Daryel Davis
Kelley Davis
Kevin Davis
Robin Davis
Fady Dawoud
Kristin Day
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Princes De Guzman
Ricardo De Guzman
Marisol De Los Rios
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Pakapol Dechathong
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Julia Denison
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Jamie Flores
Michael Flores
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Nancy Flores-Fonseca
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Peter Fong
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Jacob Freeman
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Maria Garcia
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Nathan Garcia
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Leila Ghanbari
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Ronald Gibson
Ravikanth Giguru
Mirna Gil
Jong Gill
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Rachanda Gilmore
Joseph Ginete
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Aditya Godara
Armando Godinez
Aditya Goil
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Frank Gomez
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Arturo Gonzalez Jr
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Mustajab Khan
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Manasi Khare
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Matthew Lanoue
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Reina Lasrado
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Dylan Lazar
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Jose Lepe
Luis Ley-Soto
Anthony Li
Chunpeng Li
Minyi Li
Perry Li
Shuo Li
Weiming Li
Wenwen Li
Xiang- Shawn Li
Xinghong Li
Zhilun Li
Bing Lian
Laura Licht
David Lidd

Travis Lieber
Maung Lin
Michael Linan
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Jorge Lizarraga
Juanita Llamas
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Alisia Lombardi Townson
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Isaac Loveless
Morgan Low
Georgia Loya
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Will Lui
Wilson Lui

Veronica Luna-Barraza
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Tu Luong
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Jnanardhana Lutchman
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Henry Ly
Hung Ly
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Erika Lyon
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Rigoberto Macedo
Guadalupe Machuca
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Arpit Macwan
Denielle Maddux
Praveen Madhusudanan
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Nuria Mahmood
Sammy Mahmood
Karthik Majgi
Ara Malayan
Neha Malhotra
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Lidia Mejia
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Cristian Mendoza
Zach Mendozza
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Lupita Menjivar
Brent Mercado
Imad Merkhan
David Merrill
Ailyn Mesia
Gemma Mesia
Noli Mesia
Josie Messina
George Mettee
Micah Meulmester
Elizabeth Meurer
Magdy Michael
Vanessa Michel
Lorenia Miguel
Aaron Milam
Dawn Miller
Garrick Miller
James Miller
Lisbet Miller
Paul Miller
Will Miller
Jordan Millikan

Susan Miner
Alejandra Miranda
Mariaester Miranda
Majid Mirpour
Vonnie Mirzakhanian
Aamer K Mohammed
Guadalupe Mojica
Evan Molenda
Stella Molina
Hamid Montazeri
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Isabel Morales
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Marisela Morales
Soledad Morales
Reuben Morrison
Bobbie Morrow
Gabriel Mouchawar
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Paula Moyes
Charles Muchina
Marina Muchnik
Sriveni Muddani
Diane Muff
Arjun Mukundan
Nithun Reddy Mula
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Donik Mullaademi
Maria Mulvoy
Jeffrey Mumford
Freidrich Munoz
Vlad Munteanu
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Vardan Muradyan
Vaibhav Murali
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Sunil Kumar Muthyala
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Piyush Nagar
Jessie Leah Nagler
Sajiv Nair
Pradip Nandre
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Martin Navarro
Praveen Nayani
Charan Neella
Angela Neira Franco
Anita Nepal
Jordan Nevo
Binh Ngo
Andrew Nguyen
Bao Nguyen
Christopher Nguyen
Cuong Nguyen
Hung Nguyen
Jimmy Nguyen
Lam Nguyen
Le Nguyen
Sonny Nguyen
Thong D Nguyen
Thu Nguyen
Trang Nguyen
Jayde Nichols
Peter Nichols
Stella Nichols
Barbara Nielsen
Jessica Nilsen
Kyle Nix
Akira Noda
Deja Nolasco
Nicholas Nolasco
Jorge Nunez
James Nunnelley
Karla Nuno-Silva
Norah Nyangau
Benjyna Obasuyi
Anna Ochoa
Ruben Ochoa
Sylvia Ochoa-Manriquez
Martina Odusanya
Seung Min Oh
Juanita Ojeda
Minerva Ojeda
Balerio Ontiveros
Carmen Ontiveros
Lilibeth Ontiveros
Sarun Orn
Carlos Ortiz
Elizabeth Ortiz
Robert Ortiz
Bivian Osorio
Kim Otterbach
Jaime Ovalle

Keanu Paar
Richard Pacana
Eloy Padilla
Luz Padilla
Maria Padilla
Nora Padron Perez
Glenda Pagan
Luzviminda Page
Armando Palad
Richard Palomares
Jenny Pan
Vatsal Pankaj Panchal
Pritha Pandey
Mukta Pandya
Sandeep Kumar Pandya
Crystal Papp-Austin
Thaddeus Parco
Jason Park
Seung Park
Yong Park
Christopher Parrillo
Ezequiel Partida
Sarah Pashaie
Akash Patel
Dhruvil Patel
Jignesh Patel
Mehul Patel
Mit Patel
Mitul Patel
Pruthvish Patel
Rahil Patel
Ritu Patel
Shrineel Patel
Bijal Patel- Jain
Ketaki Pathak
Tanay Pathak
Archana Patil
Tushar Patil
Magnolia Patino
Tisul Pattnaik
Doug Pearce
Glenville Pecor
Sai Charan Peddi
Elijah Peeters
Licet Peeters
Xing Pei
Sepiuta Pele
Ignacio Pena
Garrett Perdue
Anthony Pereida
Clemente Pereida
Nalin Perera
Jeanette Perez
Juan Perez
Omar Perez
Pablo Perez
Matthew Perkins
Chris Perlman
Giacomo Pescetti
Ragini Peters
Mandy Peterson
Quang Pham
To-Quyen Pham
Minh Phan
Raymond Phan
Mei Phelps
William Phillips
Suresh Kumar Pichumani
Desiree Pineda
Guillermo Pineda
Jeanne Pistillo
Denise Plascencia
Aaron Plata-Ruiz
Ronald Platz
Enid Pliego
Traci Plumb
Laura Ponce
Josch Pontiveros
Kari Poole
Charles Pope
Christopher Pope
Lori Pope
Caleb Porter
Srinath Pottam
Richard Powell
Susan Powell
Christian Prado
Rafael Prado
Shalvin Prakash
Monique Prue
Taryn Prue
Allen Anthony Puerto
Vishwanath Puggera
Manoj Kumar Pusala
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Emanuel Quezada
Bernard Quinn

Jorge Quintero
Sara Rabin
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Sassan Rahbari
Kunnath Rajendran Fidel Raj
Deepak Ramakrishna
Susmitha Ramakrishna
Chandramohan Ramamoorthi
Rengasamy Ramasamy
Marlon Rambuyan
David Ramirez
Dolores Ramirez
Erin Ramirez
Juan Ramirez
Michael Ramirez
Patricia Ramirez
Alberto Ramirez Jr
Dolapaul Ramsey
Kuldeepsinh Rana
Pooja Rana
Wendy Rangel
Paul Ranger
Yogesh Rathod
Vignarajan Ravindran
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Arnab Ray
Zaireen Razzak
Christopher Readmond
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Ramil Redondo
Jonathan Reilly
Nathan Reinhardt
Olga Renderos
Nuria Rendon
Catrina Revilleza
Eduardo Reyes
Efrain Reyes
Felipe Reyes
Ignacio Reyes
Lucila Reyes
Raymundo Reyno
Sofia Reynozo
Andrea Richardson
William Richardson
Alonzo Rico
Theresa Rini
Natalia Rios
Raul Rios
Leoncio Rivera
Ramona Rivera
Audrey Roa
Juan Robayo
Alexander Robertson
Darryl Robertson
Sheryl Robinson-Collins
Hector Robledo
Jenna Robledo
Qing Roche
Krupa Rocks
Ana Rodriguez
Irma Rodriguez
Juan Antonio Rodriguez
Ligia Rodriguez
Luisa Rodriguez
Maria Rodriguez
Monica Rodriguez
Orlando Rodriguez
Roberto Rodriguez
Hilario Rojas
Julio Romero
Laura Romero
Melissa Romero
Etelvina Romo
Robert Rooks
Jose Rosales
Miguel Rosales
Ofer Rosenzweig
Brian Ross
Megan Ross
Nancy Ross
Diane Rowland
London Rowlands
Thomas Rudolph
Karen Ruehl
Cindy Ruiz
Jorge Ruiz
Katia Ruiz
Max Ruiz
Renato Ruiz
Sonia Ruiz
Josephine Ruiz-Price
Felipe Rullamas
Kyungmoo Ryu
Jennifer Saba
Leyla Sabet
Nicholas Sachs
Mostafa Sadeghi
Kavous Sahabi

Nima Sahabi
Andranik Sahakyan
Charanjit Sahota
Marcia Salazar
Socorro Salazar
Alexander Salerno
Justin Salim
Adrian Salmon
Richard Salvador
Antonio Sanchez
Johanna Sanchez
Roberta Sanchez
Ruben Sanchez
Edgar Sandoval
Guadalupe Sandoval
Vanessa Sandoval
Sultan Sanni
Cynthia Santiago
Irma Santiago
Amanda Sargent
Juni Sarkar
Ranjit Sarpal
Tricia Sasaki
Haris Sattar
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Megan Schmidt
Christopher Schneider
Georgina Schnell
Justin Schofield
Robin Schwartz
Susan Scott
Andrew Segal
Voltaire Selverian
Prashant Sengar
Yelena Serebrennikova
Eric Serna
Eduardo Serrano
Elizabeth Servin
Aravind Seshadri
Dorab Sethna
Mohammed Shafir
Nayan Shah
Rachi Shah
Umeshkumar Shah
Reza Shahandeh
Atif Shaikh
Javed Shaikh
Yograj Sharma
Shaguna Sharma-Chhabra
Robert Shaw
Edward Shelafoe
Erik Sheldon
Younes Sherkat
Jay Sheth
Jess Shi
Simmy Shirazi
Amy Shousha
Binod Shrestha
Prakrit Shrestha
Baljit Shuven
Lorenzo Signey
Gabriela Silva
Rene Silva
Abhimanyu Pratap Singh
Anand Singh
Jonathan Singh
Navpreet Singh
Tejpal Singh
Aujencio Siojo Jr
Priyanka Sivadas
Melissa Sjoquist
Richard Skalma
Robert Sklenar
Szymon Skup
Chad Smith
Christopher Smith
Daniel Smith
Jillian Smith
Lynette Smith
Syaza Smith
Peggisue Snow
Rubal Sobti
Damon Sokol
Vadim Sokurski
Ezra Solis
Ruben Solis
Socorro Solis
Fabiola Solorio
Michael Solorio
Eric Somogyi
Zoltan Somogyi
Rupa Sonawane
Ge Song
Christopher Sorensen
Alex Soriano
Juan Sosa
Richard Soto

Laura Sparks
Cristina Sta Maria
Linda Staves
Yuri Stavitsky
Rochelle Stearns
Adam Stevens
Bruce Stofer
Brandon Stoltz
Boris Stolyarov
Daren Stone
Kevin Stout
Tyler Strang
Bradie Strauch
Stella Su
Ivan Suarez
Viswanath Subramaniam
Budankayala Subudhi
Atrish Sudheer Bhat
Jorge Sumaran Lopez
Stephanie Sun
Dilip Kumar Surapaneni
Apoorva Surat
Sanjeeb Swain
Katherine Swanson
John Szymanski
Leila Tabaa
Mariah Tackett
Javier Tafoya
Ali Taheri
Norayr Tahmazian
Katherine Talbert
Sina Taleban
Tian Tan
Dennis Tang
Glenn Tannenbaum
Jose Tarin
Nedal Tartir
Zohreh Tavakkoli
Nabil Tawil
Julianna Teixeira
Adelyn Tenorio
Brenda Terry
Sagar Thaker
Tejaswini Singh Thakur
Ashok Theyver
Sandeep Thodupunoori
Cristina Thomas
Linda Thomas
Sarah Thomas
Cam Thompson
Marivilla Tiatco
Steve Tieman
Thanh Tieu
Gopesh Tilvawala
Katherine Timashpolsky
Yash Vardhan Tiwari
Jonathan To
Rubina Todd
Berith Toledo
Jordan Toledo
Noah Tomaszewski
Shelly Tomson
Mark Tomusange
Claudia Torres
Jeanette Torres
Elizabeth Torrico De Trujillo
Cynthia Toth
Long Tran
Thinh Tran
Crystal Traverso
Arlene Trunnell
Jose Ramon Tuazon
Melissa Tucker
David Turgutyan
Wilfredo Ubaldo
Delisa Ubosi
Benedict Uiseco
Itong Ujile
Kristopher Ulstad
Tiffany Ulstad
Serdar Unal
Satyanarayana Prasad Unnam
Shivangi Uppal
Brian Urbaniak
Joanna Urbanski
Diana Urbina
Lourdes Urena
Muhammad Usman
Jeevan Uttarkar
Rahul Uttarkar
Breanna Uyeno
Michael Vaccaro
Irina Vainshtein
Raul Valdez
Erasmo Valencia
Margarita Valencia
Anna Valera
Ylie John Valeriano
Vazric Valijan

Heriberto Vallejo
Nina Valles
Perla Valles
Ricardo Vallin
Janaki Valluri
Margareta Vamos
Jordan Vance
Christopher Vargas
Krystal Vargas
Steve Vargas
Rajesh Vartekar
Corinne Vasquez
Mario Vasquez
Hemantkumar Vekaria
Melinda Velasco
Angel Velasquez
Regina Velasquez
Ernesto Velasquez Iii
Gaspar Venegas Jr
Indira Verdekel
Vicenta Verdi
Jamie Vermillion
Dee Vetter
Keith Victorine
Dianna Villafana
Alejandra Villalpando
Evelyn Villalpando
Gabriela Villalpando
Maria Villalpando
Ted Villanueva
Robert Villasenor
Mynor Villatoro
Brett Villavicencio
Fernando Villegas
Josefina Villegas
Aura Virula
Alec Vis
Christopher Vista
Braulio Vizcarra
Tam Vo
Alan Vogel
Mia Von Knorring
Melanie Vondersaar
Sam Vu
Tinh Vu
Shivangi Vyas
Morgan Walston
Amy Walter
Jan Walts
Hanbiao Wang
Justin Wang
Cynthia Webb
Roger Weber
Mark Welch
Samuel Wicoff
Tyler Wideman
Harry Wiesner
Vivian Wilcox
Lisa Wilford
Alexander Wilkins
Mary William
Eric Williams
Megan Williams
Sholone Williams
Richard Williamson
Thomas Willson
Kenneth Wilson
Pedro De Wit
Jacquelyn Withers
Kimberly Wittke
Jennifer Wong
Joshua Wong
Joy Wong
Randel Woodgrift
Jeffrey Wynn
Jianhui Xie
Xiyao Xin
Yifan Xu
Arthur Yabes
Dianna Yadao
Pooja Yadava
Jun Yang
Yuanyuan Yang
Stuart Yasukochi
Anupama Yaturu
Maria Yesayan
Man Sen Yeung
Wing Yan Yik
Leila Youssef
Daisy Yow
Joseph Yu
Marcus Yu
Stephen Yuan
Jinto Zacharias
Luis Zamora
Pamela Zamora
Armando Zarate
Frank Zawlocki
Lucy Zeng

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020 Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Abbott Laboratories Inc.

Physical Address: 42301 Zevo Drive Suite #F

City: Temecula State: CA Zip: 92590

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (951) 914-3325 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Sheryl.LaFond@Abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

SUPPLEMENTAL RESPONSES TO SECTION 2, QUESTIONS 1-5 OF NEVADA WHOLESALER APPLICATION
EXHIBIT B

ALI Applications -7

ALI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for North Chicago, Irving 1, Irving 2, Sylmar, Plano, Roseville and Temecula facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, neither Abbott Laboratories, Inc. nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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 West Distribution Center
Address: 42301 Zevo Drive City: Temecula State: CA Zip: 92590
Name: Lake Region Medical Limited
Address: Buttersland, New Ross City: Wexford Country, Ireland State: - Zip: -
Name: Coroventis Research AB
Address: Ulls Vag 29A City: Uppsala, Sweden 75651 State: Zip:
Name: Not applicable. Applicant distributes medical products and devices from the three above-referenced suppliers.
Address: - City: - State: - Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (951) 914-3325 Email: Sheryl.Lafond@abbott.com
Contact Person Name: Sheryl LaFond

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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:
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 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 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**	✓			
• **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.

Sheryl LaFond

Print Name of Authorized Person Submitting Application

Sheryl LaFond

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

August 26, 2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Accepted 1/20/22

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Laboratories Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Laboratories Inc. are listed below.

Directors

- Funck, Jr., Robert

Officers

- Ahlberg, Gregory
- Allen, Hubert
- Ambati, Venu
- Balthrop, Elizabeth
- Battaglia, Erica
- Boettiger, Keith
- Brotz, Melissa
- Burcky, P. Claude
- Calamari, Christopher
- Capek, John
- Chan, Tony
- Collins, Kathryn
- Dale, Michael D.
- Earnhardt, Lisa
- Evers, Thomas
- Ewing, Sabina
- Ford, Robert
- Frels, John
- Funck, Jr., Robert
- Gabay, Renaud
- Ginascol, John
- Haas, Jeffrey N.
- Halloran, Damian

- House, J. Scott
- Huang, Gene
- Johnson, Gary
- Kaesebier, Tara
- Karam, Sammy
- Kowalski, Daman
- Kunkler, Robert
- Lane, Andrew
- Lehman, Brian
- Leinenweber, Scott
- Manning, Joseph
- Mark, David
- McCoy, John
- Millerick, Shawn
- Moreland, Mary K.
- Morrone, Louis
- Murphy, John
- Nordenstahl, Martin
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Pederson, Michael J.
- Peterson, Karen
- Phillips, William
- Salvadori, Daniel
- Schneider, Ric
- Scoggins, Christopher
- Shroff, Eric
- Singh, Harvinder
- Tyler, Julie
- Wainer, Andrea
- Watkin, Jared
- Weitekamper, Frank
- Wellisch, Alejandro
- White, Miles
- Wilkins, Monica
- Woodgrift, Randel
- Yasger, Paul

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Laboratories Inc. owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

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CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit A attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A

CERTIFICATE OF GOOD STANDING

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STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DEVICE MANUFACTURING LICENSE

Abbott Vascular
DBA: Abbott West Distribution Center
42301 Zevo Drive
Temecula, CA 92590

LICENSE NUMBER: 46072
EXPIRATION DATE: 1/19/2022

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

Printed: 1/16/2020

Attachment E
Abbot Laboratories Inc.
42301 Zevo Drive, Suite #F, Temecula, CA 92590

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT LABORATORIES 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2803432 8300

SR# 20213050688

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

Authentication: 203983224

Date: 08-23-21

Kelsie Donaldson
Kent Lindquist
Kevin Lee
La La
Lakkia Carswell-Bey
Lay Dah
Lee Kou Moua
Louis Rowe
Lucky Choeung
Lucy Juma
Luis D Delangel
Lyle Cook
Mackenzie Osterdyk
Mandy Scott
Mark F Alpert
Massa G Kiazolu
Matt Barslou
Mauricio J Lopez
Maxwell Kangas
Melanie Yang
Melinda C Bakke Vandyne
Menhem X El Ashkar
Michael A Johnson
Michael Tereshko
Michael Van Ort
Mike O'Keefe
Minyi Hsieh
Mohamed Khadar
Muqing Li
Neal Mannel
Newton Xiong
Nicholas Huynh
Nimol Sok
Noel Christian Thingvall
Omar Ahmed Abdullahi
Pata Vang
Quintin Gossen
Rahshai Malik
Randy Burrows
Rich Smith
Richard C Cameron
Ross Olson
Ruth Cooke
Ryan Allen Heida
Ryan Baker
Ryan Behji
Samsam Abdi
Sarah V Feltault
Sharon Derhaag
Sheelah Vang
Tamara Growette
Terrence M Hogan
Theo Vue
Thomas Htoo
Thongwan Vang
Tina Dauphinais
Titus Sieh
Troy Perry
Tuyet T Nguyen
Ty Youngblood
William James Donlon Jr.
Xue Her
Yeleng Xiong
Yong Thao

ALI Temecula Facility

The workers at the ALI Temecula facility are as follows:

Lester, David B.
Adame, Elvia
Aguilar, Karen
Alkurdi, Sama S
Almaraz, Adriana R
Almiron, Charles F
Amy, Tyler
Anid, Dorian E
Arana, Maricela
Araujo, Janet
Arellano, Patricia
Avalos, Zulema Alejandra
Bannon, Donna L
Barragan, Carlos
Bennett, Tracey
Bergado, Alda Salarda
Bergado, Gregorio
Bergstein, Shalina A
Bigler, Carol
Blevins, Cynthia
Bright, Vicki Lynn

Brown, Hayley A
Brown, Jacqueline
Butto Roman, Luis A
Byler, Yolanda X
Carlisle, Ken
Castro, Maria Elena
Cavor, Ingrid J
Cicotte, Danielle
Clay, Laramie M
Corcoran, Tim
Craig, Crystal
Cunningham, Charles D
Davis, Christine G
Davis, Julie
De La Cruz, Marisela
De Leon-Hormuth, Maria Theresa X
Devore, Leah
Dimogiannis, Laura
Dodson, Jared C
East, Elaina Marie
Eknoian, Jacob
Espinoza, Gabriela
Evans, Gary
Evans, Kate
Evans, Raymond C
Flores, Kristine M
Fodor, David
Freeman, Nicole L
Galioto, Samuel
Garcia, David X
Garcia, Maricela
Garcia, Sonia
Garcia, Wesley X
Gonzalez, Jenny L
Gonzalez, Maria A
Gonzalez, Percilla
Gonzalez Castillo, Adelina
Goudswaard, Kyle
Groh, Linda
Guzman, Nicholas
Habib, Abdul-Raheem
Hafiz, Asida
Heredia Martinez, Ulises J
Hernandez, Alejandrina
Hernandez, Marvin O
Hock, Christine A
Hocson, Josefina S
Hurtado, Suzy
Inthilath, Lidta X
Jaqua, Marcy Anne
Johnson, Brittany
Johnson, Tawnee
Kearney-Johnson, Kelly A
Kelepouris, Daniel
King, Shannon
Lambert, Eugene
Lambert, Norma
Lance, Jerri Anne
Legaspi, Jeffrey S
Lewis, Debra L
Lewis, Rosa R
Lie-Perez, Greissy G
Lively, Cecilia
Lopez, Dora L
Loza, Adrian
Loza, Estela T
Loza, Selina A
Luna, Jennifer
Macias, Roselda
Madden, Deborah A
Magallanez, Gregorio R
Mahabadi, Sherri L
Mantaring, Amancio G
Martinez, Catherine L
Martinez, Michelle
Marzano, Kelley X
Maxfield, Mark R
May, Tracy
Mckay, Elizabeth Tran
Medina, Sandra K
Metchikoff, Trisha
Meyer, Cynthia D
Miller, Alexandria
Mok, Peter
Molina, Daniel J
Mora Ibarra, Rosa E
Moreno, Johanna
Morris, Deborah Ann
Moss, Michael A
Nguyen, Andrew T
Nguyen, Kenny V
Nieto, Armando
Njuguna, Maureen
Nuno, Susana I
Olalia, Yemmi S
Orellana, Amanda
Ortega, Yvette
Padilla, Philda J
Paragas, Tammy

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

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

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

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Molecular Inc.

Physical Address: 1800 Brummel Avenue.

City: Elk Grove Village State: IL Zip: 60007

Mailing Address (if different from physical address): ____

City: ____ State: ____ Zip: ____

Telephone: (224) 361-7145 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Daniel.Egeland@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

AMI Applications 2

AMI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for its Des Plaines and Elk Grove facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the past 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the past 5 years.
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)?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the past 5 years.

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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 361-7145 Email: Daniel.Egeland@abbott.com

Contact Person Name: Daniel Egeland

Date of SEC Registration: See Addendum	SEC Registration Number: 0000001800	Stock Exchange Symbol: ABT

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: _____

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 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 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**	✓			
• **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.

Daniel Egeland

Print Name of Authorized Person Submitting Application

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Processed 1/20/2022

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Molecular Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on

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certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 8: FDA REGISTRATION

See Exhibit A attached hereto.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Molecular Inc. are listed below.

Directors

- McCoy, John

Officers

- Kaesebier, Tara
- Kowalski, Daman
- McCoy, John
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Yasger, Paul

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Molecular Inc. is owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

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CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit B attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
FDA REGISTRATION

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FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ABBOTT MOLECULAR, INC.
1300 EAST TOUHY AVENUE
Des Plaines, IL 60018
Registration Number: 3005248192
FEI Number*: 3005248192
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
ABBOTT LABORATORIES[6]
100 ABBOTT PARK RD.
D-03Q3, AP52-1
Abbott Park, IL US 60064
Owner/Operator Number: 1415939[7]

Official Correspondent:
Jennifer Sloan
1350 Touhy Ave
DV9JV
Des Plaines, IL 60018
Phone: 224-3617256

* 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=1415939&OwnerOperator
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Page Last Updated: 08/23/2021

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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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3. https://www.fda.gov/
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=1415939&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1415939&OwnerOperator

9. Abbott Molecular Inc.	1800 Brummel Avenue, Elk Grove Village, IL 60007	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10
10. Abbott Rapid Dx North America, LLC	569 Halls Mill Road, Freehold, NJ 07728	See attachment F[3]
11. Abbott Rapid Dx North America, LLC	5995 Pacific Center Blvd., Ste. 108, San Diego, CA 92121	See attachment G
12. Alere San Diego Inc.	829 Town Center Drive, Pomona, CA 91767	See attachment H

Thank you for your cooperation in this matter. If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

April Veoukas

Encs.

[3] Abbott Rapid Dx North America, LLC shares the 569 Hall Mill Road facility with its sister entity, Inverness Medical LLC (Inverness). Inverness is the leaseholder of the facility, and Inverness is responsible for all warehousing and distribution activities at the facility, including all operations for Abbott Rapid Dx North America, LLC. Inverness is registered as a manufacturer and wholesaler in the state of New Jersey (Reg. No. 5003126).

EXHIBIT B
CERTIFICATE OF GOOD STANDING

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT MOLECULAR 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2260476 8300

SR# 20213050692

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

Authentication: 203983230

Date: 08-23-21

Timothy Zurow

Michael Zwolinski

AMI Elk Grove Facility

The workers at the AMI Elk Grove facility are as follows:

Paul Alcala
Lynette Anderson
Patrick Dave Asuncion
Brandon Aviles
Zaven Bell
Fayth Cherry
Rocco Colella
Chelsie Crecelius
Raul De La Huerta
Al Estacion
Paul Hamilton
Latoya Haywood
Lisa Hogan
George Kalousek
Joseph Kalousek
Jason Kovack
Noah Leslie
Jason Licari
Eric Majewski
Fred Mcgill
Cecilia Mendoza
Dagoberto Ochoa
John Platt
Ronald Reagan
Nicholas Reed
Gregory Spears
Julia Strackhouse
Sandy Sweilem
Carmen Torres
Reece Whitehead
Michael Wiacek
Daniel Wienke

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14I

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Abbott Molecular Inc.

Physical Address: 1300 East Touhy Avenue

City: Des Plaines State: IL Zip: 60018

Mailing Address (if different from physical address): ____

City: ____ State: ____ Zip: ____

Telephone: (224) 361-7145 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Daniel.Egeland@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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.

AMI Applications 2

AMI supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for its Des Plaines and Elk Grove facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the past 5 years.
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?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the past 5 years.
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)?	To our knowledge, neither Abbott Molecular, Inc., nor Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the past 5 years.

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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 361-7145 Email: Daniel.Egeland@abbott.com

Contact Person Name: Daniel Egeland

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____

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 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 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**	✓			
• **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.

Daniel Egeland

Print Name of Authorized Person Submitting Application

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 CC ✓ Received 1/20/22

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Molecular Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on

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certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 8: FDA REGISTRATION

See Exhibit A attached hereto.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Molecular Inc. are listed below.

Directors

- McCoy, John

Officers

- Kaesebier, Tara
- Kowalski, Daman
- McCoy, John
- Novak, Joseph
- Oosterbaan, Benjamin
- Paik, Jessica
- Yasger, Paul

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Abbott Molecular Inc. is owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit B attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
FDA REGISTRATION

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ABBOTT MOLECULAR, INC.
1300 EAST TOUHY AVENUE
Des Plaines, IL 60018
Registration Number: 3005248192
FEI Number*: 3005248192
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:

ABBOTT LABORATORIES[6]
100 ABBOTT PARK RD.
D-03Q3, AP52-1
Abbott Park, IL US 60064
Owner/Operator Number: 1415939[7]

Official Correspondent:
Jennifer Sloan
1350 Touhy Ave
DV9JV
Des Plaines, IL 60018
Phone: 224-3617256

* 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=1415939&OwnerOperator
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Page Last Updated: 08/23/2021

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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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EXHIBIT B
CERTIFICATE OF GOOD STANDING

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April Veoukas
Director, Regulatory Affairs
Strategic Regulatory Affairs
Abbott Quality & Regulatory

Abbott
D-03Q4, AP52
200 Abbott Park Road
North Chicago, IL 60064
T: +1 224 667 8197
april.veoukas@abbott.com

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Via Email (m.herrera@pharmacy.nv.gov & pharmacy@pharmacy.nv.gov)

December 16, 2021

Dear Maria Herrera,

In response to your December 7 email, enclosed please find the home state licenses in support of our 12 Nevada State Board of Pharmacy Wholesaler Applications for the wholesalers and facility locations identified in the table.

Wholesaler	Facility Location	Home State License
1. Abbott Laboratories Inc.	3158 Martin Luther King Jr. Drive, North Chicago, IL 60064	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10
2. Abbott Laboratories Inc.	1921 Hurd Drive, Irving, TX 75038	See attachment A
3. Abbott Laboratories Inc.	1915 Hurd drive, Irving, TX 75038	See attachment B
4. Abbott Laboratories Inc.	15900 Valley View Court, Sylmar, CA 91342	See attachment C License Number: 115222 Certificate is in the mail after confirmation from the renewal process.
5. Abbott Laboratories Inc.	6901 Preston Road Plano, TX 75024	See attachment D
6. Abbott Laboratories Inc.	2305 Walnut Street, Roseville, MN 55113	Minnesota State does not license medical device distributors.[2] Minn. Stat. § 151.01
7. Abbott Laboratories Inc.	42301 Zevo Drive, Suite #F, Temecula, CA 92590	See attachment E
8. Abbott Molecular Inc.	1300 East Touhy Avenue, Des Plaines, IL 60018	Illinois state does not license medical device distributors.[1] 68 Ill. Adm. Code 1510.10

[1] The Illinois Dept. of Financial and Professional Regulation states that no licensing is required in order to warehouse and/or distribute such product in or out of the State of Illinois. The requirements of licensure and practice are provided by the Act and Rules in Administrative Code, 68 Ill. Adm. Code 1510.10. Definitions of "wholesale distribution" and "prescription drug" do not include medical devices.

[2] Minnesota state does not license medical device distributors by the office of Minnesota Statues, Minn. Stat. § 151.01. Definitions of "prescription drug", and "manufacturing" do not include medical devices.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT MOLECULAR 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 TWENTY-THIRD DAY OF AUGUST, A.D. 2021.

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

2260476 8300

SR# 20213050692

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

Authentication: 203983230

Date: 08-23-21

File Number 5978-567-2

To all to whom these Presents Shall Come, Greeting:

I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that

ABBOTT MOLECULAR INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON JANUARY 29, 1998, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 16TH *day of* AUGUST *A.D.* 2021 .

Authentication #: 2122801594 verifiable until 08/16/2022
Authenticate at: http://www.ilsos.gov

Jesse White

SECRETARY OF STATE

Parker, Johanna
Perez, Raul
Phommachanh, Jim
Ponce, Lorena
Potter, Brianna J
Quisquirin, Jason Mendoza
Quisquirin, Marian
Ramsthaler, Somphith I
Reisinger, Cathy
Reyna, Edward
Rodriguez, Maria
Romero, Joan
Ross, Erin Kathlene
Ruelas, Manuela L
Salcedo, Serena
Sayavong, Gayle B
Schluter, Terence Lorin
See, Liliana
Sen, Channmony
Shand, Sharon K
Shaw, Ann M
Simon, Jennifer N
Sipes, Joelle D
Socito, Noel E
Soliven, Julia
Somers, Vicki A
Soun, Janet Agustin
South, Emily F
Spowart, Judy L
Story, Rachel Camille
Taylor, Tamara S
Tengco, Victor
Touth, Hoeung
Uzeta, Marissa X
Villagrana Perez, Esmeralda
Villanueva, Wilma A
Walsh, Whitney
Wark, Ginette Marie
Willson, Leslie
Woodruff, Mary Geraldine Picar D
Ybarra, Melanie
Yumol, John Frederick Juan
Zeiss, Irma L

AMI Des Plaines Facility

The workers at the AMI Des Plaines facility are as follows:

Vineela Aari
Sara Abadi
David Aboagye
Anit Abraham
David Abramson
Klara Abravaya
Kathleen Aburano
Ryan Adams
Ekundayo Adetunji
Oluwatobiloba Adeyemo
Vince Adrian Palao
Anjo Agustin
David Ahumada
Kalyan Deepthi Akula
Erica Alansari
Xenia Alava
Maria Alba
Milagros Roschelle Alcala
Nebil Alchaar
Heather Alexander
Salima Ali
Ryan Aliff
Michele Alotti
Nabil Alqam
Nizar Alqam
Tateanna Alston
Donna Amada
Hina Amin
Daniel Ammer
Christopher Anderson
David Anderson
Drew Anderson
Lynette Anderson
Marc Anderson
Doris Andujar
Nicholas Ankenbruck
Dave Annett
Shafiqur Rahman Ansari
Helen Anteliz
Jhon Arvin Antonio
Eric Aoys
Karina Aranda

Sudheer Arapelly
Precila Arceo
Gerardo Arteaga
Nestor Arteaga
Rosalia Atienza
Ali Attarwalla
Rukayaaqsa Attia
Alex Austin
Nelson Austria
William Avila
Dawn Avis
Justin Awit
Moses Ayambire
Darren Daniel Bacol
Imelda Bahni
Mirza Baig
Julie Bailey
Robert Balano
Rommel Balauag
Alind Balbuena
Sarah Bang
Margarita Baquiran
Michael Angelo Baquiran
Patricia Barbato
Brianna Barbeau
Harshal Barot
Aminatou Barry
Marianne Bartek
Jeffrey Baryenbruch
Sarah Bascharon
Raymond Bastian
John Bates
Mansoor Batliwala
Camilla (Gryffon) Baum
Kathryn Becker
Christopher Beltran
Jesusa Benzon
Joshua Bernstein
Elizabeth Best
Edwin Betancur
Tanya Beyzin
Aminah Bhatti
John Birdsall
Daniel Bisciglia
Randy Blakley
Evy Blancaflor
Adrian Blancas
Marya Alena Blando
Brian Bolliger
Melanie Bonifacio
Holly Bouma-Johnston
Vincent Bowman
Jason Brandt
Timothy Brandvold
Aaron Brannon
Erika Breidenbach
Jpmartin Brillo
Mercedes Briones
Douglas Brobst
Jessica Brosch
Betty Brown
Christopher Brown
Michael Brown
Samantha Browne
Perry Brusenbach
Mary Buckner
Preciosa Buhay-Miller
Michael Bushen
Alfonso Butera
Adeola Butler
Grayson Cain
Felipe Calubaquib
Barbra Allen Cambay
Malcolm Alexander Campbell
Erin Canning
Anna Cantrell
Anthony Carabello
Benjamin Carlson
Jill Carstens
Warren Carter
Alicia Case
Harvey Castillo
Cristian Castillo Camacho
Rodel Cave
Maria Cervantes Vargas
Irene Chaplyk
Aashay Chavan
Maria Chavez Perez
Yu-An Chen
Yuliang Chen
Fayth Cherry
Philip Chiang
Hari Chirasani
Brian Choi
Won Choi
Erich Christ
Melissa Christoffel-Capoccia
Rosa Churchman-West
Gianguido Cianci

Steven Cielocha
Justin Ciula
Noreen Clancy
Deborah Clark
Michael Clemente
Anke Coblenz-Korte
Lisa Cole
Clarissa Collier
Raquel Colon
Erik Coman
Alanna Connors
Sean Conway
Paul Cook
Madison Cooley
Kevin Cortes
Ruther Cortiguerra
Segundo Cosio
Joleen Craig
Bob Cram
John Crossley
Robert Crowley
Annabel Cruz
Karen Cruz
Wesley Cruz
Malford Cullum
William Cummings Ii
Christian Czerwonka
Tracie Czerwonka
Wei Dai
Karina Danielik
Jeremy Daughenbaugh
Lenedra Dawson
Lateefah Dawud
Maria De La Huerta
Enrique De La Sierra
Annie Lyn De Leon
Ed Noel De Leon
Naty De Leon
Toni Rose Debelen
Kimberly Debose
Angeline Dechavez
Shay Decker
Justin Deleon
Cecilia Delgadillo
Javier Delgado
Shauntea Denton
Janish Desai
John Devore
Jeffrey Di Asio
Danny Diaz
Brian Diedrich
Nhi Dinh
Lucy Dobek
Marisol Dominguez
Sean Donlevy
Henrietta Donlon
Emily Donnel
Walter Dosh
Erika Dow
David Doyle
Lauren Drake
Darren Drapp
Dawn Drella
Ben Druce
Dominik Duelli
Ashley Dunigan
Chadwick Dunn
Julie Dykstra
Mary Edgar
Frank Edgeton
Elizabeth Edwardson
Daniel Egeland
Ricardo Andres Egli
James Ehrhardt
Emily Eisenhauer - Miller
Marisela El Ghali
Andrew Ellis
Erica Ellis
Laura Estrada Rodriguez
Jean Evangelista
Joel Evangelista
Flory Ann Evia
Israel Ewing
Tim Farnsworth
Andrij Fedashchin
Huixin Fei
Christine Felton
Stacy Ferguson
William Fernandes
Cathleen Filan
William Flynn
Colin Foley
Mary Ford
Saleena Fortunato
Samuel Foss
Dana Mariel Francisco
Gracielyn Francisco
Aniceta Franklin
Leith Fremlin

Alexandra Freundlich
Errol Frias
Evan Frias
Kristine Fricano
Rebecca Frick
Hector Fuentes
Robert Gaa
Aman Gabriel
Jeffrey Gacek
Jessica Gallego
Marlon Gallego
Carmen Gamero
Khushbu Gandhi
Inessa Ganzman
Danilo Garcia
Mateo Garcia
Michael Garcia
Omar Garcia
Lavare Garrett
Theresa Garwood-Graham
Vivian Geneta-Shoemake
Gene Genis
Kenneth George
Jeffrey Gersch
David Gloss
Dessislava Gochkarian
Gregory Godfrey
Carlos Gomez
Luis Gomez
Maria Eugenia Gomez Montes
Rebecca Gonner
Kevin Dale Gonzales
Sully Gonzalez
Kathryn Goodreau
Angelica Gorospe
James Goucher
Bruce Gowan
John Grace
Michael Graham
Justy Ann Grande
Jean Green
Shirley Griffin
Kelly Gross
Andrew Gruber
Tatyana Grushko
Asta Grzybicki
Vivian Gu
Kevin Gubat
Steven Gubin
Michelle Guerzon
Maria Guillen
Sherman Gumaya
Chase Gunderud
Gerard Gundling
Robert Gutierrez
Senan Hafez
Michael Hahn
Getahun Haile
Andrew Hajduk
David Hale
Paul Hamilton
Mark Hansen
Jonathan Hanson
Kristina Harper
Alia Hasan
Ameer Hashw
Catherine Haskins
Scott Hastings
Jaquilla Haynes-Upshaw
Latoya Haywood
Suzanne Head
James Heagy
David Hecht
Eric Heikkinen
Laura Herbert
Miguel Hernandez
Romeo Hernandez
Erika Herrero Garcia
Philip Hession
Benedetta Hicks
Jennifer Hill
Keith Hill
Douglas Hively
Shiaolan Ho
Charles Hogan
Lisa Hogan
Derwin Holgado
Carolyn Hollands
Theodore Hom
Rebecca Hoo
Karlie Horton
Sophia Hou
Karrie Hovis
Danping Hu
Shihai Huang
Sarah Hughes
Ghalib Husain
Zoe Huss
Syed Hussain

Timothy Hussey
Charles Ingersoll
Mahin Islam
Jennifer Izenstark
Matthew Izenstark
Jordan Jacob
Kristine Jacobson
Keeve Jaffe
Tilak Jain
Adam Jamrozy
Jyothi Janardanan
Alan Jankowski
Kris Jaramilla
Margaret Jasiewicz
Andrew Jaske
Diana Ji
Hao Jiang
Jeany Jimenez
Milica Jocovic
Julie Johanson
Brett Johnson
Jean Johnson
Judith Johnson
Robert Johnson
Sara Jones
Vincent Jones
Francine Jones-Bell
Hemalata Joshi
Nira Joshi
Joseph Kalousek
Monika Kamburova
Gaurav Kapila
John Karavitis
Rachel Karpen-King
Silpa Katragadda
Zev Katz
Tyler Keady
Keolay Keath
Jarrod Kec
Kenji Kennedy-Kunugi
Colleen Kerr
Atif Khan
Mohammad Khan
Noshir Khory
Jinsoo Kim
Jung-In Kim
Kevin Kim
Mark Kim
Wilson Kim
Rickey King
Pavel Kislitsyn
Lucinda Koger
Kristen Kohler
James Kolterman
Jeffrey Kooyenga
Cassandra Kopec
Anne Korponya
Algis Korzonas
Joshua Kostera
Tamara Kovtun
Jacqueline Kramer
Tomasz Krupinski
Richard Krzysik
Ramesh Kuchipudi
Apurva Kulabkar
Rupinder Kular
Stephanie Kunkel
Sharif Kurdi
Prashant Kurdukar
Caroline Kusmierz
Wendy Lacey
Torianna Lamah
Gerald Lamina
Rachel Lander
Thomas Langner
Sandra Lara
Anandi Lasrado
Melanie Latta
Ernest Laurentin
Candice Lazzara Bianchi
Gregor Leckie
Andrew Lee
Hyunjin Lee
Jinhun Lee
Mona Legator
Frances Lennon
James Leone
Kyle Lepek
Noah Leslie
Benjamin Letherer
Joslyn Lewis
Cheng Li
Jiawen Li
Sarah Li
Yuhong Li
Jason Licari
Yuan Yun Lin
Carmina Llanos
Marta Llende

Reneé Lomas
Kennedy Lomillo
Patricia Lonosky
Elvis Lourdes
Johaira Lozada-Cruz
Limin Lu
Laura Lubbers
Jack Lubinski
Danijela Lucic
Jose Luis
Brendan Lynch
Rebecca Lynch
Bernard Lyons
Matthew Maginot
Fareeha Mahmood
Thu Mai
Wai-Bing Mak
Magdalena Maka
Roman Makarewicz
Milena Maksimovic
Pooja Malhotra
Richard Manda
David Mann
Sharmila Manoj
Allison Marder
Ariel Maret
Riley Marion
Rodica Marlo
Benjamin Marszalek
Arthur Martinez
Ashley Martinez
Josselyn Martinez
Joel Mason
Samuel Mathew
Paul Matushek
John Mauk
Jakayla Mccalley
Kevin Mccoy
Carl Mcgill
Jessica Mckillip
Bryan Mcknight
Dawn Mcnulty
Nathan Mcwilliams
Christopher Meiners
Jossie Mendonca
Joswin Mendonca
Cecilia Mendoza
Mario Menendez
Yuhong Meng
James Menges
Daniela Merlos
Andrey Meshem
Kaniz Mettresswala
Lizette Meza
John Mikrut
Thomas Miller
Tracy Miller
Dawid Miltko
Mitchell Mims
Roseann Mireles-Hannigan
Zdzislawa Jessica Mirowski
Bhaveshkumar Mistry
Binaisha Mistry
Larry Mitcham
Kenya Mitchell
Eleanor Mogongwa
Erum Mohammed
Omar Mohammed
Eric Molina
Sandra Moore
Veronica Moore
Vivian Moore
Gregory Morehouse
Hallie Morrison
Kristyn Morrison
Simone Morrison
Susmita Mukherjee
Christina Muñoz
Danielle Murphy
Stephen Murphy
Lauren Myczek
Mohammed Nadeem
Catherine Nash
Lorella Nasis
J Nava
Akkamma Navada
Jonand Ndrio
Katrina Nebrija
Kevin Nelson
Anh Nguyen
Vinh Nguyen
Karolina Niemczyk
Timothy Niles
Stephen Nofs
Kara Nordin
Michael Nosek
Yelina Noskina
Katheryn Nottoli
Jake Novack

Zoe Nykaza
John O'Brien
Anna O'Hare
David Odzer
Wanda Oehrli
Reuben Ofsaiof
Thaddeus Olbrys
Candice Oldenburg
Oscar Ortega
Muyibat Osomo
Thomas Over
Edward Pabich
Daniel Packard
Eric Packard
Keerthana Padamata
Maurice Padilla
Vihanga Pahalawatta
Vince Christian Palao
Darshana Panchal
Nirmala Pandidurai
Jeffrey Panella
Nicku Parameswaran
Joonyoung Park
Melanie Parker
Sarah Parker
Bharat Patel
Bhargav Patel
Bhavesh Patel
Bhavna Patel
Harsh Patel
Hirenkumar Patel
Jitendra Patel
Kinjal Patel
Krishn Patel
Manhar Patel
Maunang Patel
Nimisha Patel
Prakruti Patel
Reema Patel
Sandip Patel
Sanjay Patel
Sneh Patel
Trusha Patel
Varunkumar Patel
Digant Pathak
Eric Payne
Brian Peacha
Paris Pedroza
James Pelletiere
Curtis Pepe
Carina Perez
Cristian Perez
Eliezer Perez
Thomas Perez
Nicole Perez Crespo
Tina Perkins
Lauren Pesceone
Ekaterina Pestova
Torey Peterson
Keith Pettis
William Pfeifle
Natasha Phillips
Jeffrey Pickett
Alyssa Pilac
Arnelio Pilac
Christian Pimentel
Andrew Piquette
Melissa Piwowar
Anna Podsiadlo
Timothy Pointer
Kenneth Pokusa
Laura Polakowski
Regina Postrado
Tyler Potter
Arjun Poudel
Anna Prokhorova
Ankita Puri
Esteban Quinones
Kristine Rabaca
Pierre Radlowski
Magda Radziszewski
Emaad Rahman
Rajeev Rajakumar
Shane Rakow
Dennis Michael Ramirez
Maria Perez Ramirez
Francisco Ramos
Kristine Ramsay-Schnor
Jack Ramsey
Praveen Rao
Tracy Raoul
Abner Rarang
Umar Rathore
Jagmohan Rawat
Shiv Ray
Carla Real
John Rebellato
Samantha Reddy
Pamela Redmond

Matthew Reif
Gabriel Reyes
James Rhoads
Justin Riebe
Dolev Rimmerman
Veronica Rios
Karen Ritacca
Michele Rivelli-Bucci
Ariel Rivera
Kenneth Roberson
Jennifer Roberts
Matthew Roberts
Patrick Robertson
Dana Robinson
Paul Rollins Jr.
Jashira Roman
Romy Rose
Michael Rowan
Venus Roxas
Katheryn Ruffalo
Leonard Rutherford
Thomas Rybski
Wafiyyah Saiyed
John Salituro
Thomas Sallese
Umme Salma
Raymundo Alfredo Salto Dominguez
Edward Salvador
Gina Sammarco
Mark Anthony San Diego
Rachelle San Diego
Francisco Sanchez
Stephanie Sanders
Jose Santiago
Mark Sasaki
Clint Satorre
Maria Satorre
Carol Scher
Colleen Schmidt
Paul Schmitt
Daniel Schroeder
Ian Schroeder
Steve Schroeder
Deborah Schultz
John Schulz
Daniel Schwartz
Darius Scott
Kevin Sears
Andrew Senanayake
Adam Seraphin
Ramya Seshadri
Noah Seto
Mary Jo Sexton
Shruti Shah
Chitra Shaligram
Montaha Shawabkeh
Ruchita Sheth
Dereck Shi
Kelley Shorr
Todd Short
Ivailo Shostenko
Aslam Siddiqui
Jose Silva
Joy Silva
Martin Silva
Michael Silvestri
Gemmalaine Simbahan
Leonid Sitailo
Joseph Skinner
Christopher Slachta
Carl Slenk
Jennifer Sloan
Lauren Smart
Kaitlin Smith
Rhiannon Smith-Marsh
Sherry Smoot
Anna Sobol
Irina Sokolova
Taeyil Son
Liwei Song
Rinkal Soni
Jasmine Soto
Gregory Spears
Maria Spirovski
Maya Springer
Meredith Stafford
Brian Stannis
Rebecca Steuck
Lindsay Stewart-Schmidt
Andrew Stone
Julia Strackhouse
Julie Strom
Michael Struck
Hong Su
Mary Sullivan
Danilo Sumague
Ellia Sun
Yun-Min Sung
Oluwadamilola Sunmola

Roopa Suresh Kumar
Nizar Sweilem
Sandy Sweilem
David Swihart
Magdalena Szostak
Ralston Tabang
Nino Tabatadze
Sashankha Tallapudi
Jing Tang
Justin Tanner
Joseph Tantillo
Christina Tassone
Matthew Taylor
Justin Thomas
Majorca Thomas
Scott Thompson
Eriel Thornton
Stacia Thorson
Skyler Tiarks
Recy Ticzon
Gordon Tommy
Shao Tong
Dan Toolsie
Joseph Toonen
Jennifer Topor
Carmen Torres
Henry Torrez
Ketrija Touw
Moria Trautman
Jennifer Travis
Douglas True
Anatoly Ulyanov
Rajith Unnikrishnan
Tami Urban-Schneider
Elena Usacheva
Elsy Valentin-Eggert
Jessica Van Camp
Alexandre Vaz
Padmaja Vellanki
Sarah Ventura
Patrick Verhoef
Amit Verma
Cecilia Villafan
Jivem Rose Villanueva
Francis Villar
Amanda Villardita
Guy Viti
Robert Vogel
Drashti Vora
Priscilla Walker
Scotty Walker
Matthew Wallace
Brandon Walton
Xin Wang
Yue Wang
Wendell Watanabe
Erika Webb
Carmon Weeks
Yanina Weingast
Susan Weiss
Hazel Welch
Melissa Welk
Matthew Wenzel
Kathleen Wessberg
Mark White
Sarah White
Taiylar White
Claire Whitfield
Daniel Wiacek
Michael Wiacek
Julia Widmaier
Matthew Wienke
Russell Wiesneth
Kimberly Wilber-Mader
James Williams
Adam Winter
Bryant Wojcik
Ieok Wong
Megan Wood
Nick Woodman
Andrew Woolery
Xiangchun Wu
Xiaomao Wu
Jeffrey Wuitschick
Guifa Xi
Gail Yang
Marina Yesilevich
Josephine Yorpo-Lane
Drew Youngblood
Kevin Yu
Jacob Zaguri
Mary Zajakala
Luke Zander
Vicky Zecevich
Lei Zhang
Qingbei Zhang
Yan Zhang
Yue Zhou
Julie Zohn

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ■ No

Section 1: General Information

Facility Name: Abbott Rapid Dx North America, LLC

Physical Address: 569 Halls Mill Road

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (224) 668-9106 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Maria.Vrabie@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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 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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 668-9106 Email: Maria.Vrabie@abbott.com

Contact Person Name: Maria Vrabie

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____

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: _____

ARDxNA Applications - 2

ARDxNA supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for its Freehold and San Diego facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not surrendered a license, permit or certificate of

Section 2 Questions	Response
otherwise (other than upon voluntary close of a facility)?	registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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 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 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**	✓			
• **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.

Maria Vrabie

Print Name of Authorized Person Submitting Application

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 cc ✓ Processed 1/20/22

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Rapid Dx North America, LLC

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on

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certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 8: FDA REGISTRATION

See Exhibit A attached hereto. Please note that Abbott Rapid Dx North America, LLC does not distribute medical devices or otherwise engage in wholesaler activity at the manufacturing site identified in Exhibit A.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Rapid Dx North America, LLC are listed below.

Directors

- None.

Officers

- Kaesebier, Tara
- McCoy, John
- Morrone, Louis
- Oosterbaan, Benjamin

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the membership interest in Abbott Rapid Dx North America, LLC is owned by Alere US Holdings, LLC, a Delaware limited liability company. 100% of the membership interest of Alere US Holdings, LLC is owned by Alere, Inc., a Delaware corporation. 100% of the stock of Alere, Inc. is owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

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CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit B attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
FDA REGISTRATION

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FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Abbott Rapid Dx North America, LLC
Business Trade Name:
Shared Services Center (SSC)

30 S. Keller Road, Suite 100
Orlando, FL 32810
Registration Number: 3006984151
FEI Number*: 3006984151
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
Abbott[6]
100 Abbott Park
Building J49
Abbott Park, IL US 60064
Owner/Operator Number: 9006731[7]

Official Correspondent:
Sherly Jules-Fleury
30 S Keller Rd, Ste 100
Orlando, FL 32810
Phone: 1-904-4265406

* Firm Establishment Identifier (FEI) should be used for identification of entities within the Imports message set

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Page Last Updated: 08/23/2021

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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

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

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=9006731&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9006731&OwnerOperator

ARDxNA Freehold Facility

The workers at the ARDxNA Freehold facility are as follows:

Acacia, Marie
Accardo, Donald
Adams Swaby, Laciann
Aime, Emenus
Alexander, David
Alvarado, Karen
Assuntino, Lorenzo
Ayala, Rolando
Banerjee, Shyamalima
Baron, Nancy
Bertman, Robert
Boice, Chris
Borish, Marc
Boros, Emanuel
Cano, Jesus
Carrera, Jose
Carrillo, Consorcia
Cassidy, Kevin
Castaneda, Cynthia
Castro, Jessica
Clark, Richard
Coleman, Thomas
Coley, Shericka
Collins, Erick
Colon, Melissa
Conte, Thomas
Cordero, Tameka
Cruz Valladares, Eva
D'Amore, Andrew
Darden, Jqwon
Diaz, Olga
Dinome, Christie
Doyle, Ana
Ellis, Jinnel
Fernandez, Edgar
Fernandez, Sergio
Fink, Ted
Gocmen, Ismail
Godoy, Jeniffer

Handley, Kimberly
Handley, Tyler
Hemmings, Marvin
Hyman, Wyatt
James Barnes, Nadine
Johnson, Josette
Jones, Barkiem
King, Davian
Lagreco, Stephanie
Llacma, Edgar
Llacma, Eleazar
Lopez, Jorge
Lopez Guerrero, Alexi
Lordi, Melissa
Lovero, Donovan
Lovero, Mitzi
Luna, Fany
Maldonado, Norma
Martin, Moises
Martin, Rayon
Mason, Christine
Merrick, Joseph
Miller, Jamear
Miller, Nyzir
Mitchell, Alfred
Monfleury, Daddy
Moreta Santos, Alexander
Moto, Dancaris
Nguyen, Lai Ying
Palillero, Ricardo
Paredes, Kevin
Penn, Vivian
Prince, Catherine
Pringle, Jeremy
Rios, Adriana
Rosario, Annfrank
Samms, Larry
Santana, Jessica
Santos, Rosalie
Santos, Ruel
Santos, Sheryl
Segoviano, Elidad
St.Germain, Roudy
Stalowski, Michael
Suarez, Rafael
Torres, Lorenzo
Tuozzolo, Michael
Vazquez, Jorge
Vrabie, Maria
Water, Annetta
Williams-Lawton, Kareem

EXHIBIT B
CERTIFICATE OF GOOD STANDING

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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 3/17/2021

Registration Number: 5003126 **Registered as:** Manufacturer and Wholesale

Parent Company Name: INVERNESS MEDICAL LLC

Trade Name:

Original Issue Date: 11/10/2004 **Expiration Date:** 01/31/2022

Current Issue Date: 12/16/2020

Disciplines: No

Attachment F
Abbott Rapid Dx North America, LLC
569 Halls Mill Road, Freehold, NJ 07728

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	ABBOTT RAPID DX NORTH AMERICA, LLC
California Name:	ABBOTT RAPID DX NORTH AMERICA, LLC
File Number:	201324210001
Registration Date:	08/28/2013
Entity Type:	FOREIGN LIMITED LIABILITY COMPANY
Jurisdiction:	DELAWARE
Status:	ACTIVE (GOOD STANDING)

As of September 19, 2021 (Certification Date), the entity is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect 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 September 20, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: RMA7X5R

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at *bebizfile.sos.ca.gov/certification/index*.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT RAPID DX 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-THIRD DAY OF AUGUST, A.D. 2021.

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

Jeffrey W. Bullock, Secretary of State

4460813 8300

SR# 20213056307

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

Authentication: 203987790

Date: 08-23-21

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott bas four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipantbyl™ and TriCor™, for tbe treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Abbott Rapid Dx North America, LLC

Physical Address: 5995 Pacific Center Blvd., Ste. 108

City: San Diego State: CA Zip: 92121

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (224) 668-9106 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Maria.Vrabie@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 — Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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 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: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Name: Refer to addendum for responses.

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

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois

Parent Company (if any): Abbott Laboratories

Corporation Name: Abbott Laboratories

Mailing Address: 100 Abbott Park Road

City: Abbott Park State: IL Zip: 60064

Telephone: (224) 668-9106 Email: Maria.Vrabie@abbott.com

Contact Person Name: Maria Vrabie

Date of SEC Registration: See Addendum | SEC Registration Number: 0000001800 | Stock Exchange Symbol: ABT

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: _____

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: _____

ARDxNA Applications - 2

ARDxNA supplements the responses set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for its Freehold and San Diego facilities, each as follows:

Section 2 Questions	Response
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)?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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	To our knowledge, Abbott Rapid Dx North America, LLC, Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not surrendered a license, permit or certificate of

Section 2 Questions	Response
otherwise (other than upon voluntary close of a facility)?	registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

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 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 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**	✓			
• **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.

Maria Vrabie

Print Name of Authorized Person Submitting Application

Maria Vrabie

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 500 CC

NEVADA WHOLESALER APPLICATION ADDENDUM
Abbott Rapid Dx North America, LLC

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 8: FDA REGISTRATION

See Exhibit A attached hereto. Please note that Abbott Rapid Dx North America, LLC does not distribute medical devices or otherwise engage in wholesaler activity at the manufacturing site identified in Exhibit A.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Abbott Rapid Dx North America, LLC are listed below.

Directors

- None.

Officers

- Kaesebier, Tara
- McCoy, John
- Morrone, Louis
- Oosterbaan, Benjamin

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the membership interest in Abbott Rapid Dx North America, LLC is owned by Alere US Holdings, LLC, a Delaware limited liability company. 100% of the membership interest of Alere US Holdings, LLC is owned by Alere, Inc., a Delaware corporation. 100% of the stock of Alere, Inc. is owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit B attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
FDA REGISTRATION

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BOARD OF PHARMACY

ISSUANCE DATE
MAY 19, 2021
EXPIRATION DATE
MAY 1, 2022
CURRENT DATE / TIME
NOVEMBER 10, 2021
12:12:55 PM

LICENSING DETAILS FOR: WLS 7290

NAME: ABBOTT RAPID DX NORTH AMERICA LLC
LICENSE TYPE: WHOLESALER
LICENSE STATUS: CLEAR

ADDRESS
5995 PACIFIC CENTER BLVD STE 100
SAN DIEGO CA 92121
SAN DIEGO COUNTY

LICENSE RELATIONSHIPS

NAME: SADIG, HALEH
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 56682 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

Attachment G
Abbott Rapid Dx North America, LLC
5995 Pacific Center Blvd., Ste. 108, San Diego, CA 92121

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ABBOTT RAPID DX NORTH AMERICA, LLC
0600402374

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign Limited Liability Company was registered by this office on August 15, 2013.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey. Annual Reports are outstanding for the following year(s): 2021

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 20th day of September, 2021

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6123261777

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABBOTT RAPID DX 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-THIRD DAY OF AUGUST, A.D. 2021.

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

Jeffrey W. Bullock, Secretary of State

4460813 8300

SR# 20213056307

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

Authentication: 203987790

Date: 08-23-21

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Abbott Rapid Dx North America, LLC
Business Trade Name:
Shared Services Center (SSC)

30 S. Keller Road, Suite 100
Orlando, FL 32810
Registration Number: 3006984151
FEI Number*: 3006984151
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
Abbott[6]
100 Abbott Park
Building J49
Abbott Park, IL US 60064
Owner/Operator Number: 9006731[7]

Official Correspondent:
Sherly Jules-Fleury
30 S Keller Rd. Ste 100
Orlando, FL 32810
Phone: 1-904-4265406

Verified M.H 1/27/2022

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 08/23/2021

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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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start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9006731&OwnerOperator

ARDxNA San Diego Facility

The workers at the ARDxNA San Diego facility are as follows:

Bryce Adams
John Adams
Emmanuel Alcaraz
Carmen Alicea
Maria Alvarez
Jose Mancillas Araiza
Cesar Baltazar
Diego Cervantes
Martin Cervantes
Brian Davis
Miguel Diaz De Leon
Darius Fangon
Christopher Fortin
Kyle Fortner
Jonathan Hendricks
Lonny Hendrickson
Angel Huerta
Elnaz Jokar
Michael Kendrick
Manisha Khatri
Michael Ladao
Susan Littrel
Bianca Lopez
Ian Macdiarmid
Dania Major
Christian Marin
Jason Marritt
Maurice Mason
Cielo Michel
Michael Joseph Morin
David Nguyen
Brandon Nielson
Michael Oberle
Manuel Palma
Joseph Pendarvis
Elise Proctor

EXHIBIT B
CERTIFICATE OF GOOD STANDING

CONFIDENTIAL AND PROPRIETARY – NOT FOR PUBLIC DISCLOSURE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020 — Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler		☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change	* If making a change, provide current license number:	☐ 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)

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Alere San Diego Inc.

Physical Address: 829 Towne Center Drive

City: Pomona State: CA Zip: 91767

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (224) 668-9106 Website: https://www.abbott.com/

Name of Designated Representative (DR): Not applicable per NAC 639.5935(1)(a)

Licensing Company Email: Maria.Vrabie@abbott.com DR Email: Not applicable per NAC 639.5935(1)(a)

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 Refer to addendum for questions 1-5.	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)?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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?	Refer to addendum for responses.	
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)?	Refer to addendum for responses.	

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 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: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____
Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____
Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____
Name: Refer to addendum for responses.
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Illinois
Parent Company (if any): Abbott Laboratories
Corporation Name: Abbott Laboratories
Mailing Address: 100 Abbott Park Road
City: Abbott Park State: IL Zip: 60064
Telephone: (224) 668-9106 Email: Maria.Vrabie@abbott.com
Contact Person Name: Maria Vrabie

Date of SEC Registration: See Addendum	SEC Registration Number: 0000001800	Stock Exchange Symbol: ABT

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: _____
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 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 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**	✓			
• **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.

Maria Vrabie

Print Name of Authorized Person Submitting Application

Maria Vrabie

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

08/26/2021

Date

Board Use Only	Date Received: _____	Amount: 900 CC ✓ Received 1/20/22

ASD Application

ASD supplements the response set forth in the Wholesaler Application Addendum to Questions 1-5 of Section 2 of the Nevada Wholesaler Application for its Pomona facility as follows:

Section 2 Questions	Response
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)?	To our knowledge, Alere San Diego, Inc., Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been charged, or convicted of a felony or gross misdemean or (including by way of a guilty plea or no contest plea) within the last 5 years.
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?	To our knowledge, Alere San Diego, Inc., Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been denied a license, permit or certificate of registration within the last 5 years.
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?	To our knowledge, Alere San Diego, Inc., Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been the subject of an administrative action or proceeding relating to the pharmaceutical industry within the last 5 years.
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?	To our knowledge, Alere San Diego, Inc., Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not been found guilty, pled guilty or entered a plea of nolo contendere to any offense, federal or state, related to controlled substances within the last 5 years.
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)?	To our knowledge, Alere San Diego, Inc., Alere US Holdings, LLC, Alere, Inc. and Abbott Laboratories – the entities identified in Section 9 of the Wholesaler Application Addendum – have not surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility) within the last 5 years.

NEVADA WHOLESALER APPLICATION ADDENDUM
Alere San Diego Inc.

SECTION 2: HISTORY OF COMPANY

Question	Response
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)?	Abbott Laboratories (Abbott), the parent company of the prospective licensee, is a publicly traded company. All material investigations, lawsuits, administrative proceedings, and other legal matters involving Abbott and its subsidiaries are disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material registration and licensure information involving Abbott and its subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material administrative actions and proceedings involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
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?	All material investigations, lawsuits, administrative proceedings and other legal matters involving Abbott and its subsidiaries is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least	All material registration and licensure information involving Abbott and its

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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)?	subsidiaries is disclosed in Abbott's Annual Report on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

SECTION 3: SUPPLIER INFORMATION

The applicant distributes medical products and devices manufactured by or for Abbott only. It does not distribute pharmaceuticals.

SECTION 4: PUBLICLY TRADED CORPORATION

SEC REGISTRATION

Abbott Laboratories (Abbott) completed its initial public offering in 1929.

SECTION 8: FDA REGISTRATION

See Exhibit A attached hereto.

SECTION 9: APPLICABLE DOCUMENTS

LIST OF OFFICERS AND DIRECTORS

The officers and directors of Alere San Diego Inc. are listed below.

Directors

- McCoy, John

Officers

- Frey, Randolph
- Kaesebier, Tara
- McCoy, John
- McCoy, John
- Morrone, Louis
- Oosterbaan, Benjamin
- Paik, Jessica
- Yasger, Paul

LIST OF TOP FOUR CORPORATION SHAREHOLDERS

100% of the stock of Alere San Diego, Inc. is owned by Alere US Holdings, LLC, a Delaware limited liability company. 100% of the membership interest of Alere US Holdings,

LLC is owned by Alere, Inc., a Delaware corporation. 100% of the stock of Alere, Inc. is owned by Abbott. Abbott is a publicly traded company that is listed on the New York Stock Exchange.

CERTIFICATE OF CORPORATE STATUS OR CERTIFICATE OF GOOD STANDING

See Exhibit B attached hereto.

DEA CERTIFICATE IF HANDLING CONTROLLED SUBSTANCES

Not applicable.

LIST OF EMPLOYEES, AGENTS, INDEPENDENT CONTRACTORS, CONSULTANTS, GUARDIANS, PERSONAL REPRESENTATIVES, LENDER OR HOLDER OF INDEBTNESS OF THE APPLICANT

All material information is disclosed in Abbott's Annual Reports on form 10-K, Quarterly Reports on form 10-Q, and/or Proxy Statements, which are available at the Securities and Exchange Commission's website.

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EXHIBIT A
FDA REGISTRATION

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STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Alere San Diego, Inc.
DBA: Immunalysis Corporation
829 Towne Center Drive / 828 Towne Center Drive
832 Towne Center Drive/ 821 Towne Center Drive
Pomona, CA 91767

LICENSE NUMBER: 96320
EXPIRATION DATE: 3/20/2022

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

Printed: 4/8/2020

2527

Attachment H
Alere San Diego Inc.
829 Town Center Drive, Pomona, CA 91767

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	ALERE SAN DIEGO, INC.
File Number:	C1503440
Registration Date:	06/28/1988
Entity Type:	FOREIGN STOCK CORPORATION
Jurisdiction:	DELAWARE
Status:	ACTIVE (GOOD STANDING)

As of September 19, 2021 (Certification Date), the entity is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect 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 September 20, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: R41P6WR

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at *bebizfile.sos.ca.gov/certification/index*.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALERE SAN DIEGO, 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 TWENTY-SIXTH DAY OF AUGUST, A.D. 2021.

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

2156383 8300

SR# 20213093273

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

Authentication: 204018266

Date: 08-26-21

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Alere San Diego Inc.
Business Trade Name:
Immunalysis Corporation

829 Towne Center Drive
Pomona, CA 91767
Registration Number: 2020952
FEI Number*: 2020952
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
Abbott[6]
100 Abbott Park
Building J49
Abbott Park, IL US 60064
Owner/Operator Number: 9006731[7]

Official Correspondent:
Jason Gumaer
829 Towne Center Drive
Pomona, CA 91767
Phone: 1-909-4516780

Verified mlt 01/13/24

* 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=9006731&OwnerOperator
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Page Last Updated: 08/23/2021

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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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start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9006731&OwnerOperator

Haleh Sadig
Masaya Sueyoshi
Timmy Lac Tang
Steven Teel
Lisa Thing
Ranny Thorn
Timothy Toy
Tung Tran
Carlos Troche
Stanford Tuupo
Jaleen Williams-Mack
Nancy Xaysanasith
Sam Yang
Cusfer Zweifel

ASD Pomona Facility

The workers at the ASD Pomona facility are as follows:

Humberto Aceves
Alpana Agrawal
Amber Allan
Gregory Amador
Pauline Arman
Monica Arredondo
Elina Arroyo
Adam Atwell
Sreenath Babu
Elizabeth Barajas
Kelvin Barnes
Erin Bartos
Michael Bick
Tanesha Bland
John Blomquist
Deborah Brinkman
Marye Brooks
Jill Campbell
Jennifer Cassidy
Adam Castro
Catherine Castro
Philip Catbagan
Marina Caylao
Pedro Chagolla
Chia-Wen Chen
Weiyu Chen
Ardelia Chokry
Joshua Chou
Rebecca Chou
Eva Chow
Stephen Coutts
Reina Covarrubias
Scott Craig
Maria Cruz
Maria Cruz
Marina Cuevas
Richard Dang
Kathryn Deluca
Sean Dicesare
Anh Dinh
John Doan
Gregory Dowdeswell
Michael Duchemin
Kevin Emerick
John Ervin
Amelia Flores
Desiree Flores
Erika Frank
Brian Frey
Yvonne Gailliard
Maria Garcia
John Giddens
San Juana Gomez
Yvette Gonzalez
Congying Gu
Jason Gumaer
Usha Gundimeda
Xinru Guo
Leibniz Hang
Ahmed Helmy
Cecilia Henry
Ebelin Hernandez
Noelia Herrera Vazquez
Mary Hetrick
Rebecca Houston
Gabriel Huacuja
Mary Hubbard
Kim Huynh
Mark Jasperse

Estela Jimenez
Saffi Khan
Anita Khosravan Ahoura
Krystle Kitts
Sara Klug
Scott Kostner-Nicholson
Senthil Kumar Krishnaswamy
Wei-Ying Kuo
Ron Leugoud
Evan Lewis
Feng Liu
Jialin Liu
Michael Liu
Zhiling Liu
Alicia Lopez
Sherry Lott
Kyle Maier
Parvez Malek
Steven Martinez
Kimberly Mccall
Nan Mcintosh
Zachary Mcnabb
Maria Mercado
Huda Milbes
Vikash Mishra
Nooruddin Farooq Mohammed
Sarah Morgan
Janet Murillo
Christel Nassif
Timothy Nelson
Diane Nguyen
Michelle Nguyen
James Nilawat
Michael O'Sullivan
Monica Ortiz
Ricardo Ortiz
Gustavo Palmer
Kayla Panora
Hernan Parra
Margaret Pearson
Zhenghong Peng
Joshua Pulido
Ruby Quevedo
Billy Reynoso
Diane Ricotta
Esperanza Rios
Pedro Rivera
Brittanie Robinson
Warren Rodrigues
Minerva Ruiz
Alcides Saavedra
Russell Salaz
Jorge Sandoval
Youssef Sawires
Karl Scheidweiler
Tania Serrano
Manik Sharma
Carly Shipman
Alice Silva
Leigh Smith
Catherine Srisamai
Brenda Stallworth
Veronica Stockdale
Scott Taillie
David Tam
Phillip Tam
Ryan Tang
Sydney Tang
Gina Thi
Nadine Thompson
Rochelle Timbang
Michelle Tong
Jeffrey Tran
Trish Tran Le-Vi
David Tsao
Maria Valencia
Keith Valley
Suzanne Van Dalen
David Ver
Mark Villoria
Phi Vu
Amy Wang
Guohong Wang
Yijia Wang
Rafik Wasief
Shannon Weston
Paul Widjaja
Antoine Williams Jr.
Jennifer Wynn
Roxana Zuleta
Ingrid Zurbaran Perez

EXHIBIT B
CERTIFICATE OF GOOD STANDING

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

Commission file number 1-2189

Abbott Laboratories

An Illinois Corporation
100 Abbott Park Road
Abbott Park, Illinois 60064-6400

36-0698440
(I.R.S. employer identification number)
(224) 667-6100
(telephone number)

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 Shares, Without Par Value	ABT	New York Stock Exchange Chicago Stock Exchange, Inc.

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 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 shorter 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. ☒

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 1,727,625,764 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2020), was $157,956,823,602. Abbott has no non-voting common equity. Number of common shares outstanding as of January 31, 2021: 1,771,529,358

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 Abbott Laboratories Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 12, 2021.

PART I

ITEM 1. BUSINESS

GENERAL DEVELOPMENT OF BUSINESS

Abbott Laboratories is an Illinois corporation, incorporated in 1900. Abbott's* principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products.

NARRATIVE DESCRIPTION OF BUSINESS

Abbott has four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

Established Pharmaceutical Products

These products include a broad line of branded generic pharmaceuticals manufactured worldwide and marketed and sold outside the United States in emerging markets. These products are generally sold directly to wholesalers, distributors, government agencies, health care facilities, pharmacies, and independent retailers from Abbott-owned distribution centers and public warehouses, depending on the market served. Certain products are co-marketed or co-promoted with, or licensed from, other companies.

The principal products included in the broad therapeutic area portfolios of the Established Pharmaceutical Products segment are:

- gastroenterology products, including Creon™, for the treatment of pancreatic exocrine insufficiency associated with several underlying conditions, including cystic fibrosis and chronic pancreatitis; Duspatal™ and Dicetel™, for the treatment of irritable bowel syndrome or biliary spasm; Heptral™, Transmetil™, and Samyr™, for the treatment of intrahepatic cholestasis (associated with liver disease) or depressive symptoms; and Duphalac™, for regulation of the physiological rhythm of the colon;
- women's health products, including Duphaston™, for the treatment of many different gynecological disorders; and Femoston™, a hormone replacement therapy for postmenopausal women;
- cardiovascular and metabolic products, including Lipanthyl™ and TriCor™, for the treatment of dyslipidemia; Teveten™ and Teveten™ Plus, for the treatment of essential hypertension, and Physiotens™, for the treatment of hypertension; and Synthroid™, for the treatment of hypothyroidism;
- pain and central nervous system products, including Serc™, for the treatment of Ménière's disease and vestibular vertigo; Brufen™, for the treatment of pain, fever, and inflammation; and Sevedol™, for the treatment of severe migraines; and
- respiratory drugs and vaccines, including the anti-infective clarithromycin (sold under the trademarks Biaxin™, Klacid™, and Klaricid™); and Influvac™, an influenza vaccine.

The Established Pharmaceutical Products segment directs its primary marketing efforts toward building strong brands with key stakeholders, including consumers, pharmacists, physicians, and other healthcare providers. Government agencies are also important customers.

Competition in the Established Pharmaceutical Products segment is generally from other health care and pharmaceutical companies. In addition, the substitution of generic drugs for the brand prescribed and introduction of additional forms of already marketed established products by generic or branded competitors may increase competitive pressures.

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* As used throughout the text of this report on Form 10-K, the term "Abbott" refers to Abbott Laboratories, an Illinois corporation, or Abbott Laboratories and its consolidated subsidiaries, as the context requires.

14M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Allergan USA, Inc.

Physical Address: 5 Giralda Farms

City: Madison State: NJ Zip: 07940

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 862-261-7000 Website: www.allergan.com

Name of Designated Representative (DR): Christopher Reynolds

Licensing Company Email: lynn.dacunha@abbvie.com DR Email: creynolds@abbvie.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.

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: McKesson Corporation
Address: 655 Stat Highway City: Irving State: TX Zip: 75039
Name: Cardinal Health
Address: 700 Cardinal Place City: Dublin State: OH Zip: 43017
Name: AmerisourceBergen Drug Corp.
Address: 1 W. ist Avenue City: Conshohocken State: PA Zip: 19428
Name: Express Scripts Pharmacy, Inc. DBA Express Scripts
Address: 1 Express Way City: St. Louis State: MO Zip: 63121

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Allergan Sales, LLC (Ultimate Parent - AbbVie, Inc.)
Corporation Name: AbbVie, Inc.
Mailing Address: 1 North Waukegan Road
City: North Chicago State: IL Zip: 60064
Telephone: 847-932-7900 Email: liz.shea@abbvie.com
Contact Person Name: Elizabeth Shea

Date of SEC Registration: 11/30/2012	SEC Registration Number: 001-35565	Stock Exchange Symbol: ABBV

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:

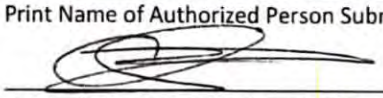
Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

Christopher Reynolds (updated application)

Print Name of Authorized Person Submitting Application



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

11/16/2021

Date

Board Use Only	Date Received: _____ Amount: _____

Mark I. Sedar

From: DaCunha, Lynn <lynn.dacunha@abbvie.com>
Sent: Monday, January 10, 2022 8:47 AM
To: Mark I. Sedar; Maria Herrera
Subject: RE: Allergan updated application

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Mark,

Sorry for the delay, I was out of the office on Friday. Hope this answers your question. Allergan USA, Inc. is a wholly-owned, indirect subsidiary of AbbVie Inc.

Thanks, Lynn

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, January 6, 2022 5:10 PM
To: DaCunha, Lynn <lynn.dacunha@abbvie.com>; Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: [EXTERNAL] RE: Allergan updated application

Lynn, are they wholly-owned?

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

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 1/19/2022

Registration Number: 5004950 **Registered as:** Manufacturer and Wholesale

Name: ALLERGAN, INC.

DBA: ALLERGAN USA, INC.

Address: 5 GIRALDA FARMS , MADISON, NJ 07940

Original Issue Date: 05/09/2016 **Expiration Date:** 01/31/2023

Current Issue Date: 12/27/2021

Disciplines: No

Additional Registered Addresses:

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0742967

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:

5 GIRALDA FARMS MADISON, NJ 07940-

Reg. No.
5004950

ALLERGAN, INC.
ALLERGAN USA, INC.
5 GIRALDA FARMS
MADISON, NJ 07940-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALLERGAN 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 TWENTIETH DAY OF JANUARY, 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

3877897 8300

SR# 20220188159

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

Authentication: 202441505

Date: 01-20-22

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ALLERGAN USA, INC.
0100948116

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 June 29, 2005.

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:

CORPORATE CREATIONS NETWORK INC.
181 NEW ROAD #304
PARSIPPANY, NJ 07054

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 20th day of January, 2022

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6127573847

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

ALLERGAN USA, INC.
(a Delaware Corporation)

Robert A. Michael – Sole Director
1 North Waukegan Road
North Chicago, IL 60064

Mark I. Sedar

From: DaCunha, Lynn <lynn.dacunha@abbvie.com>
Sent: Tuesday, October 26, 2021 1:15 PM
To: Mark I. Sedar
Subject: FW: Allergan USA Inc. - Pending Application

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Mark,

Below is a list of employees that you requested from Maggie Lam from Porzio who is assisting us with some of our state licensing applications. This is for our pending wholesaler application for Allergan USA, Inc. located in Madison NJ.

Robert A. Michael – Sole Director
Christopher Reynolds – Director Customer Logistics – (Designated Rep – Madison)
Alex Rork – Sr. Mgr. US Distribution
Andres Valencia – Director North American Distribution
Jesse Lopez – Assoc. Director Distribution & Warehousing
Mary Woods – Executive Director Customer Relations Operations

Maggie also stated that an appearance before the Board would be required. Would that be our Designated Rep and is this appearance a virtual one? Please let me know if you require anything further and the date and time of the meeting.

Thank you and have a nice afternoon.

Kind Regards,

Lynn

Allergan
an AbbVie Company

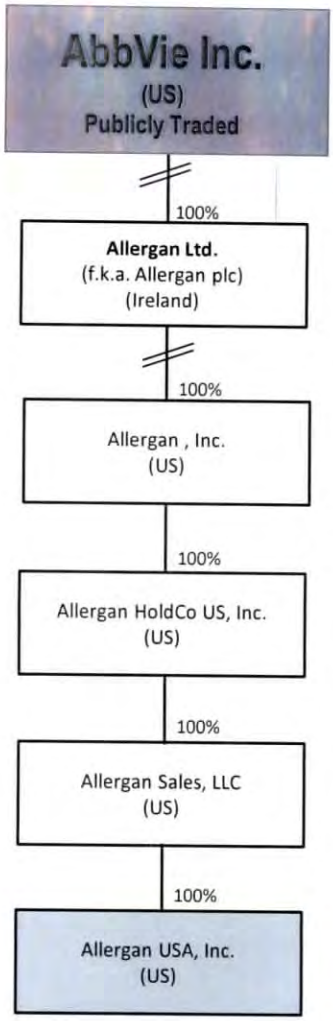
Lynn DaCunha
Principal US Trade Compliance Specialist
Global Distribution & Logistics
DEA & State Licensing

abbvie
5 Giralda Farms
Madison, NJ, 07940
OFFICE 862-261-7179
EMAIL lynn.dacunha@abbvie.com

www.allergan.com

Allergan USA, Inc.

2021



Allergan USA, Inc.
5 Giralda Farms
Madison, NJ 07940

Section 9 Statement Responses:

List of all corporation shareholders and their percent ownership.

Allergan USA, Inc. is 100% owned by Allergan Sales, LLC.

A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the application.

CT Corporation – Registered Agent

Mark I. Sedar

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Allergan
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Lynn DaCunha
Principal US Trade Compliance Specialist
Global Distribution & Logistics
DEA & State Licensing

abbvie
5 Giralda Farms
Madison, NJ, 07940
OFFICE 862-261-7179
EMAIL lynn.dacunha@abbvie.com

www.allergan.com

3PL Distributor
DEA Registration

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RU0346088	05-31-2022	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	05-04-2021

U P S SUPPLY CHAIN SOLUTION INC,
1860 OUTER LOOP ROAD
LOUISVILLE, KY 402190000

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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U P S SUPPLY CHAIN SOLUTION INC,
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LOUISVILLE, KY 402190000

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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 (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Allergan USA, Inc.

Physical Address 5 Giralda Farms

City Madison State NJ Zip 07940

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 862-261-7000 Website www.allergan.com

Licensing Company Email lynn.dacunha@allergan.com

Section 2: Personal Information

First Christopher Middle Troy Last Reynolds

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

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

Mailing Address [redacted] Abbott Road

City Towaco State NJ Zip 07082

Telephone 862-261-7031 Email creynolds@abbvie.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: June 1, 1994 to: July 1, 2001

Military Occupation/Specialty Office of Special Investigations

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 _____

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 Michigan			08/05-04/07	
Address		City	State	Zip
500 S. State St		Ann Arbor	MI	48109
Diploma/Degree obtained, if any				
Master's, Business Administration				

School Name			From - To (MM/YY – MM/YY)	
United States Air Force Academy			06/90-06/94	
Address		City	State	Zip
2304 Cadet Drive, Suite 3100		USAF Academy	CO	80840
Diploma/Degree obtained, if any				
Bachelor of Science				

School Name			From - To (MM/YY – MM/YY)	
Madison Heights High School			09/85-06/89	
Address		City	State	Zip
4610 Madison Ave		Anderson	IN	46013
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
12/17-Present	[redacted] Abbott Rd	Towaco	NJ	07082
11/15-12/17	19 Fawn Dr	Montville	NJ	07045
06/12-11/15	6591 Oak Grove Rd	Burlington	MI	49029
06/11-06/12	8012 Claytie Circle	Nashville	TN	37221

Applicant's initials _____

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: AbbVie				From - To (MM/YY – MM/YY): 05/2020-Present
Business Address: 5 Giralda Farms		City: Madison	State: NJ	Zip: 07940
Phone: 862.261.7031	Title: Director, U.S. Logistics			Number of Employed Hours: 3400
Description of Duties: Manage the distribution of all pharmaceutical shipments from U.S. distribution centers to U.S. and international customers				

Business Name: Allergan				From - To (MM/YY – MM/YY): 09/2016-05/2020
Business Address: 5 Giralda Farms		City: Madison	State: NJ	Zip: 07940
Phone: 862.261.7031	Title: Director, U.S. Logistics			Number of Employed Hours: 10000+
Description of Duties: Manage the distribution of all pharmaceutical shipments from U.S. distribution centers to U.S. and international 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				

Continue on next page if additional space is needed.

Applicant's initials _____

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

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

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

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

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)

7/7/2021
Date

Applicant's initials _____

I, Christopher Reynolds, **certify that as the designated representative for**

Allergan USA, 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

Christopher Reynolds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/7/2021

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.

Christopher Reynolds

Print Name (~~First, Last~~)

Original ~~Signature~~ (electronic, copies or stamps not accepted)

7/1/2021

Date

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

State of New Jersey, ss. County of Morris

I, Christopher Reynolds, 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~~

7/1/2021

Date

Subscribed and Sworn to before me this 7th day of July 2021

Lynn DaCunha

Notary Public Signature

LYNN DACUNHA
Commission # 2301239
Notary Public, State of New Jersey
My Commission Expires
June 04, 2023

(Seal)

Applicant's initials

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: Allergan USA, Inc.

Physical Address: 5 Giralda Farms

City: Madison State: NJ Zip: 07940

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 862-261-7000 Website: www.allergan.com

Licensing Company Email: lynn.dacunha@allergan.com

Section 2: Personal Information

First: Christopher Middle: Troy Last: Reynolds

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

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

Mailing Address: [redacted] Abbott Road

City: Towaco State: NJ Zip: 07082

Telephone: [redacted] Email: creynolds@abbvie.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: June 1, 1994 to: July 1, 2001

Military Occupation/Specialty: Office of Special Investigations

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: [illegible]

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 Michigan		08/05-04/07	
Address	City	State	Zip
500 S. State St	Ann Arbor	MI	48109
Diploma/Degree obtained, if any			
Master's, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
United States Air Force Academy		06/90-06/94	
Address	City	State	Zip
2304 Cadet Drive, Suite 3100	USAF Academy	CO	80840
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Madison Heights High School		09/85-06/89	
Address	City	State	Zip
4610 Madison Ave	Anderson	IN	46013
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
12/17-Present	[redacted]Abbott Rd	Towaco	NJ	07082
11/15-12/17	19 Fawn Dr	Montville	NJ	07045
06/12-11/15	6591 Oak Grove Rd	Burlington	MI	49029
06/11-06/12	8012 Claytie Circle	Nashville	TN	37221
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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 _____

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)
AbbVie			05/2020-Present
Business Address	**City**	**State**	**Zip**
5 Giralda Farms	Madison	NJ	07940
Phone	**Title**		
862.261.7031	Director, U.S. Logistics		
Description of Duties			
Manage the distribution of all pharmaceutical shipments from U.S. distribution centers to U.S. and international customers			

Business Name			From - To (MM/YY – MM/YY)
Allergan			09/2016-05/2020
Business Address	**City**	**State**	**Zip**
5 Giralda Farms	Madison	NJ	07940
Phone	**Title**		
862.261.7031	Director, U.S. Logistics		
Description of Duties			
Manage the distribution of all pharmaceutical shipments from U.S. distribution centers to U.S. and international customers			

Business Name			From - To (MM/YY – MM/YY)
Stryker			02/07-06/16
Business Address	**City**	**State**	**Zip**
2825 Airview Dr	Kalamazoo	MI	49002
Phone	**Title**		
269.385.2600	Director		
Description of Duties			
Oversaw regional distribution centers; coordinated development and deployment for logistics-related computer systems around the globe			

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 _____

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)

7/7/2021
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.

Christopher Reynolds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/7/2021

Date

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

State of New Jersey, ss. County of Morris

I, Christopher Reynolds, 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

7/7/2021

Date

Subscribed and Sworn to before me this 7th day of July 2021

Lynn DaCunha

Notary Public Signature

LYNN DACUNHA
Commission # 2301239
Notary Public, State of New Jersey
My Commission Expires
June 04, 2023

(Seal)

Applicant's initials

COLORADO DISCLOSURE

In the interest of full disclosure, following are the events that occurred between Allergan USA, Inc. for our Lewisville, Texas distribution center and the State of Colorado. This was resolved quickly and Colorado issued the Lewisville, Texas distribution center a license on March 10, 2009.

Date	Activity
2 Feb 2009	The Colorado Board of Pharmacy changed their policy with regard to Manufacturer registrations.
5 Feb 2009	The Colorado Board of Pharmacy issued a Cease and Desist Order to the Lewisville, Texas Distribution Center which Allergan received on February 9, 2009.
24 Feb 2009	Allergan completed and mailed a Colorado state application for the Lewisville, Texas facility.
4 Mar 2009	Allergan submitted a response to the State of Colorado agreeing to the Stipulation and Final Agency Order (included as an attachment).
10 Mar 2009	The State of Colorado sent to Allergan a letter (included as an attachment) stating that all obligations regarding the Stipulation and Final Agency Order have been cleared and that the State of Colorado has issued on out-of-state prescription drug wholesaler license #7514 (included as an attachment) to the Lewisville, Texas Distribution Center effective March 10, 2009.

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

Damon Burrows
Vice President,
Assistant General Counsel Regulatory
Phone: (714) 246-6159
Fax: (714) 246-4774
Email: burrows_damon@Allergan.com

March 4, 2009

Via Federal Express

Wendy Anderson, Program Director
Colorado Department of Regulatory Agencies
Division of Registrations Board of Pharmacy
1560 Broadway, Suite 1350
Denver, CO 80202

Re: State of Colorado Board of Pharmacy

Ms. Anderson,

As we indicated to you and your counsel on the telephone yesterday, Allergan does not believe the Wholesaler Licensure Statute was intended to regulate samples that are shipped to a contract sales force directly from a manufacturer. We believe the Colorado State Legislature made it very clear that the provision of samples is specifically exempted by Colorado State Statute12-22-801 (2) (d).

12-22-801. Definitions - exemption from licensing requirements.

(2) For the purposes of this part 8, "wholesale distribution" means distribution of prescription drugs to persons or entities other than a consumer or patient. "Wholesale distribution" does not include:
***
(d) The distribution of prescription drug samples by a manufacturer's representative;

Shipments to our manufacturer's representative, in this case, Promotech, are clearly excluded from the definition of wholesale distribution and therefore not subject to licensure requirements. However, in the interest of closing this matter as expeditiously as possible, we are enclosing the requested payment and agreeing to the enclosed, non-negotiable Stipulation and Final Agency Order.

Your prompt assistance with processing our approval for the Lewisville facility would be greatly appreciated.

Sincerely,

Damon Burrows
Vice President, Assistant General Counsel—Regulatory
Allergan, Inc.

Enclosures

STATE OF COLORADO

STATE BOARD OF PHARMACY
Wendy L. Anderson, Program Director

1560 Broadway, Suite 1300
Denver, Colorado 80202-5146
Phone (303) 894-7800
Fax (303) 894-7692
V/TDD: Dial 711 for Relay Colorado
www.dora.state.co.us/pharmacy

RECEIVED
MAR 17 2009
LEGAL DEPARTMENT

Department of Regulatory Agencies
D. Rico Munn
Executive Director

Division of Registrations
Rosemary McCool
Director

Bill Ritter, Jr.
Governor

March 10, 2009

Allergan USA, Inc.
Attn: David Henderson, Designated Representative
1800 Waters Ridge Drive #100
Lewisville, TX 75057

RE: Stipulation and Final Agency Order
Case #2009-2899

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS AN OUT-OF=STATE WHOLESALER IN THE STATE OF COLORADO OF **ALLERGAN USA, INC.**,

Dear Mr. Henderson:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above-mentioned matter, which became effective March 10, 2009.

Accordingly, and pursuant to Item 8 – Conditional Registration of the Stip/FAO, Allergan USA, Inc., at the above listed location, has been issued out-of-state prescription drug wholesaler registration #7514, effective March 10, 2009.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint/Licensing Analyst

Enclosure

cc: Damon Burrows, Esq.
Jazell Carter, Licensing Specialist, Office of Licensing
File

G:\Healthcare\Pharmacy\JOHNSON\Complaints\Monitoring\2009 corresp\STIP FAO LETTER.doc

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2009-2899

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF **ALLERGAN USA, INC.,**

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Allergan USA, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2009-2899 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state 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. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. On December 24, 2008, Wholesaler Applicant distributed prescription drugs into Colorado without having first registered as an out-of-state wholesaler in the State of Colorado.

4. On February 5, 2009, the Board issued Wholesaler Applicant a Cease and Desist Order for engaging in unregistered wholesale distribution of drugs into the State of Colorado.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

Colorado Revised Statutes

PAID
2619560 $5,150-

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 drugs.

12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

* * *

12-22-802. Wholesaler license requirements. (1) A wholesaler that resides in this state shall be licensed by the board. A wholesaler that does not reside in this state shall be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state...

* * *

6. On February 25, 2009, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION
Conditional Registration;
$5,000.00 Fine Plus 15% Surcharge and Terms
Agreement to Comply with §§12-22-801, *et seq.* C.R.S.
Release from Cease and Desist Order

8. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

9. **Fine with Surcharge.** Wholesaler Applicant accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Wholesaler Applicant shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Wholesaler Applicant understands and acknowledges, pursuant to §24-34-108, C.R.S., that the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Wholesaler Applicant shall therefore pay a total amount of **Five Thousand, Seven Hundred Fifty Dollars and No Cents ($5,750.00).** The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Wholesaler Applicant submits this signed Final Agency Order to the Board.

10. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

11. **Release from Cease & Desist Order.** Upon execution of this Final Agency Order, payment of the required fine as required above in paragraph 9, and issuance of Wholesaler Applicant's registration as an out-of-state wholesaler in the state of Colorado as set forth above in paragraph 8, the terms of the Cease and Desist Order entered on February 5, 2009 no longer apply and Wholesaler Applicant is hereby RELEASED from the Cease and Desist Order. The Cease and Desist Order shall remain a public record published in accordance with the Colorado Open Records Act and Board policy along with this Final Agency Order, as set forth below in paragraph 16.

12. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a 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 §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

13. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

14. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency 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 its 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 Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

15. **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.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Dated: 3/4/2009

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by DAMON DRAN BURROUGHS, II in his/her capacity as an authorized agent of Allergan USA, Inc before me in the County of Orange, State of California this 4th day of March 2009.

ISABEL ZAVALA
Commission # 1871236
Notary Public - California
Orange County
My Comm. Expires Apr 19, 2009

Notary Public

My commission expires:

April 19, 2009

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 10th day of March, 2009.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

APPROVED AS TO FORM

Attorneys for Respondent:

* Damon Burrows

2525 Dupont Drive
Irvine, CA 92612
Telephone: (714) 246 – 6159

* Counsel of Record

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 10th day of March 2009, addressed as follows:

Allergan USA, Inc.
Attn: Designated Representative
1800 Waters Ridge Dr., Ste 100
Lewisville, TX 75057

Allergan USA, Inc.
Attn: Damon Burrows, Esq.
2525 Dupont Drive
Irvine, CA 92612

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STATE OF COLORADO
Department of Regulatory Agencies
Division of Registrations

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Number	Issue Date	Expires

Allergan USA, Inc.
Lewisville, TX 75057
United States

Director

Signature

Allergan USA, Inc.

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NEVADA STATE BOARD OF PHARMACY

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Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285067023

Application/License No. _____

Allergan USA, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5 Giralda Farms, Madison, NJ 07940 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (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 June 28, 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 28th day of June, 2021.

APPLICANT/PRINCIPAL
Allergan USA, Inc.

Authorized Representative

SURETY COMPANY
Liberty Mutual Insurance Company

Cynthia L. Choren
Surety Company's Representative

Cynthia L. Choren
print name, Attorney-in-fact

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Jo Ann R. Frank
Witness

Brittany A. Stuckel
Witness

Countersigned by:

N/A
Nevada Resident Agent

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute 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 have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 28th day of June, 2021.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549
FORM 10-K

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-35565

abbvie

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware	32-0375147
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification number)

1 North Waukegan Road
North Chicago, Illinois 60064-6400
(847) 932-7900
(Address, including zip code, and telephone number of principal executive offices)

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 $0.01 per share	ABBV	New York Stock Exchange Chicago Stock Exchange
0.500% Senior Notes due 2021	ABBV21C	New York Stock Exchange
1.500% Senior Notes due 2023	ABBV23B	New York Stock Exchange
1.375% Senior Notes due 2024	ABBV24	New York Stock Exchange
1.250% Senior Notes due 2024	ABBV24B	New York Stock Exchange
0.750% Senior Notes due 2027	ABBV27	New York Stock Exchange
2.125% Senior Notes due 2028	ABBV28	New York Stock Exchange
2.625% Senior Notes due 2028	ABBV28B	New York Stock Exchange
2.125% Senior Notes due 2029	ABBV29	New York Stock Exchange
1.250% Senior Notes due 2031	ABBV31	New York Stock Exchange

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 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 during the preceding 12 months (or for such shorter 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Large Accelerated Filer Accelerated Filer

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. ☒

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 1,747,782,344 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of AbbVie Inc.'s most recently completed second fiscal quarter (June 30, 2020), was $171,597,270,533. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2021: 1,765,881,690

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 22, 2021.

ABBVIE INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2020
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PART I

ITEM 1. BUSINESS

Overview

AbbVie[1] is a global, research-based biopharmaceutical company. AbbVie uses its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases.

On May 8, 2020, AbbVie completed the acquisition of Allergan plc (Allergan). The acquisition of Allergan creates a diversified biopharmaceutical company positioned for success with a comprehensive product portfolio that has leadership positions in key therapeutic areas of immunology, hematologic oncology, aesthetics, neuroscience, eye care and women's health. AbbVie's existing product portfolio and pipeline is enhanced with numerous Allergan assets and Allergan's product portfolio benefits from AbbVie's commercial strength, expertise and international infrastructure. See Note 5, "Licensing, Acquisitions and Other Arrangements—Acquisition of Allergan," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data." Subsequent to the acquisition date, AbbVie's consolidated financial statements include the assets, liabilities, operating results and cash flows of Allergan.

AbbVie was incorporated in Delaware on April 10, 2012. On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories (Abbott) of 100% of the outstanding common stock of AbbVie to Abbott's shareholders.

Impact of the Coronavirus Disease 2019 (COVID-19)

The novel coronavirus (COVID-19) pandemic continues to spread throughout the United States and around the world. In response to the growing public health crisis, AbbVie has partnered with global authorities to support the experimental use of multiple AbbVie assets to determine their efficacy in the treatment of COVID-19. AbbVie continues to closely manage manufacturing and supply chain resources around the world to help ensure that patients continue to receive an uninterrupted supply of their medicines. Clinical trial sites are being monitored locally to protect the safety of study participants, staff and employees. While the impact of COVID-19 on AbbVie's operations to date has not been material, AbbVie has experienced lower new patient starts across the therapeutic portfolio. AbbVie expects this matter could continue to negatively impact its results of operations throughout the duration of the outbreak. The extent to which COVID-19 may impact AbbVie's financial condition and results of operations remains uncertain.

Segments

AbbVie operates as a single global business segment dedicated to the research and development, manufacturing, commercialization and sale of innovative medicines and therapies. This operating structure enables the Chief Executive Officer, as chief operating decision maker (CODM), to allocate resources and assess business performance on a global basis in order to achieve established long-term strategic goals. Consistent with this structure, a global research and development and supply chain organization is responsible for the discovery, development, manufacturing and supply of products. Commercial efforts that coordinate the marketing, sales and distribution of these products are organized by geographic region or therapeutic area. All of these activities are supported by a global corporate administrative staff. The determination of a single

(1) As used throughout the text of this report on Form 10-K, the terms "AbbVie" or "the company" refer to AbbVie Inc., a Delaware corporation, or AbbVie Inc. and its consolidated subsidiaries, as the context requires.

business segment is consistent with the consolidated financial information regularly reviewed by the CODM for purposes of assessing performance, allocating resources and planning and forecasting future periods. See Note 16, "Segment and Geographic Area Information" to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" and the sales information related to AbbVie's key products and geographies included under Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Products

AbbVie's portfolio of products includes a broad line of therapies that address some of the world's most complex and serious diseases.

Immunology products. AbbVie maintains an extensive immunology portfolio across rheumatology, dermatology and gastroenterology. AbbVie's immunology products address unmet needs for patients with autoimmune diseases. These products are:

Humira. Humira (adalimumab) is a biologic therapy administered as a subcutaneous injection. It is approved to treat the following autoimmune diseases in the United States, Canada and Mexico (collectively, North America) and in the European Union:

Condition	Principal Markets
Rheumatoid arthritis (moderate to severe)	North America, European Union
Psoriatic arthritis	North America, European Union
Ankylosing spondylitis	North America, European Union
Adult Crohn's disease (moderate to severe)	North America, European Union
Plaque psoriasis (moderate to severe chronic)	North America, European Union
Juvenile idiopathic arthritis (moderate to severe polyarticular)	North America, European Union
Ulcerative colitis (moderate to severe)	North America, European Union
Axial spondyloarthropathy	European Union
Pediatric Crohn's disease (moderate to severe)	North America, European Union
Hidradenitis suppurativa (moderate to severe)	North America, European Union
Pediatric enthesitis-related arthritis	European Union
Non-infectious intermediate, posterior and panuveitis	North America, European Union
Pediatric ulcerative colitis (moderate to severe)	European Union
Pediatric uveitis	European Union

Humira is also approved in Japan for the treatment of intestinal Behçet's disease and pyoderma gangrenosum.

Humira is sold in numerous other markets worldwide, including Japan, China, Brazil and Australia, and accounted for approximately 43% of AbbVie's total net revenues in 2020.

Skyrizi. Skyrizi (risankizumab) is an interleukin-23 (IL-23) inhibitor that selectively blocks IL-23 by binding to its p19 subunit. It is a biologic therapy administered as a quarterly subcutaneous injection following an induction dose. Skyrizi is approved in the United States, Canada and the European Union and is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. In Japan, Skyrizi is approved for the treatment of plaque psoriasis, generalized pustular psoriasis, erythrodermic psoriasis and psoriatic arthritis in adult patients who have an inadequate response to conventional therapies.

Rinvoq. Rinvoq (upadacitinib) is an oral, once-daily selective and reversible JAK inhibitor and is approved in the United States, Canada, Japan and the European Union. Rinvoq is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients

who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Rinvoq is also approved in the European Union for the treatment of adult patients with active psoriatic arthritis and adult patients with active ankylosing spondylitis. Rinvoq may be used as monotherapy or in combination with methotrexate. Rinvoq is also indicated in Japan in patients with rheumatoid arthritis with inadequate response to conventional therapy (including inhibition of the progression of structural damage).

Oncology products. AbbVie's oncology products target some of the most complex and difficult-to-treat cancers. These products are:

Imbruvica. Imbruvica (ibrutinib) is an oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase (BTK). Imbruvica was one of the first medicines to receive a United States Food and Drug Administration (FDA) approval after being granted a Breakthrough Therapy Designation and is one of the few therapies to receive four separate designations. Imbruvica currently is approved for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) and CLL/SLL with 17p deletion;
- Mantle cell lymphoma (MCL) who have received at least one prior therapy*;
- Waldenström's macroglobulinemia (WM);
- Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy*; and
- Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

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* Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Venclexta/Venclyxto. *Venclexta* (venetoclax) is a BCL-2 inhibitor used to treat hematological malignancies. Venclexta is approved by the FDA for adults with CLL or SLL. In addition, Venclexta is approved in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly-diagnosed acute myeloid leukemia (AML) who are 75 years of age or older or have other medical conditions that prevent the use of standard chemotherapy. Venclyxto is approved in Europe for CLL in combination with obinutuzumab for patients with previously untreated CLL and in combination with rituximab in patients who have received at least one previous treatment.

Aesthetics products. AbbVie's Allergan Aesthetics portfolio consists of toxins and dermal fillers, plastics and regenerative medicine, body contouring, and skincare products, which hold market-leading positions in the U.S. and in key markets around the world. In 2020, U.S. sales comprised approximately two-thirds of total global sales. These products are:

Botox Cosmetic. Botox Cosmetic is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for temporary improvement in the appearance of moderate to severe glabellar lines (frown lines between the eyebrows), moderate to severe crow's feet and forehead lines in adults. Having received its initial U.S. Food and Drug Administration (FDA) approval in 2002, Botox Cosmetic is now approved for use in all major markets around the world and has become one of the world's most recognized and iconic brands.

Juvederm Collection. The Juvederm Collection is a portfolio of hyaluronic acid-based dermal fillers with a variety of approved indications in the U.S. and in all other major markets around the world to treat volume loss in the cheeks, chin, lips and lower face.

Other aesthetics. Other aesthetics products include, but are not limited to, Coolsculpting body contouring technology, Alloderm regenerative dermal tissue, Natrelle breest implants, the SkinMedica skincare line, and DiamondGlow.

Neuroscience products. AbbVie's neuroscience products address some of the most difficult-to-treat neurologic diseases. These products are:

Botox Therapeutic. Botox Therapeutic (onabotulinumtoxinA injection) is a neuromuscular blocking agent that is injected into muscle tissue in treatment for the following indications in the United States:

- For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- For the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- For the prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
- For the treatment of spasticity in patients 2 years of age and older.
- For the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
- For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.
- For the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Licenses around the world vary.
- Focal spasticity associated with dynamic equinus foot deformity due to spasticity in ambulant pediatric cerebral palsy patients, two years of age or older.
- Focal spasticity of the wrist and hand in adult post stroke patients.
- Focal spasticity of the ankle and foot in adult post stroke patients.

Vraylar. Vraylar (cariprazine) is a dopamine D3-preferring D3/D2 receptor partial agonist and a 5-HT1A receptor partial agonist. Its D3 binding profile may be linked to observed improvements in the negative symptoms of schizophrenia and to antidepressant effects in Bipolar I disorder. Vraylar is indicated for acute and maintenance treatment of schizophrenia in adults, acute treatment of manic or mixed episodes associated with bipolar disorder in adults and acute treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults.

Duopa and Duodopa (carbidopa and levodopa). AbbVie's levodopa-carbidopa intestinal gel for the treatment of advanced Parkinson's disease is marketed as Duopa in the United States and as Duodopa outside of the United States.

Ubrelvy. Ubrelvy (ubrogepant) is indicated for the acute treatment of migraine with or without aura in adults and is only commercialized in the United States.

Eye care products. AbbVie's eye care products address unmet needs and new approaches to help preserve and protect patients' vision. These products are:

Lumigan/Ganfort. Lumigan (bimatoprost ophthalmic solution) 0.01% is a once daily, topical prostaglandin analog indicated for the reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). Ganfort is a once daily topical fixed combination of bimatoprost 0.03% and timolol 0.5% for the reduction of IOP in adult patients with OAG or OHT. Lumigan is sold in the United States and numerous markets around the world, while Ganfort is approved in the EU and some markets in South America, the Middle East, and Asia.

Alphagan/Combigan. Alphagan (brimonidine tartrate ophthalmic solution) is an alpha-adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Combigan (brimonidine tartrate/ timolol maleate ophthalmic solution) is approved for reducing elevated intraocular pressure (IOP) in patients with glaucoma who require additional or adjunctive IOP-lowering therapy. Both Alphagan and Combigan are available for sale in the United States and numerous markets around the world.

Restasis. Restasis is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Restasis is approved in the United States and a number of other markets in South America, the Middle East, and Asia.

Other eye care. Other eye care products include Xen, Durysta, Ozurdex and Refresh/Optive.

Women's health products. AbbVie's women's health products are:

Lo Loestrin. Lo Loestrin Fe is an oral contraceptive. It is indicated for prevention of pregnancy with the lowest dose of estrogen with only 10mcg and is dispensed in a unique 24/2/2 regimen with a two-day hormone-free interval. It is marketed in the U.S. as Lo Loestrin Fe (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets) and in select markets outside the U.S. as Lolo.

Orilissa/Oriahnn. Orilissa (elagolix) is the first and only orally-administered, nonpeptide small molecule gonadotropin-releasing hormone (GnRH) antagonist specifically developed for women with moderate to severe endometriosis pain. The FDA approved Orilissa under priority review. It represents the first FDA-approved oral treatment for the management of moderate to severe pain associated with endometriosis in over a decade. Orilissa inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration results in dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone, leading to decreased blood concentrations of ovarian sex hormones, estradiol and progesterone. Outside the United States, Orilissa is also launched in Canada and Puerto Rico. Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is a combination prescription medicine used to control heavy menstrual bleeding related to uterine fibroids in women before menopause.

Other women's health. Other women's health includes Liletta, a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to six years. It is the only hormonal IUS (Intrauterine System) approved in the U.S. for up to six years of pregnancy prevention.

Other key products. AbbVie's other key products include, among other things, treatments for patients with hepatitis C virus (HCV), metabolic and hormone products that target a number of

conditions, including exocrine pancreatic insufficiency and hypothyroidism, as well as endocrinology products for the palliative treatment of advanced prostate cancer, treatment of endometriosis and central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids. These products are:

Mavyret/Maviret. Mavyret (glecaprevir/pibrentasvir) is approved in the United States and European Union (Maviret) for the treatment of adult and pediatric patients (12 years and older or weighing at least 45 kilograms) with chronic HCV genotype 1-6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). It is also indicated for the treatment of adult and pediatric patients (12 years and older or weighing at least 45 kilograms) with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. It is an 8-week, pan-genotypic treatment for patients without cirrhosis and following the EXPEDITION-8 study, also in patients with compensated cirrhosis who are new to treatment.

Creon. Creon (pancrelipase) is a pancreatic enzyme therapy for exocrine pancreatic insufficiency, a condition that occurs in patients with cystic fibrosis, chronic pancreatitis and several other conditions.

Lupron. Lupron (leuprolide acetate), which is also marketed as Lucrin and Lupron Depot, is a product for the palliative treatment of advanced prostate cancer, treatment of endometriosis and central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids. Lupron is approved for daily subcutaneous injection and one-month, three-month, four-month and six-month intramuscular injection.

Linzess/Constella. Linzess (linaclotide) is a once-daily guanylate cyclase-C agonist used in adults to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC). The product is marketed as Linzess in the United States and as Constella outside of the United States.

Synthroid. Synthroid (levothyroxine sodium tablets, USP) is used in the treatment of hypothyroidism.

AbbVie has the rights to sell Creon and Synthroid only in the United States. AbbVie's commercial rights to the sale and distribution of Synagis outside of the United States will revert to AstraZeneca upon the expiry of the current agreement in 2021.

Marketing, Sales and Distribution Capabilities

AbbVie utilizes a combination of dedicated commercial resources, regional commercial resources and distributorships to market, sell and distribute its products worldwide. AbbVie directs its primary marketing efforts toward securing the prescription, or recommendation, of its brand of products by physicians, key opinion leaders and other health care providers. Managed care providers (for example, health maintenance organizations and pharmacy benefit managers), hospitals and state and federal government agencies (for example, the United States Department of Veterans Affairs and the United States Department of Defense) are also important customers. AbbVie also markets directly to consumers themselves, although in the United States many of the company's products must be sold pursuant to a prescription. Outside of the United States, AbbVie focuses its promotional and market access efforts on key opinion leaders, payers, physicians and health systems. AbbVie also provides patient support programs closely related to its products. Throughout the COVID-19 pandemic AbbVie has maintained its promotional activities with key stakeholders by leveraging digital engagement where permitted and in compliance with the locally applicable government guidance.

AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. Certain products (including aesthetic products and devices) are also sold directly to physicians and other licensed healthcare providers. Although AbbVie's business does not have significant seasonality, AbbVie's product revenues may be affected by end customer and retail buying patterns, fluctuations in wholesaler inventory levels and other factors.

In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to retailers, pharmacies and patients. In 2020, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation) accounted for substantially all of AbbVie's sales in the United States. No individual wholesaler accounted for greater than 38% of AbbVie's 2020 gross revenues in the United States. Outside the United States, AbbVie sells products primarily to customers or through distributors, depending on the market served.

Certain products are co-marketed or co-promoted with other companies. AbbVie has no single customer that, if the customer were lost, would have a material adverse effect on the company's business. No material portion of AbbVie's business is subject to renegotiation of profits or termination of contracts at the election of the government. Orders are generally filled on a current basis and order backlog is not material to AbbVie's business.

Competition

The markets for AbbVie's products are highly competitive. AbbVie competes with other research-based pharmaceuticals and biotechnology companies that discover, manufacture, market and sell proprietary pharmaceutical products, therapies and biologics. For example, Humira competes with anti-TNF products and other competitive products intended to treat a number of disease states and Mavyret/Maviret competes with other available HCV treatment options. In addition, in the past few years, a number of other companies have started to develop, have successfully developed and/or are currently marketing products that are being positioned as competitors to Botox. The search for technological innovations in pharmaceutical products is a significant aspect of competition. The introduction of new products by competitors and changes in medical practices and procedures can result in product obsolescence. Price is also a competitive factor. In addition, the substitution of generic pharmaceutical products for branded pharmaceutical products creates competitive pressures on AbbVie's products that do not have patent protection. New products or treatments brought to market by AbbVie's competitors could cause revenues for AbbVie's products to decrease due to price reductions and sales volume decreases.

Biosimilars. Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as "biosimilars." Biologics have added major therapeutic options for the treatment of many diseases, including some for which therapies were unavailable or inadequate. The cost of developing and producing biologic therapies is typically dramatically higher than for conventional (small molecule) medications, and many biologic medications are used for ongoing treatment of chronic diseases, such as rheumatoid arthritis or inflammatory bowel disease, or for the treatment of previously untreatable cancer. Significant investments in biologics infrastructure and manufacturing are necessary to produce biologic products.

Humira is now facing direct biosimilar competition in Europe and other countries, and AbbVie will continue to face competitive pressure from these biologics and from orally administered products.

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act (the FFDCA), the Public Health Service Act (PHSA) and the regulations implementing such acts.

The enactment of federal health care reform legislation in March 2010 provided a pathway for approval of biosimilars under the PHSA, but the approval process for, and science behind, biosimilars is complex. Approval by the FDA is dependent upon many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity and potency. The types of data that could ordinarily be required in an application to show similarity may include analytical data, bioequivalence studies and studies to demonstrate chemical similarity, animal studies (including toxicity studies) and clinical studies.

Furthermore, the law provides that only a biosimilar product that is determined to be "interchangeable" will be considered by the FDA as substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The law continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning remains subject to uncertainty.

Intellectual Property Protection and Regulatory Exclusivity

Generally, upon approval, products may be entitled to certain kinds of exclusivity under applicable intellectual property and regulatory regimes. AbbVie's intellectual property is materially valuable to the company, and AbbVie seeks patent protection, where available, in all significant markets and/or countries for each product in development. In the United States, the expiration date for patents is 20 years after the filing date. Given that patents relating to pharmaceutical products are often obtained early in the development process and given the amount of time needed to complete clinical trials and other development activities required for regulatory approval, the length of time between product launch and patent expiration is significantly less than 20 years. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) permits a patent holder to seek a patent extension, commonly called a "patent term restoration," for patents on products (or processes for making the product) regulated by the FFDCA. The length of the patent extension is roughly based on 50 percent of the period of time from the filing of an Investigational New Drug Application (NDA) for a compound to the submission of the NDA for such compound, plus 100 percent of the time period from NDA submission to regulatory approval. The extension, however, cannot exceed five years and the patent term remaining after regulatory approval cannot exceed 14 years. Biological products licensed under the PHSA are similarly eligible for terms of patent restoration.

Pharmaceutical products may be entitled to other forms of legal or regulatory exclusivity upon approval. The scope, length, and requirements for each of these exclusivities vary both in the United States and in other jurisdictions. In the United States, if the FDA approves a drug product that contains an active ingredient not previously approved, the product is typically entitled to five years of non-patent regulatory exclusivity. Other products may be entitled to three years of exclusivity if approval was based on the FDA's reliance on new clinical studies essential to approval submitted by the NDA applicant. If the NDA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days all existing exclusivities (patent and regulatory) related to the product. For products that are either used to treat conditions that afflict a relatively small population or for which there is not a reasonable expectation that the research and development costs will be recovered, the FDA may designate the pharmaceutical as an orphan drug and grant it seven years of market exclusivity. Other types of regulatory exclusivity may also be

available, such as Generating New Antibiotic Incentives Now (GAIN) exclusivity, which can provide new antibiotic or new antifungal drugs an additional 5 years of marketing exclusivity to be added to certain exclusivities already provided for by law.

Applicable laws and regulations dictate the scope of any exclusivity to which a product or particular characteristics of a product is entitled upon approval in any particular country. In certain instances, regulatory exclusivity may offer protection where patent protection is no longer available or for a period of time in excess of patent protection. It is not possible to estimate for each product in development the total period and scope of exclusivity to which it may become entitled until regulatory approval is obtained or sometimes even later. However, given the length of time required to complete clinical development of a pharmaceutical product, the periods of exclusivity that might be achieved in any individual case would not be expected to exceed a minimum of three years and a maximum of 14 years. These estimates do not consider other factors, such as the difficulty of recreating the manufacturing process for a particular product or other proprietary knowledge that may delay the introduction of a generic or other follow-on product after the expiration of applicable patent and other regulatory exclusivity periods.

Biologics may be entitled to exclusivity under the Biologics Price Competition and Innovation Act, which was passed on March 23, 2010 as Title VII to the Patient Protection and Affordable Care Act. The law provides a pathway for approval of biosimilars following the expiration of 12 years of regulatory exclusivity for the innovator biologic and a potential additional 180 day-extension term for conducting pediatric studies. Biologics are also eligible for orphan drug exclusivity, as discussed above. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability. The European Union has also created a pathway for approval of biosimilars and has published guidelines for approval of certain biosimilar products. The more complex nature of biologics and biosimilar products has led to close regulatory scrutiny over follow-on biosimilar products, which can reduce the effect of biosimilars on sales of the innovator biologic as compared to the sales erosion caused by generic versions of small molecule pharmaceutical products.

AbbVie owns or has licensed rights to a substantial number of patents and patent applications. AbbVie licenses or owns a patent portfolio of thousands of patent families, each of which includes United States patent applications and/or issued patents and may also contain the non-United States counterparts to these patents and applications.

These patents and applications, including various patents that expire during the period 2021 to the late 2030s, in aggregate are believed to be of material importance in the operation of AbbVie's business. However, AbbVie believes that no single patent, license, trademark (or related group of patents, licenses, or trademarks), except for those related to adalimumab (which is sold under the trademark Humira), are material in relation to the company's business as a whole. The United States composition of matter (that is, compound) patent covering adalimumab expired in December 2016, and the equivalent European Union patent expired in October 2018 in the majority of European Union countries. In the United States, non-composition of matter patents covering adalimumab expire no earlier than 2022. AbbVie has entered into settlement and license agreements with several adalimumab biosimilar manufactures. Under the agreements, the license in the United States will begin in 2023 and the license in Europe began in 2018.

In addition, the following patents, licenses, and trademarks are significant: those related to ibrutinib (which is sold under the trademark Imbruvica) and those related to risankizumab (which is sold under the trademark Skyrizi). The United States composition of matter patent covering ibrutinib is expected to expire in 2027. The United States composition of matter patent covering risankizumab is expected to expire in 2033.

AbbVie may rely, in some circumstances, on trade secrets to protect its technology. AbbVie seeks to protect its technology and product candidates, in part, by confidentiality agreements with its employees, consultants, advisors, contractors, and collaborators. These agreements may be breached and AbbVie may not have adequate remedies for any breach. In addition, AbbVie's trade secrets may otherwise become known or be independently discovered by competitors. To the extent that AbbVie's employees, consultants, advisors, contractors, and collaborators use intellectual property owned by others in their work for the company, disputes may arise as to the rights in related or resulting know-how and inventions.

Licensing, Acquisitions and Other Arrangements

In addition to its independent efforts to develop and market products, AbbVie enters into arrangements such as acquisitions, option-to-acquire agreements, licensing arrangements, option-to-license arrangements, strategic alliances, co-promotion arrangements, co-development and co-marketing agreements, and joint ventures. The acquisitions and option-to-acquire agreements typically include, among other terms and conditions, non-refundable purchase price payments or option fees, option exercise payments, milestones or earn-outs, and other customary terms and obligations. The licensing and other arrangements typically include, among other terms and conditions, non-refundable upfront license fees, option fees and option exercise payments, milestone payments and royalty and/or profit sharing obligations. See Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

Third Party Agreements

AbbVie has agreements with third parties for process development, product distribution, analytical services and manufacturing of certain products. AbbVie procures certain products and services from a limited number of suppliers and, in some cases, a single supply source. In addition, AbbVie has agreements with third parties for active pharmaceutical ingredient and product manufacturing, formulation and development services, fill, finish and packaging services, transportation and distribution and logistics services for certain products. AbbVie does not believe that these manufacturing related agreements are material because AbbVie's business is not substantially dependent on any individual agreement. In most cases, AbbVie maintains alternate supply relationships that it can utilize without undue disruption of its manufacturing processes if a third party fails to perform its contractual obligations. AbbVie also maintains sufficient inventory of product to minimize the impact of any supply disruption.

AbbVie is also party to certain collaborations and other arrangements, as discussed in Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

Sources and Availability of Raw Materials

AbbVie purchases, in the ordinary course of business, raw materials and supplies essential to its operations from numerous suppliers around the world. In addition, certain medical devices and components necessary for the manufacture of AbbVie products are provided by unaffiliated third party suppliers. Other than the Lupron near-term supply issue which has impacted availability of certain formulations, AbbVie has not experienced any recent significant availability problems or supply shortages that impacted fulfillment of product demand.

Research and Development Activities

AbbVie makes a significant investment in research and development and has numerous compounds in clinical development, including potential treatments for complex, life-threatening diseases. AbbVie's ability to discover and develop new compounds is enhanced by the company's use of integrated discovery and development project teams, which include chemists, biologists, physicians and pharmacologists who work on the same compounds as a team. AbbVie also partners with third parties, such as biotechnology companies, other pharmaceutical companies and academic institutions to identify and prioritize promising new treatments that complement and enhance AbbVie's existing portfolio. AbbVie also supplements its research and development efforts with acquisitions.

The research and development process generally begins with discovery research which focuses on the identification of a molecule that has a desired effect against a given disease. If preclinical testing of an identified compound proves successful, the compound moves into clinical development which generally includes the following phases:

- Phase 1—involves the first human tests in a small number of healthy volunteers or patients to assess safety, tolerability and potential dosing.
- Phase 2—tests the drug's efficacy against the disease in a relatively small group of patients.
- Phase 3—tests a drug that demonstrates favorable results in the earlier phases in a significantly larger patient population to further demonstrate efficacy and safety based on regulatory criteria.

The clinical trials from all of the development phases provide the data required to prepare and submit an NDA, a Biological License Application (BLA) or other submission for regulatory approval to the FDA or similar government agencies outside the United States. The specific requirements (e.g., scope of clinical trials) for obtaining regulatory approval vary across different countries and geographic regions.

The research and development process from discovery through a new drug launch typically takes 8 to 12 years and can be even longer. The research and development of new pharmaceutical products has a significant amount of inherent uncertainty. There is no guarantee when, or if, a molecule will receive the regulatory approval required to launch a new drug or indication.

In addition to the development of new products and new formulations, research and development projects also may include Phase 4 trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug.

Regulation—Discovery and Clinical Development

United States. Securing approval to market a new pharmaceutical product in the United States requires substantial effort and financial resources and takes several years to complete. The applicant must complete preclinical tests and submit protocols to the FDA before commencing clinical trials. Clinical trials are intended to establish the safety and efficecy of the pharmaceutical product and typically are conducted in sequential phases, although the phases may overlap or be combined. If the required clinical testing is successful, the results are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA or BLA to determine whether a product is safe and effective for its intended use and whether its manufacturing is compliant with current Good Manufacturing Practices (cGMP).

Even if an NDA or a BLA receives approval, the applicant must comply with post-approval requirements. For example, holders of an approval must report adverse reactions, provide updated

safety and efficacy information and comply with requirements concerning advertising and promotional materials and activities. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and certain changes to the manufacturing procedures and finished product must be submitted and approved by the FDA prior to implementation. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and record keeping requirements. In addition, as a condition of approval, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety or efficacy after commercialization, which may require additional clinical trials, patient registries, observational data or additional work on chemistry, manufacturing and controls. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future. Further, the FDA continues to regulate product labeling, and prohibits the promotion of products for unapproved or "off-label" uses along with other labeling restrictions.

Outside the United States. AbbVie is subject to similar regulatory requirements outside the United States for approval and marketing of pharmaceutical products. AbbVie must obtain approval of a clinical trial application or product from applicable supervising regulatory authorities before it can commence clinical trials or marketing of the product in target markets. The approval requirements and process for each country can vary, and the time required to obtain approval may be longer or shorter than that required for FDA approval in the United States. For example, AbbVie may submit marketing authorizations in the European Union under either a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products and provides for a single marketing authorization that is valid for all European Union member states. Under the centralized procedure, a single marketing authorization application is submitted to the European Medicines Agency (EMA). After the agency evaluates the application, it makes a recommendation to the European Commission, which then makes the final determination on whether to approve the application. The decentralized procedure provides for mutual recognition of individual national approval decisions and is available for products that are not subject to the centralized procedure.

In Japan, applications for approval of a new product are made through the Pharmaceutical and Medical Devices Agency (PMDA). Japan-specific trials and/or bridging studies to demonstrate that the non-Japanese clinical data applies to Japanese patients may be required. After completing a comprehensive review, the PMDA reports to the Ministry of Health, Labour and Welfare, which then approves or denies the application.

Similarly, applications for a new product in China are submitted to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) for technical review and approval of a product for marketing in China. Clinical data in Chinese subjects are required to support approval in China, requiring the inclusion of China in global pivotal studies, or a separate China/Asian clinical trial.

The regulatory process in many emerging markets continues to evolve. Many emerging markets, including those in Asia, generally require regulatory approval to have been obtained in a large developed market (such as the United States or Europe) before the country will begin or complete its regulatory review process. Similar to the requirements in Japan and China, certain countries (notably South Korea, Taiwan and Russia) also require that local clinical studies be conducted in order to support regulatory approval in the country.

The requirements governing the conduct of clinical trials and product licensing also vary. In addition, post-approval regulatory obligations such as adverse event reporting and cGMP compliance generally apply and may vary by country. For example, after a marketing authorization has been granted in the European Union, periodic safety reports must be submitted and other pharmacovigilance measures may be required (such as Risk Management Plans).

Regulation—Commercialization, Distribution and Manufacturing

The manufacture, marketing, sale, promotion and distribution of AbbVie's products are subject to comprehensive government regulation. Government regulation by various national, regional, federal, state and local agencies, both in the United States and other countries, addresses (among other matters) inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, labeling, packaging, marketing and promotion, pricing and reimbursement, sampling, distribution, quality control, post-marketing surveillance, record keeping, storage and disposal practices. AbbVie's operations are also affected by trade regulations in many countries that limit the import of raw materials and finished products and by laws and regulations that seek to prevent corruption and bribery in the marketplace (including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act, which provide guidance on corporate interactions with government officials) and require safeguards for the protection of personal data. In addition, AbbVie is subject to laws and regulations pertaining to health care fraud and abuse, including state and federal anti-kickback and false claims laws in the United States. Prescription drug manufacturers such as AbbVie are also subject to taxes, as well as application, product, user and other fees.

Compliance with these laws and regulations is costly and materially affects AbbVie's business. Among other effects, health care regulations substantially increase the time, difficulty and costs incurred in obtaining and maintaining approval to market newly developed and existing products. AbbVie expects compliance with these regulations to continue to require significant technical expertise and capital investment to ensure compliance. Failure to comply can delay the release of a new product or result in regulatory and enforcement actions, the seizure or recall of a product, the suspension or revocation of the authority necessary for a product's production and sale and other civil or criminal sanctions, including fines and penalties.

In addition to regulatory initiatives, AbbVie's business can be affected by ongoing studies of the utilization, safety, efficacy and outcomes of health care products and their components that are regularly conducted by industry participants, government agencies and others. These studies can lead to updates to the data regarding utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of, or limitations on, marketing of such products domestically or worldwide, and may give rise to claims for damages from persons who believe they have been injured as a result of their use.

Access to human health care products continues to be a subject of oversight, investigation and action by governmental agencies, legislative bodies and private organizations in the United States and other countries. A major focus is cost containment. Efforts to reduce health care costs are also being made in the private sector, notably by health care payers and providers, which have instituted various cost reduction and containment measures. AbbVie expects insurers and providers to continue attempts to reduce the cost of health care products. Outside the United States, many countries control the price of health care products directly or indirectly, through reimbursement, payment, pricing, coverage limitations, or compulsory licensing. Political and budgetary pressures in the United States and in other countries may also heighten the scope and severity of pricing pressures on AbbVie's products for the foreseeable future.

United States. Specifically, U.S. federal laws require pharmaceutical manufacturers to pay certain statutorily-prescribed rebates to state Medicaid programs on prescription drugs reimbursed under state Medicaid plans, and the efforts by states to seek additional rebates affect AbbVie's business. Similarly, the Veterans Health Care Act of 1992, as a prerequisite to participation in Medicaid and other federal health care programs, requires that manufacturers extend additional discounts on pharmaceutical products to various federal agencies, including the United States Department of Veterans Affairs, Department of Defense and Public Health Service entities and

institutions. In addition, recent legislative changes would require similarly discounted prices to be offered to TRICARE program beneficiaries. The Veterans Health Care Act of 1992 also established the 340B drug discount program, which requires pharmaceutical manufacturers to provide products at reduced prices to various designated health care entities and facilities.

In the United States, most states also have generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed. In addition, the federal government follows a diagnosis-related group (DRG) payment system for certain institutional services provided under Medicare or Medicaid and has implemented a prospective payment system (PPS) for services delivered in hospital outpatient, nursing home and home health settings. DRG and PPS entitle a health care facility to a fixed reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many health care products. Medicare reimburses Part B drugs based on average sales price plus a certain percentage to account for physician administration costs, which have been reduced in the hospital outpatient setting. Medicare enters into contracts with private plans to negotiate prices for most patient-administered medicine delivered under Part D.

Under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (together, the Affordable Care Act), AbbVie pays a fee related to its pharmaceuticals sales to government programs. In addition, AbbVie provides a discount of 50% for branded prescription drugs sold to patients who fall into the Medicare Part D coverage gap, or "donut hole."

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs and biologics covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring disclosure of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

AbbVie expects debate to continue during 2021 at all government levels worldwide over the marketing, availability, method of delivery and payment for health care products and services. AbbVie believes that future legislation and regulation in the markets it serves could affect access to health care products and services, increase rebates, reduce prices or the rate of price increases for health care products and services, change health care delivery systems, create new fees and obligations for the pharmaceuticals industry, or require additional reporting and disclosure. It is not possible to predict the extent to which AbbVie or the health care industry in general might be affected by the matters discussed above.

European Union. The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the European Union and permits member states to supplement these standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent to launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical

products. Differences between national pricing regimes create price differentials within the European Union that can lead to significant parallel trade in pharmaceutical products.

Most governments also promote generic substitution by mandating or permitting a pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed and by permitting or mandating that health care professionals prescribe generic versions in certain circumstances. Many governments are also following a similar path for biosimilar therapies. In addition, governments use reimbursement lists to limit the pharmaceutical products that are eligible for reimbursement by national health care systems.

Japan. In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the Ministry of Health, Labour and Welfare sets the prices of the products on this list. The government generally introduces price cut rounds every other year and also mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. The government has also promoted the use of generics, where available.

Emerging Markets. Many emerging markets take steps to reduce pharmaceutical product prices, in some cases through direct price controls and in others through the promotion of generic/biosimilar alternatives to branded pharmaceuticals.

Since AbbVie markets its products worldwide, certain products of a local nature and variations of product lines must also meet other local regulatory requirements. Certain additional risks are inherent in conducting business outside the United States, including price and currency exchange controls, changes in currency exchange rates, limitations on participation in local enterprises, expropriation, nationalization and other governmental action.

Regulation—Medical Devices

Medical devices are subject to regulation by the FDA, state agencies and foreign government health authorities. FDA regulations, as well as various U.S. federal and state laws, govern the development, clinical testing, manufacturing, labeling, record keeping and marketing of medical device products agencies in the United States. AbbVie's medical device product candidates, including AbbVie's breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. The lengthy process of clinical development and submissions for clearance or approval, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory clearance or approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Cleared or approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, and/or use or require their withdrawal from the market.

United States. AbbVie's medical device products are subject to extensive regulation by the FDA in the United States. Unless an exemption applies, each medical device AbbVie markets in the United States must have a 510(k) clearance or a Premarket Approval Application (PMA) in accordance with the FFDCA and its implementing regulations. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety end effectiveness. Devices deemed to pose a lower risk are placed in either Class I or Class II, and devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or a device deemed to be not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. In

general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA, and any changes to the device subsequent to initial FDA approval must also be reviewed and approved by the FDA. The majority of AbbVie's medical device products, including AbbVie's breast implants, are regulated as Class III medical devices. A Class III device may have significant additional obligations imposed in its conditions of approval, and the time in which it takes to obtain approval can be long. Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA and other regulatory authorities, and these inspections may include the manufacturing facilities of AbbVie's subcontractors or other third-party manufacturers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters or untitled letters; fines, injunctions and civil penalties; recall or seizure of AbbVie' products; operating restrictions, partial suspension or total shutdown of production; refusing AbbVie' request for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals that are already granted; and criminal prosecution.

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. Clinical trials generally require submission of an application for an investigational device exemption (IDE), which must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A study sponsor must obtain approval for its IDE from the FDA, and it must also obtain approval of its study from the Institutional Review Board (IRB) overseeing the trial. The results of clinical testing may not be sufficient to obtain approval of the investigational device.

Once a device is approved, the manufacture and distribution of the device remains subject to continuing regulation by the FDA, including Quality System Regulation requirements, which involve design, testing, control, documentation and other quality assurance procedures during the manufacturing process. Medical device manufacturers and their subcontractors are required to register their establishments and list their manufactured devices with the FDA and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with regulatory requirements. Manufacturers must also report to the FDA if their devices may have caused or contributed to a death or serious injury or malfunctioned in a way that could likely cause or contribute to a death or serious injury, or if the manufacturer conducts a field correction or product recall or removal to reduce a risk to health posed by a device or to remedy a violation of the FFDCA that may present a health risk. Further, the FDA continues to regulate device labeling, and prohibits the promotion of products for unapproved or "off-label" uses along with other labeling restrictions.

European Union. Medical device products that are marketed in the European Union must comply with the requirements of the Medical Device Regulation (the MDR), which will come into effect in May 2021. The MDR provides for regulatory oversight with respect to the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices to ensure that medical devices marketed in the European Union are safe and effective for their intended uses. Medical devices that comply with the MDR are entitled to bear a Conformité Européenne marking evidencing such compliance and may be marketed in the European Union. Failure to comply with these domestic and international regulatory requirements could affect AbbVie's ability to market and sell AbbVie's products in these countries.

Environmental Matters

AbbVie believes that its operations comply in all material respects with applicable laws and regulations concerning environmental protection. Regulations under federal and state environmental laws impose stringent limitations on emissions and discharges to the environment from various manufacturing operations. AbbVie's capital expenditures for pollution control in 2020 were

approximately $6 million and operating expenditures were approximately $34 million. In 2021, capital expenditures for pollution control are estimated to be approximately $9 million and operating expenditures are estimated to be approximately $36 million.

Abbott was identified as one of many potentially responsible parties in investigations and/or remediations at several locations in the United States, including Puerto Rico, under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. Some of these locations were transferred to AbbVie in connection with the separation and distribution, and AbbVie has become a party to these investigations and remediations. Abbott was also engaged in remediation at several other sites, some of which have been transferred to AbbVie in connection with the separation and distribution, in cooperation with the Environmental Protection Agency or similar agencies. While it is not feasible to predict with certainty the final costs related to those investigations and remediation activities, AbbVie believes that such costs, together with other expenditures to maintain compliance with applicable laws and regulations concerning environmental protection, should not have a material adverse effect on the company's financial position, cash flows, or results of operations.

Employees

AbbVie employed approximately 47,000 employees in over 70 countries as of January 31, 2021. Outside the United States, some of AbbVie's employees are represented by unions or works councils. AbbVie believes that it has good relations with its employees.

Human Capital Management

Attracting, retaining and providing meaningful growth and development opportunities to AbbVie's employees is critical to the company's success in making a remarkable impact on people's lives around the world. AbbVie leverages numerous resources to identify and enhance strategic and leadership capability, foster employee engagement and create a culture where diverse talent is productive and engaged. AbbVie invests in its employees through competitive compensation, benefits and employee support programs and offers best-in-class development and leadership opportunities. AbbVie has developed a deep talent base through ongoing investment in functional and leadership training and by sourcing world-class external talent, ensuring a sustainable talent pipeline. AbbVie continuously cultivates and enhances its working culture and embraces equality, diversity and inclusion as fundamental to the company's mission.

Attracting and Developing Talent. Attracting and developing high-performing talent is essential to AbbVie's continued success. AbbVie implements detailed talent attraction strategies, with en emphasis on STEM skill sets, a diverse talent base and other critical skillsets, including drug discovery, clinical development, market access, and business development. AbbVie also invests in competitive compensation and benefits programs. In addition to offering a comprehensive suite of benefits ranging from medical and dental coverage to retirement, disability and life insurance programs, AbbVie also provides health promotion programs, mental health awareness campaigns and employee assistance programs in several countries, financial wellness support, on-site health screenings and immunizations in several countries and on-site fitness and rehabilitation centers. In addition, the AbbVie Employee Assistance Fund (a part of the AbbVie Foundation) supports two programs for global employees: the AbbVie Possibilities Scholarship for children of employees, which is an annual merit-based scholarship for use at accredited colleges, universities or vocational-technical schools; and the Employee Relief Program, which is financial assistance to support short term needs of employees when faced with large-scale disasters (e.g. a hurricane), individual disasters (e.g. a home fire) or financial hardship (e.g. the death of a spouse). Finally, AbbVie empowers managers and their teams with tools, tips and guidelines on effectively managing workloads, managing teams from a distance and supporting flexible work practices.

New AbbVie employees are given a tailored onboarding experience for faster integration and to support performance. AbbVie's mentorship program allows employees to self-nominate as mentors or mentees and facilitates meaningful relationships supporting employees' career and development goals.

AbbVie also provides structured, broad-based development opportunities, focusing on high-performance skills and leadership training. AbbVie's talent philosophy holds leaders accountable for building a high-performing organization, and the company provides development opportunities to all levels of leadership. AbbVie's Learn, Develop, Perform program offers year-long, self-directed leadership education, supplemented with tools and resources, and leverages leaders as role models and teachers. In addition, the foundation to AbbVie's leadership pipeline is the company's Professional Development Programs, which attract graduates, postgraduates and post-doctoral talent to participate in formal development programs lasting up to three years, with the objective of strengthening functional and leadership capabilities. AbbVie also recently introduced additional development support to senior leaders who are managing increased integration and operational complexity following the transformational acquisition of Allergan.

Culture. AbbVie's shared values of transforming lives, acting with integrity, driving innovation, embracing diversity and inclusion, and serving the community form the core of the company's culture. AbbVie articulates the behaviors associated with these values in the Ways We Work, a core set of working behaviors that emphasize how the company achieves results is equally as important as achieving them. The Ways We Work are designed to ensure that every AbbVie employee is aware of the company's cultural expectations. AbbVie integrates the Ways We Work into all talent processes, forming the basis for assessing performance, prioritizing development, and ultimately rewarding employees. AbbVie believes it culture creates strong engagement, which is measured regularly through a confidential, third party all-employee survey, and this engagement supports AbbVie's mission of making a remarkable impact on people's lives.

Equity, Equality, Diversity & Inclusion (EED&I). A cornerstone of AbbVie's human capital management approach is to prioritize fostering an inclusive and diverse workforce. In 2019, AbbVie adopted a five-year Equality, Diversity & Inclusion roadmap that defines key global focus areas, objectives and associated initiatives, and includes implementation plans organized by business function and geography. AbbVie's senior leaders have adopted formal goals aligned with executing this strategy. Over the past year, AbbVie's board of directors has prioritized oversight of AbbVie's response to the U.S. racial justice movement, including overseeing internal programs designed to ensure that AbbVie is attracting, retaining and developing diverse talent. Through June 2020, women represented 49 percent of management positions globally and in the United States, 33 percent of AbbVie's workforce was comprised of members of historically underrepresented populations, an increase from 2019. Further, AbbVie is committed to pay equity and conducts pay equity analyses annually. A critical component of AbbVie's strategy is to instill an inclusive mindset in all AbbVie leaders and employees, so the company can realize the full value of a diverse workforce from recruitment through retirement. AbbVie recently launched a new toolkit for people who manage others to reinforce the importance of EED&I to the business, educate leaders on inclusive recruiting practices and modeling inclusive behavior, and encourage participation in the company's inclusive culture learning opportunities. AbbVie's Employee Resource Groups also help the company nurture an inclusive culture by building community, hosting awareness events and providing leadership and career opportunities. In 2020, AbbVie reiterated its commitment to racial equality and social justice by appointing two additional senior level positions to drive change and awareness company-wide and taking deliberate steps to ensure AbbVie leads by example in promoting racial equity, as further described on the company's website at: https://www.abbvie.com/our-company/our-principles/our-commitment-to-racial-justice.html.

COVID-19 Health and Safety. AbbVie has effectively prioritized the health and safety of its employees during the COVID-19 pandemic, while continuing to drive strong business performance. AbbVie also implemented, among other things, temporary office and facility closures and establishment of new safety and cleaning protocols and procedures; regular communication regarding the effect of the pandemic on AbbVie's business and employees; establishment of physical distancing procedures, modification of workspaces, and provision of personal protective equipment and cleaning supplies for employees; temperature screening at all company locations; a variety of testing resources including on-site and at-home testing and COVID case management programs; and remote working accommodations and related services to support employees' needs for flexibility. In addition, COVID-19 is a covered event under the AbbVie Employee Assistance Fund's Employee Relief Program, entitling eligible AbbVie employees and their families to financial assistance to pay for mortgage/rent, utilities, food, childcare and medical expenses not covered by insurance. AbbVie also provided paid leave and other support and accommodations to the company's employees with relevant medical, pharmaceutical, R&D, science, public health and public safety skills, knowledge, training and experience who desired or were requested or mandated to serve as volunteers during the pandemic. Lastly, AbbVie's commitment to employees was evidenced by no workforce reductions and no salary reductions associated with COVID-19.

Internet Information

Copies of AbbVie's Annual Reports 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 are available free of charge through AbbVie's investor relations website (*www.abbvieinvestor.com*) as soon as reasonably practicable after AbbVie electronically files the material with, or furnishes it to, the Securities and Exchange Commission (SEC).

AbbVie's corporate governance guidelines, outline of directorship qualifications, code of business conduct and the charters of AbbVie's audit committee, compensation committee, nominations and governance committee and public policy committee are all available on AbbVie's investor relations website (*www.abbvieinvestor.com*).

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (08/12/2021)

Where is the facility located?	☑ Nevada ☐ Out-of-State
Is your facility a reverse distributor?	☐ Yes ☑ No

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 _____	☑ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: GREEN BAY SPECIALTY PHARMACY

Physical Address: 3483 S EASTERN AVE, SUITE #101

City: LAS VEGAS State: NV Zip: 89169

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 419-408-8840 Website: GREENBAYPHARMACYLV@GMAIL.COM

Name of Designated Representative (DR): _____

Licensing Company Email: Greenbaypharmacylv@gmail.com DR Email: Greenbaypharmacylv@gmail.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.

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: _____

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: PARAG. H. PATEL

Business Name: GREENBAY SPECIALTY PHARMACY

Business Address: 3483 S EASTERN AVE, SUITE 100

City: LAS VEGAS State: NV Zip: 89169

Telephone: → 419-408-8840 Email: Greenbaypharmacylv@gmail.com

→ 443-616-7285

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 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 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 **6 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**	✓			
• **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)**	✓	✓	✓	✓
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.

KARAM D. PANJABI

Print Name of Authorized Person Submitting Application

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

10/28/2021

Date

Board Use Only	Date Received: _____	Amount: $500 check 1008

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, 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, **green leaf pharmacy llc**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 08/05/2021, 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 08/17/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202108171917920
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

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

HASMUKH PATEL
27950 Orchard Lake Rd 110
Farmington Hills, MI 48334, USA

Work Order #: W2021081700268
August 17, 2021
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 482993

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Certificates	Fees	20211684297	8/17/2021 8:57:22 AM	Approved	1	$50.00	$50.00
Total							$50.00

Payments

Type	Description	Payment Status	Amount
Credit Card	6292158267486435803098	Success	$50.00
Total			$50.00

Credit Balance: $0.00

HASMUKH PATEL
27950 Orchard Lake Rd 110
Farmington Hills, MI 48334, USA

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 Green Bay Specialty Pharmacy

Physical Address 3483 S Eastern Ave., Suite 101

City Las Vegas State NV Zip 89169

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 419-408-8840 Website _____

Licensing Company Email _____

Section 2: Personal Information

First PARAG Middle HARSHADBHAI Last PATEL

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

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

Mailing Address [redacted] DUSTY PINE DR

City APOPKA State FL Zip 32703

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.)		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?		X

Applicant's initials PLP

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)	
Fairleigh Dickinson University, School of Pharmacy			08/2012 – 05/16	
Address		City	State	Zip
230 Park Ave		Florham Park	NJ	07932
Diploma/Degree obtained, if any				
Doctorate of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Fairleigh Dickinson University - School of Pharmacy			08/12 - 05/16	
Address		City	State	Zip
230 Park Ave		Florham Park	NJ	07932
Diploma/Degree obtained, if any				
Master In Health Science - Health Informatics				
School Name			From - To (MM/YY – MM/YY)	
Hemchandracharya North Gujarat University			06/2003 - 05/07	
Address		City	State	Zip
PA NO 21 Rajmahal Road		Patan Gujarat	India	384265
Diploma/Degree obtained, if any				
Bechelor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Vijaynagar High School			06/01 - 05/03	
Address		City	State	Zip
Vijaynagar Road, Vijaynagar		Ahmedabad	Gujarat	380013
Diploma/Degree obtained, if any				
High School				
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] Dusty Pine Dr	Apopka	FL	32703
05/17 - 06/19	2467 Route 10 E, Bldg 27-3B	Morris Plains	NJ	07950
10/14 - 08/17	16A Grouse Road	Lake Hiawatha	NJ	07034
09/12 - 09/14	1100 Parsippany Blvd APT 213	Parsippany	NJ	07054
08/11 - 09/12	109 E Waldon Road	Abingdon	MD	21009
12/10 - 08/11	309 S Parke St, APT B47	Aberdeen	MD	21001
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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: Angel's Pharmacy | From - To (MM/YY – MM/YY): 04/18 - Current
Business Address: 7455 S US-1, Ste A | City: Titusville | State: FL | Zip: 32780
Phone: 321-225-4833 | Title: Pharmacy Manager, Co-owner
Description of Duties: Handling of Pharmacy Business, Filling Prescription. Hiring Pharmacy Personal. Inventory ...

Business Name: CVS Pharmacy | From - To (MM/YY – MM/YY): 8/16 - 4/18
Business Address: 514 Park Ave | City: Scotch Plains | State: NJ | Zip: 07076
Phone: 908-322-7455 | Title: Pharmacist
Description of Duties: Filling Prescriptions, Inventory Management, Hiring Pharmacy Tech Operational mangement; Maintaining Policy Procedure of Pharmacy.

Business Name: CVS Pharmacy | From - To (MM/YY – MM/YY): 01/13 - 07/16
Business Address: 187 Columbia turnpike | City: Florham Park | State: NJ | Zip: 07932
Phone: 973-377-2420 | Title: Pharmacy Intern
Description of Duties: Data entry, Inventory Management, Prescription Filling, Counting, Customer Service.

Business Name: Medicap Pharmacy | From - To (MM/YY – MM/YY): 09/11 – 08/12
Business Address: 602 S Atwood Road | City: Belair | State: MD | Zip: 21014
Phone: 410-638-2730 | Title: Pharmacy Tech.
Description of Duties: Data Entry, Filling Prescription, Counting Meds, Customer Service.

Business Name: Weis Market Inc Pharmacy | From - To (MM/YY – MM/YY): 08/11 – 11/11
Business Address: 943 Pulaski Hway | City: Havre-De-Grace | State: MD | Zip: 21078
Phone: 410-939-4282 | Title: Pharmacy Tech.
Description of Duties: Customer Service. Filling Prescription.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Dunkin Donuts			05/11 – 8/14
Business Address	**City**	**State**	**Zip**
2105 Calvary Road	Belair	MD	21015
Phone	**Title**		
410-734-6500	Cashier		
Description of Duties			
Customer Service, Order Pick-up & Preparation of orders.			

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 plq

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:

N/A

Original Signature (electronic, copies or stamps not accepted)

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.

Parag Patel

Print Name (First, Last)

P.H.

Original Signature (electronic, copies or stamps not accepted)

10/25/2021

Date

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

State of Florida, ss. County of Brevard

I, PARAG PATEL, 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.

Amanda Cunningham

Original Signature

10/25/2021

Date

Subscribed and Sworn to before me this 25th day of October.

Amanda Cunn

Notary Public Signature

AMANDA M. CUNNINGHAM
Commission # GG 348577
Expires June 25, 2023
Bonded Thru Troy Fain Insurance 800-385-7019

(Seal)

Applicant's initials PHP

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. 10129339

Application/License No. _____

Greenbay Specialty Pharmacy (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3483 S. Eastern Avenue #100 Las Vegas, NV 89169 (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, Suite 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 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 12/01/2021 (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.

RECEIVED
NOV 19 2021
NEVADA STATE BOARD OF PHARMACY

10129339

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 16th day of November, 2021.

APPLICANT/PRINCIPAL
Greenbay Specialty Pharmacy

P. H. Patel
Authorized Representative

SURETY
Hudson Insurance Company

SpecialValueSeal

Surety Company's Representative

Dee Ann Spilsbury, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Kavdam D. Panyabi
Witness

Witness

SIGNED and SEALED in the presence of:

CYNTHIA A. NELSON
Witness

Witness

Countersigned by:

Nevada Resident Agent

10129339

HUDSON INSURANCE GROUP®

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

Dee Ann Spilsbury

of the State of NV

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 ($100,000.00)

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 on this 6th day of February, 20 20 at New York, New York.

SEAL (Corporate seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 6th day of February, 20 20 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)

CAMERON GOURLAY NOTARY PUBLIC STATE OF NEW YORK

.....
CAMERON GOURLAY
Notary Public, State of New York
No. 01GO6372305
Qualified in New York County
Commission Expires June 4, 2022

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.

In witness the hand of the undersigned and the seal of said Corporation this 16th day of November, 20 21.

SEAL (Corporate seal)

By.....
Dina Daskalakis, Corporate Secretary

Nevada State Board of Pharmacy

985 DAMONTE RANCH PKWY • SUITE 206 • RENO, NEVADA 89521
(775) 850-1440 • FAX (775) 850-1444 • www.bop.nv.gov

October 19, 2021

Sent via U.S. Mail and Email: greenbaypharmacylv@gmail.com
Kardam Panjabi
Parag Harshadbhai Patel
Greenbay Specialty Pharmacy
3483 South Eastern Avenue, Suite 100
Las Vegas, NV 89169

RE: Greenbay Specialty Pharmacy's ("Greenbay") application

Dear Gentlemen,

The Nevada State Board of Pharmacy ("Board") considered Greenbay's application for a new Nevada pharmacy at the Board meeting on October 14, 2021. The Board approved Greenbay's application pending a positive opening inspection along with quarterly inspections, (4) additional inspections, for one year (by November 30, 2022) at Greenbay's expense.

Please contact me with additional questions.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of 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 GREENBAY SPECIALTY PHARMACY

Physical Address 3483 S EASTERN AVE STE 101

City Las VEGAS State NV Zip 89169

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First KARDAM Middle D Last PANJABI

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

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

Mailing Address [redacted] Aliso CREEK STREET

City HENDERSON State NV Zip 89044

Telephone [redacted] Email Greenbaypharmacy LV@gmail.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 KP

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 Findlay.			From - To (MM/YY – MM/YY): 2009 - 2010	
Address: 1000 N Main Street	City: Findlay		State: OH	Zip: 45840
Diploma/Degree obtained, if any: Master's in Health Care Administration				
School Name: Sardar patel University.			From - To (MM/YY – MM/YY): 2006 - 2008	
Address: Motabazar Vallabh Vidyanagar	City: V.V. Nagar		State: Gujarat	Zip: 388001
Diploma/Degree obtained, if any: Bachelor In Sciene (Biotechnology)				
School Name: Angel High School			From - To (MM/YY – MM/YY): 2004 - 2006	
Address: Aagmon Society	City: Anand		State: Gujarat	Zip: 388001
Diploma/Degree obtained, if any: 12th Grade				
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] Aliso Creek St	Henderson	NV	89044
	[redacted] Sand Rock Place	N. Las Vegas	NV	89031
	[redacted] Lloyd Cir.	Plano (Dallas)	TX	75252
	[redacted] Tara Oak Circle	Lady Lake	FL	32159

Applicant's initials KP

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: Asp Cares Pharmacy.			From - To (MM/YY – MM/YY): 2015-2021
Business Address: 501 S Rancho Dr G46	City: Las Vegas	State: NV	Zip: 89106
Phone: 702-912-4844	Title: Pharmaceutical Operation	Number of Employed Hours: 12400	
Description of Duties: -Prepar quarterly Budget of Pharmacy, -Marketing Strategy. — Reconciliation report,			

Business Name: Asp Cares Pharmacy.			From - To (MM/YY – MM/YY): 2013-2015
Business Address: 2743 W 15th st	City: Plano	State: Tx	Zip: 75075
Phone: 214-919-2090	Title: Pharmaceutical Operation Analyst	Number of Employed Hours: 4000	
Description of Duties: — Prepar training material of staffs. — Collect data and analyze data on cashier demo			

Business Name: Rx One Pharmacy			From - To (MM/YY – MM/YY): 2011-2013.
Business Address: 717 W Lancaster Rd	City: Orlando	State: Fl	Zip: 32809.
Phone: 407-855-4770	Title: Pharmaceutical Operation Analyst	Number of Employed Hours: 4000	
Description of Duties: — Create new business strategy — Evaluate Vendor opportunity of company, Negotiate Insure Contracts.			

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

Applicant's initials KP

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 KP

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)

10/28/21
Date

Applicant's initials KP

I, Kavdam D. Panjabi, **certify that as the designated representative for** Greenbay Specialty 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

Kavdam Panjabi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/21

Date

Applicant's initials KP

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.

Kardam. D. Panjabi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/2021

Date

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

State of Nevada, ss. County of Clark

I, Kardam. D. Panjabi, 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

10/28/2021

Date

Subscribed and Sworn to before me this 28 day of October 2021.

Notary Public Signature

JEROD PEREZ
Notary Public, State of Nevada
Appointment No. 17-3175-1
My Appt. Expires Aug 31, 2025

(Seal)

Applicant's initials _____

16

16A

RECEIVED
9/30/2020

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: **Eagle Pharmacy, Inc. d/b/a Eagle, Inc.**

Physical Address: **2200 Riverchase Center, Suite 675**

City: **Hoover** State: **AL** Zip Code: **35244**

Telephone: **205-682-7999** Fax: **205-682-7616**

Toll Free Number: **877-682-7994** (Required per NAC 639.708)

E-mail: **eaglepharmacy@gmail.com** Website: **eaglepharmacy.org**

Supervising Pharmacist: **Zahir Hamid** Nevada License #: **20667** OK Exp 10/31/21

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☒ ☐ Other Services: **Manufactured Product Distribution**

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

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

FEI Number (From FDA application): **26-1499219**

Please provide the name of the facility as registered with the FDA and the registration number:
Eagle Pharmacy, Inc. 69852

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Eagle, Inc., Eagle Rx, Inc.

Please provide the name and Nevada license number of the supervising pharmacist:
Name: **Zahir Hamid** Nevada License Number: **20667**

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

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

Robert Bradford Johnson

Print Name of Authorized Person

9.28.2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY Page 5

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Alabama

Parent Company if any: _____

Address: 2200 Riverchase Center, Suite 675

City: Hoover State: AL Zip: 35244

Telephone: 205-682-7999 Fax: 205-682-7616

Contact Person: Charlotte Denney

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Robert Bradford Johnson 307 Commercial St SE, Hanceville, AL 35077
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 333

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 11-29-2007

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

Robert Bradford Johnson, President - 100% Owner

REGISTER OF STOCK CERTIFICATES

CERTIFICATE NO.			SHARES IN EACH CERTIFICATE	SHAREHOLDER	ISSUE DATE	TRANSFERRED TO	NEW CERTIFICATE		CERTIFICATE SURRENDERED	
ORIGINAL	RE-ISSUE	DATED					NO.	NO. OF SHARES	NO.	NO. OF SHARES
~~1~~		~~11/29/07~~	~~500~~	~~R. Brad Johnson~~		Cancelled				
~~2~~		~~11/29/07~~	~~500~~	~~Christine T. Feenker~~		Cancelled				
3		1/1/09	333 1/3	R. Brad Johnson						
4		1/1/09	333 1/3	Christine T. Feenker	1/2/2015	Eagle Pharmacy, Inc. (Treasury)			4	333 1/3
5		1/1/09	333 1/3	V. Michelle Maly	1/2/2015	Eagle Pharmacy, Inc. (Treasury)			5	333 1/3

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NUMBER 3

SHARES 333 1/3

INCORPORATED UNDER THE LAWS OF THE STATE OF ALABAMA

Eagle Pharmacy, Inc.

The Corporation is authorized to issue 1,000 Common Shares -- Par Value $1.00 each

This Certifies that R. Brad Johnson is the owner of

Three hundred thirty-three and one-third (333 1/3) fully paid and non-assessable Shares of the above Corporation transferable only on the books of the Corporation by the holder hereof in person or by duly authorized Attorney upon surrender of this Certificate properly endorsed.

In Witness Whereof, the said Corporation has caused this Certificate to be signed by its duly authorized officers and to be sealed with the Seal of the Corporation.

Dated 1-1-09

PRESIDENT

State of Alabama
Department of Revenue

Certificate of Compliance

Eagle Pharmacy, Inc. is found to be in compliance for purposes of the issuance of a Certificate of Compliance from the Alabama Department of Revenue. An examination of the Alabama Department of Revenue's records for the following accounts: Corporate Income, Excise, Pass Through Entity, Business Privilege, Business & License Tax, Withholding, International Fuel Tax Agreement, International Registration Plan, and Sales and Use Tax, reveals that the aforementioned taxpayer/entity has filed all applicable tax returns and paid the tax or taxes, interest amounts, and any penalties that were reported due for all tax returns, assessments, and/or audit liabilities that were owed, as of October 25, 2021. No representation is made as to the accuracy of the amounts reported. Like all taxpayers, this taxpayer is subject to audit and billing for additional amounts for periods within the statute of limitations.

IN WITNESS WHEREOF, I hereunto set my hand this date of October 25, 2021.

Curtis E. Stewart

Disclosure Officer

Phone: 334-242-1189
Fax: 334-242-1030

Request Date: October 25, 2021
Request Code: 2110254196921

Alabama State Board of Pharmacy 2022

This is to certify:

EAGLE, INC.
2200 RIVERCHASE CENTER SUITE 675
HOOVER, AL 35244

Permit Number:

193612

Is Duly Licensed as a:

503-B Outsourcing Facility

Specialty Services:

Supervising Pharmacist

HALEIGH JORDAN WILKES

15025

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2022

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

Donna C Yeatman
EXECUTIVE SECRETARY

Alabama State Board of Pharmacy

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE 2022

Controlled Substance Number:	Business Activity:	Schedules:
193612	503-B Outsourcing Facility	III,IV,V

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:
(1) Has furnished false or fraudulent material information in any application filed under this Act,
(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or
(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances
(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: 01/01/2022

Expiration Date: 12/31/2022

EAGLE, INC.
2200 RIVERCHASE CENTER SUITE 675
HOOVER, AL 35244

CERTIFICATE MUST BE PROMINENTLY DISPLAYED AT ALL TIMES

THIS REGISTRATION IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax: (615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	7/26/2021-8/12/2021* FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Haleigh J. Cawood, Quality Control Manager	
FIRM NAME Eagle Pharmacy, Inc.	STREET ADDRESS 2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED 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. Environmental monitoring surface sampling conducted in the vial filling room (ISO-5) is not taken in the most critical areas where aseptic manipulations occur. According to the Lead Quality Technician, surface samples are collected on the outer most areas of the LAFW (ISO-5); however, according to the Lead Compounding Technician, aseptic manipulations are performed in the center of the LAFW (ISO-5).
2. Your firm's mobile particle counting probe is not placed in an orientation demonstrated to obtain a meaningful sample to monitor non-viable particles during production of your firm's non-dedicated vial filling machine (ISO-5), located in your firm's vial filling machine (ISO-5). According to your firm's Lead Quality Technician, who conducts routine environmental monitoring sampling, the mobile particle counting probe is located greater than 1 foot from the most critical area, where the greatest potential risk and highest exposure to the sterilized product occurs.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Susan O Oladeji, Investigator June P Page, Investigator Demario L Walls, Investigator	X	8/12/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax: (615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	7/26/2021-8/12/2021* FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Haleigh J. Cawood, Quality Control Manager	
FIRM NAME Eagle Pharmacy, Inc.	STREET ADDRESS 2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

On 7/27/2021, a stainless-steel bin was observed being transferred from the ISO-7 classified area (lab) into the ISO-5 classified area (vial filling machine room) via pass-through box during the production of Triamcinolone, Lot 4115TA50, without being sanitized.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

1. During our review of the smoke study conducted in June 2020, by your firm's 3rd party contractor,
   a. We observed turbulence within the ISO-5 classified area of your firm's automated vial filling machine. The turbulence is observed at your most critical area of production (between filling and stoppering) during routine interventions. For example, but not limited to, at approximately:

Timestamp	Intervention description
00:12 – 00:17	while opening the access panel located near the crimp seal feeder
00:24 – 00:31	while opening the pass-thru window that connects the Lab (ISO-7) area to the Machine Filling Room (ISO-5)
00:38 – 00:39	while opening the entry door to the Machine Filling room (ISO-5) from the vestibule (ISO-7) area

The vial filling machine is used to aseptically fill all sterile drug products at your firm.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Susan O Oladeji, Investigator June P Page, Investigator Demario L Walls, Investigator X	8/12/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax: (615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	7/26/2021-8/12/2021* FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Haleigh J. Cawood, Quality Control Manager	
FIRM NAME Eagle Pharmacy, Inc.	STREET ADDRESS 2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

2. Your firm's autoclave validation conducted by your 3rd party contractor has not adequately specified a load pattern for your terminally sterilized drug product, Triamcinolone, in 10-mL vials. According to your firm's inventory management software, your firm distributed approximately 57,700 vials of Triamcinolone Acetonide 50mg and Triamcinolone Acetonide 80mg from 05/18/2018 to 07/31/2021.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

1. The document used to capture your firm's personnel and environmental monitoring results is pre-populated with CFU counts of zero (0). According to your firm's Lead Quality Technician, they do not contemporaneously document their review of personnel and environmental monitoring plates.
2. Your suspension products (Betamethasone, Dexamethasone, Methylprednisolone, Triamcinolone) do not include a specification for particle size.

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Your firm's media fills did not conduct media fill under worst-case, most challenging conditions. For example, but not limited to, prior to this FDA inspection, planned/unplanned interventions were not capture on your firm's batch records. On 08/02/2021, during the media fill, lot DEAPSBETA080221, at least 20 interventions were observed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Susan O Oladeji, Investigator June P Page, Investigator Demario L Walls, Investigator	X	8/12/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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	FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Haleigh J. Cawood, Quality Control Manager	
FIRM NAME Eagle Pharmacy, Inc.	STREET ADDRESS 2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

In addition, on 07/27/2021, during the manufacture of Triamcinolone 50 mg, lot 4115TA50, at least 9 interventions (manual opening of small window, manual opening of big door, manual adjustment of crimp/cap feeder with hands, manual adjustment of crimper) were observed during a 6-minute time period. These interventions were not documented on your firm's batch records.

OBSERVATION 6
Deviations from written specifications, sampling plans and test procedures are not recorded.

Specifically,

Your firm's Quality Unit failed to initiate investigations when you deviated from your stability protocols by placing one lot instead of three lots on stability, missing pre-established time points for testing and testing outside of the protocol. Your Quality Control Manager acknowledged that she should have initiated a deviation investigation. Your firm does not have a quality agreement with the laboratory who conducted your stability testing.

***DATES OF INSPECTION**
7/26/2021(Mon), 7/27/2021(Tue), 7/28/2021(Wed), 7/29/2021(Thu), 7/30/2021(Fri), 8/02/2021(Mon), 8/03/2021(Tue), 8/04/2021(Wed), 8/05/2021(Thu), 8/06/2021(Fri), 8/09/2021(Mon), 8/10/2021(Tue), 8/11/2021(Wed), 8/12/2021(Thu)

June P Page
Investigator
Signed By: 2000405709
X Date Signed: 08-12-2021 13:15:21

Susan O Oladeji
Investigator
Signed By: Susan O. Oladeji -S
X Date Signed: 08-12-2021 13:16:19

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Susan O Oladeji, Investigator June P Page, Investigator Demario L Walls, Investigator	Demario L Walls Investigator Signed By: Demario L Walls -93 Date Signed: 08-12-2021 13:14:48 X	DATE ISSUED 8/12/2021

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."

EAGLE PHARMACY

09-01-2021

Food and Drug Administration
Division of Pharmaceutical Quality Operations II
ATTN: Monica Maxwell, Acting Program Division Director
4040 Central Expressway, Suite 900
Dallas, Texas 75204

Re: Eagle Pharmacy 483 Issued 08/12/2021, FEI Number: 3011688532

Dear Ms. Maxwell,

The FDA conducted a routine inspection of our pharmacy, Eagle Pharmacy on 7/26/2021 (Mon), 7/27/2021 (Tue), 7/28/2021 (Wed), 7/29/2021 (Thu), 7/30/2021 (Fri), 8/02/2021 (Mon), 8/03/2021 (Tue), 8/04/2021 (Wed), 8/05/2021 (Thu), 8/06/2021 (Fri), 8/09/2021 (Mon), 8/10/2021 (Tue), 8/11/2021 (Wed), 8/12/2021 (Thu). At the conclusion of the inspection, a Form FDA 483 listing six inspectional observations was issued. Enclosed you will find our responses to these six observations and pertinent documentation to serve as evidence of corrective actions taken.

Eagle Pharmacy is an outsourcing facility that is currently licensed and in good standing with the Alabama Board of Pharmacy ("BOP") and complies with all BOP regulations. Eagle Pharmacy conducts its operations in accordance with the conditions outlined in Section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA").

Eagle Pharmacy wishes to emphasize that it takes the inspectional observations detailed on the Form FDA 483 very seriously. As Eagle Pharmacy strives to provide our patients with the safe and efficacious compounded medications that they rely upon, we are committed to adhering to applicable regulations and best practices that ensure that compounded medications are packed, prepared, and held under sanitary conditions.

Eagle Pharmacy has engaged a consulting firm, Eagle Analytical Services, with relevant sterile drug manufacturing experience and subject matter expertise in microbiology and regulatory compliance to assist with the development and implementation of the corrective actions outlined in the enclosed FDA 483 response.

Eagle Pharmacy will provide the Agency with a status update on the commitments detailed in the enclosed response within 30 days of this letter. Included in this status update will be documentation to serve as further evidence of corrective actions that have been taken.

In conclusion, we hope this response demonstrates our continued commitment to patient safety and continuous quality improvement. Thank you for your consideration of this response. If you should have any questions, please do not hesitate to contact Haleigh J. (Cawood) Wilkes at haleighc.eaglepharmacy@gmail.com.

Sincerely,

Haleigh Wilkes

Haleigh J. (Cawood) Wilkes, RPh, PharmD
Quality Control Manager

Observation 1

1. **Environmental monitoring surface sampling conducted in the vial filling room (ISO-5) is not taken in the most critical areas where aseptic manipulations occur. According to the Lead Quality Technician, surface samples are collected on the outer most areas of the LAFW (ISO-5); however, according to the Lead Compounding Technician, aseptic manipulations are performed in the center of the LAFW (ISO-5).**
2. **Your firm's mobile particle counting probe is not placed in an orientation demonstrated to obtain a meaningful sample to monitor non-viable particles during production of your firm's non-dedicated vial filling machine (ISO-5). According to your firm's Lead Quality Technician, who conducts routine environmental monitoring sampling, the mobile particle counting probe is located greater than 1 foot from the most critical area, where the greatest potential risk and highest exposure to the sterilized product occurs.**

Response to Observation 1:

1. The environmental monitoring surface sampling in the vial filling room (ISO-5) will be collected from the most critical area where aseptic manipulations occur, which is in the center of the LAFW (ISO-5). Please see Attachment 1 for revised SOP P2.15.6 Environmental Monitoring Revision 6 Appendices 1-4 to indicate location of sampling. The revision was drafted and approved on 08/13/2021. Attachment 2, Documentation of Training on Updated Environmental Monitoring Procedures dated 08/16/2021 acknowledges training was provided to the Quality Control Technician.

2. The mobile particle counting probe will be placed in an orientation to obtain a meaningful sample to monitor non-viable particles during production. The probe will be placed in an area where the greatest potential risk and highest exposure to the sterilized product occurs. Please see Attachment 1 for revised SOP P2.15.6 Environmental Monitoring Revision 6 Appendices 1-4 to indicate location of sampling. Attachment 2, Documentation of Training on Updated Environmental Monitoring Procedures dated 08/16/2021 acknowledges training was provided to the Quality Control Technician.

Observation 2

On 7/27/2021, a stainless-steel bin was observed being transferred from the ISO-7 classified area (lab) into the ISO-5 classified area (vial filling machine room) via pass-through box during production of Triamcinolone, Lot 4115TA50, without being sanitized.

Response to Observation 2:

The Stainless-steel bins will be disinfected while transferring from ISO-7 classified area into the ISO-5 classified area (vial filling machine room). See Attachment 3 for revised SOP P2.18.7 Standard Operating Procedures for the Controlled Compounding Areas Revision 7 drafted and approved on 08/17/2021 to include staging of the stainless-steel bins Section 2.g. Attachment 4 includes documentation of Retraining of Compounding Personnel on the Staging of Supplies Entering the ISO Areas dated 08/17/2021.

Observation 3

1. **During our review of the smoke study conducted in June 2020, by your firm's 3rd party contractor,**
   a. **We observed turbulence within the ISO-5 classified area of your firm's automated vial filling machine. The turbulence is observed at your most critical area of production (between filling and stoppering) during routine interventions. For example, but not limited to, at approximately:**

Timestamp	Intervention description
00:12-00:17	while opening the access panel located near the crimp seal feeder
00:24-00:31	while opening the pass-thru window that connects the Lab (ISO-7) area to the Machine Filling Room (ISO-5)
00:38-00:39	While opening the entry door to the Machine Filling room (ISO-5) from the vestibule (ISO-7) area

   The vial filling machine is used to aseptically fill all sterile drug products at your firm.

2. **Your firm's autoclave validation conducted by your 3rd party contractor has not adequately specified a load pattern for your terminally sterilized drug product, Triamcinolone, in 10-mL vials. According to your firm's inventory management software, your firm distributed approximately 57,700 vials of Triamcinolone Acetonide 50mg and Triamcinolone Acetonide 80mg from 05/18/2018-07/31/2021.**

Response to Observation 3:

1. A third-party contractor was contacted to evaluate the cause of the turbulence inside the automated filling machine. After inspection, the equipment was modified to provide better air flow characteristics. Investigative Report 001 is provided in Attachment 5 and describes the findings of the investigation and the corrective action. After modifications were made to the automated filling machine, a smoke study was performed under dynamic conditions to simulate worst case operation of the equipment, captured in protocol PR-21035. The smoke study demonstrates that the vial filling machine now provides unidirectional airflow above the critical area during dynamic conditions while performing interventions. Summary Report REP-21035 is a summary of the smoke study and the results and is provided in Attachment 6.

2. Additional autoclave qualification activities will be performed to validate a specific load pattern for terminally sterilized Trimcinolone in 10-mL vials. A detailed description of the load pattern, including photos, is provided in Attachment 7. This validation study will be executed by the week of September 13, 2021.

Observation 4

1. **The document used to capture your firm's personnel and environmental monitoring results is pre-populated with CFU counts of zero (0). According to your firm's Lead**

Quality Technician, they do not contemporaneously document their review of personnel and environmental monitoring plates.

2. **Your suspension products (Betamethasone, Dexamethasone, Methylprednisolone, Triamcinolone) do not include a specification for particle size.**

Response to Observation 4:

1. The document used to record personnel and environmental monitoring results will not be pre-populated. Personnel and environmental monitoring results will be contemporaneously documented. Haleigh Wilkes, Quality Manager has password-restricted the Environmental and Personnel Monitoring forms. This limits the fields that can have information typed in them by the Quality Technicians preventing them from prepopulating any fields. See Attachment 8 which represents the unpopulated documents. The highlighted cells in Attachment 8 are the only areas that the Quality Technician has the ability to type in.

2. Dissolution/Particle size distribution studies were provided to Investigator Susan Oladeji on Day 2 of the inspection. Particle size distribution range has been established for batch release for both Methylprednisolone and Triamcinolone and the specifications are part of the batch records that were provided to Investigator Susan Oladeji on Day 4 of the inspection Attachments 9 and 10. Day 0 particle and dissolution testing has recently been completed on Dexamethasone and Betamethasone. Attachment 11 indicates the timeline for completion. Betamethasone and dexamethasone time zero particle distribution has been completed and the master batch records have been updated, see Attachments 12 and 13. All suspension products produced by Eagle Pharmacy now have the particle size distribution criteria for batch release.

Observation 5

Your firm's media fills did not conduct media fill under worst-case, most challenging conditions. For example, but not limited to, prior to this FDA inspection, planned/unplanned interventions were not capture on your firm's batch records. On 08/02/2021, during media fill, lot DEAPSBETA080221, at least 20 interventions were observed.

In addition, on 07/27/2021, during the manufacture of Triamcinolone 50mg, lot 4115TA50, at least 9 interventions (manual opening of small window, manual opening of big door, manual adjustment of crimp/cap feeder with hands, manual adjustment of crimper) were observed during a 6-minute time period. These interventions were not documented on your firm's batch records.

Response to Observation 5:

During the inspection, Eagle Pharmacy implemented corrective actions to capture all interventions, both planned and unplanned, that occur during routine batch production, as well as all media fill trials. Attachment 14 is the In-Process Interventions Form that is now part of all product and media fill batch records.

The media fill mentioned in the observation comment, DEAPSBETA080221, that was performed on 08/02/2021 during the FDA inspection, did contain the In-Process Interventions Form. The number of interventions (20) that were observed by the FDA investigator Demario Walls matched identically to the number recorded on the In-Process Interventions Form by the Eagle Pharmacy Quality Technician during the media fill. A copy of the form (Attachment 15) was provided during the inspection on the Day 7 USB.

Additionally, the batch production of Triamcinolone Lot# 4115TA50 was cancelled and discarded due to the malfunction of the crimp seal portion of the vial filling machine. The batch record for 4115TA50 along with the associated OOS report number Lot#4115TA50 was provided to the FDA during the inspection on the Day 8 USB.

Observation 6

Your firm's Quality Unit failed to initiate investigations when you deviated from your stability protocols by placing one lot instead of three lots on stability, missing pre-established time points for testing and testing outside of the protocol. Your Quality Control Manager acknowledged that she should have initiated a deviation investigation. Your firm does not have a quality agreement with the laboratory who conducted your stability testing.

Response to Observation 6:

Eagle Pharmacy responded to the investigators with documentation that three lots were part of the stability study, lot numbers LIPO1000 dated May 2018, LIPO1022 dated July 2019, and LIPO1024 dated September 2019. The original lot LIPO1000 was placed on stability with dates per the established protocol and Eagle Quality management planned to change the test dates due to results of the first lot LIPO1000. The deviation that occurred during the stability study has been documented and closed by quality (Attachment 16). A quality agreement with the 3rd-party laboratory who conducted stability studies has been executed (Attachment 17).

Discussion Item:

503b (5) Outsourcing facility must report ADR. Statement to SOP to promptly submit report with 15 days 21 CFR 310.305 C2 and add failure to report is prohibit.

Response to Discussion Item:

Statement added to SOP to promptly submit report within 15 days 21 CFR 310.305 C2, added failure to report is prohibit. Attachment 18 is the updated SOP.

Standard Operating Procedure

Eagle Pharmacy	SOP CODE: P2.15.6 REVISION NUMBER: 6 ISSUE DATE: August 13, 2021 IMPLEMENTATION DATE: August 16, 2021

TITLE : Environmental Monitoring

DRAFTED BY: ☐	SIGNATORY: Haleigh Wilkes TITLE: Quality Manager	Haleigh Wilkes SIGNATURE	8/13/21 DATE
APPROVED BY:	SIGNATORY: Zahir Hamid TITLE: General Manager	 SIGNATURE	8/13/21 DATE

RELATED LOGS & FORMS

TYPE OF RECORD	FREQUENCY OF USE	Form Number	SPECIFICATION / DESCRIPTION
Form	Each batch	P2.15-A1	Batch Surface Sampling Form
Form	Each batch	P2.15-A2	Batch Viable Air Sampling Form
Form	Weekly	P2.15-A3	Weekly Surface Sampling Form
Form	Weekly	P2.15-A4	Weekly Viable Sampling Form
Form	As needed	P2.15-A5	Environmental Monitoring Controls Form
From	Twice Daily	P2.13-A1	Daily Temperature Log for Compounding Areas
Form	Twice Daily	P2.13-A2	Daily Temperature Log for Controlled Drug Storage Areas
Form	Twice Daily	P2.13-A3	Daily Pressure Log for Compounding Areas
Form	Twice Daily	P2.13-A4	Daily Humidity Log for Compounding Areas

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
P2.13	Policy on the Environmental and Personnel Monitoring Program

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RESPONSIBILITIES

1. Lead Sterile Compounding Technician
   a. Manage equipment and supplies necessary for sampling and testing.
2. Quality Control Technician
   a. Perform sampling in accordance with this SOP.
   b. Author trending reports of environmental monitoring data at least quarterly.
   c. Order and maintain equipment and supplies necessary for sampling and testing.
3. Quality Control Manager and General Pharmacy Manager
   a. Review documentation associated with the Environmental Monitoring Program at least weekly.
   b. Review and approve trending reports of environmental monitoring data at least quarterly.
   c. Author, review and approve results of investigations and product impact assessments.
   d. Perform an investigation and product impact assessment, when applicable.

PURPOSE

1. This Standard Operating Procedure (SOP) describes how to perform Environmental Monitoring (EM) sampling and testing at Eagle Pharmacy (Eagle).

SCOPE

1. This SOP applies to all personnel and facilities at Eagle engaged in aseptic processing of sterile drug products (SDPs).

DEFINITIONS

1. ATCC: American Type Culture Collection
2. BSC: Biological Safety Cabinet
3. CAPA: Corrective Action Preventative Action
4. CFR: Code of Federal Regulations
5. CFU: Colony Forming Units
6. CoA: Certificate of Analysis
7. EM: Environmental Monitoring
8. FD&C: Federal Food, Drug, and Cosmetic Act
9. FDA: Food and Drug Administration
10. GPT: Growth Promotion Testing
11. IPA: Isopropyl Alcohol
12. ISO: International Organization on Standardization
13. LAFW: Laminar Airflow Workbench
14. MEA: Malt Extract Agar
15. N/A: Not Applicable
16. SDA: Sabaroud Dextrose Agar
17. SDP: Sterile Drug Product
18. SOP: Standard Operating Procedure
19. TSA: Tryptic Soy Agar
20. USP-NF: United States Pharmacopeia – National Formulary
21. Action Levels: Established criteria (e.g., microbiological or particulate levels) that when met or exceeded, require immediate investigation, including assessment of product quality impact, and corrective action based on the investigation.
22. Alert Levels: Established criteria (e.g., microbiological or particulate levels) that when met or exceeded, indicate potential drift from normal operating conditions, which should be investigated and may require corrective action.
23. Aseptic Processing: Handling sterile materials in a controlled environment, in which the air supply, materials, equipment, and personnel are regulated to control microbiological and particulate contamination to specified levels.
24. Bioburden: The level and type of microorganisms that can be present in raw materials, starting materials, intermediates, or active pharmaceutical ingredients. Bioburden shall not be considered

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contamination unless the levels have been exceeded or defined objectionable organisms have been detected.

25. Compounding: The process of combining together active ingredients, excipients, and solvent components into a homogenous mixture.
26. Environmental Monitoring Program: Defined, documented program that describes the routine particulate and microbiological monitoring of processing areas, and includes a corrective action plan when action levels are exceeded.
27. Growth Promotion: Test performed to demonstrate that media will support microbiological growth.
28. Sampling Frequency: Established period for collecting samples.
29. Sterile: Free of any detectable viable organisms. Note: In practice, no such absolute statement regarding the absence of microorganisms can be proven.
30. Sterilization: Validated process used to render a product free of viable organisms. Note: In a sterilization process, the nature of microbiological death or reduction is described by an exponential function. Therefore, then number of microorganisms, which survive a sterilization process, can be expressed in terms of probability. While the probability may be reduced to a very low number, it can never be reduced to zero.

SPECIAL CIRCUMSTANCE

1. Not applicable.

PROCEDURE

This SOP is divided into the following sections:

1. Viable Surface Sampling
2. Active Viable Air Sampling
3. Passive Viable Air Sampling
4. Non-Viable Air Sampling
5. Growth Promotion Testing
6. Positive and Negative Controls
7. Analysis of Results
8. Room Condition Monitoring

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1. Section 1: Viable Surface Sampling

    1. For each batch, collect samples at the locations specified in Appendices 1 and 2 or 3 depending on location of Batch Production – Manual Room or Machine Room (Appendix 1 – EM Map; Appendix 2 – EM Legend for Batch Sampling in Machine Room; Appendix 3 – EM Legend for Batch Sampling in Manual Room).
    2. For weekly sampling, collect samples at the locations specified in Appendix 1 and Appendix 4 (Appendix 1 – EM Map; Appendix 4 – EM Legend for Weekly Sampling)

3. Don the appropriate gowning for the area being sampled, including the use of sterile gloves when handling contact plates.
4. Remove the 60 mm TSA contact plates containing neutralizing agents from the refrigerator (if applicable) and allow them to warm to room temperature prior to sampling.
5. Label the outside of the contact plate with a permanent fine tip marker or a pre-printed translucent label, indicating the following: sampler initials, sampling date, and sample ID.
    i. If samples are taken inside an ISO Class 5 post-process, include the batch number of the SDP on the label.
6. To obtain a surface sample, firmly press the surface of each contact plate to the surface being sampled for approximately 5 seconds.
7. For sampling surfaces that are irregular (e.g., stopper bowl, filling nozzle), use a sterile swab to collect the sample (See Appendix 7 for instructs to obtain a proper sample with a swab). Use the swab to inoculate the surface sampling agar plate using method outlined in Appendix 8.
8. Replace the lid on each contact plate and secure it.
9. Immediately clean agar residue from the sampled surface with a non-shedding wipe with sterile 70% IPA.
10. Complete the Surface Sampling Form (P2.15-A1 for batch sampling; P2.15-A3 for weekly sampling).
    i. TSA plates are first incubated at 30 to 35°C for 48 – 72 hours (as this temperature is suited to promote growth of bacteria if present on the plates), and then they will be moved to the incubator held at 20 - 25 °C for 5-7 days (suitable for the growth of fungi).
11. Following the incubation period, record the results obtained on the Surface Sampling Form (P2.15-A1 for batch sampling; P2.15-A3 for weekly sampling) and have a Quality Control Manager or General Pharmacy Manager verify the results.

2. Section 2: Active Viable Air Sampling

1. For each batch, collect samples at the locations specified in Appendix 1 and 2 or 3 depending on location of production. Samples are to be taken relative to critical processes.
    i. In the Laminar Airflow Work area, air samples will be taken within 12 inches of critical operations
    ii. In the Vial Filling Machine, air samples will be taken within 12 inches of the point of filling and withing 12 inches of the point of stopper insertion.
2. For weekly sampling, collect samples at the locations specified in Appendix 4.
3. Don the appropriate garb for the area being sampled, including the use of sterile gloves when handling the active viable air sampler and agar plates.
4. Remove TSA plates from the refrigerator (if applicable) and allow them to warm to room temperature prior to sampling.
5. Label the plates with a permanent marker or a pre-printed translucent label, indicating the following: sampler initials, sampling date, and Sample ID.
    i. If samples are taken inside an ISO Class 5 area during processing, include the batch number of the SDP on the label.
6. To obtain an active air sample, follow the instructions provided in Appendix 5 (Buck Bio-Culture Model B30120 OR Lighthouse Active Count 100H depending on what air sampler used) for a 1000 L air sample.

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7. If sampling different classifications of air, begin with the cleanest room or area classification first and work progressively toward the lower room or area classifications (e.g., sample ISO Class 5 locations first, then ISO Class 7 locations, and then ISO Class 8 locations).
8. Complete the Viable Air Sampling Form (P2.15-A2 for batch sampling; P2.15-A4 for weekly sampling).
    i. TSA plates are first incubated at 30 to 35°C for 48 – 72 hours (as this temperature is suited to promote growth of bacteria if present on the plates), and then they will be moved to the incubator held at 20 - 25 °C for 5-7 days (suitable for the growth of fungi).
9. Following the incubation period, record the results obtained on the Viable Air Sampling Form (P2.15-A2 for batch sampling; P2.15-A4 for weekly sampling) and have the Quality Control Manager or General Pharmacy Manager verify and sign off on the results.

3. Section3: Passive Viable Air Sampling

1. For each batch processed in a LAFW, collect samples at the locations specified in Appendix 2 or 3 depending on the location of production.
2. For weekly sampling, collect samples at the locations specified in Appendix 4.
3. Don the appropriate gowning for the area being sampled, including the use of sterile gloves when handling the settling plates.
4. Remove the 100 mm TSA settling plates from the refrigerator (if applicable) and allow them to warm to room temperature prior to sampling.
5. Label the outside of all settling plates with a permanent marker or a pre-printed translucent label, indicating the following: sampler initials, sampling date, and Sample ID.
6. To obtain a passive air sample, open one TSA settling plate and place it at each of the sample locations, "agar-side-up" to expose them to the surrounding air.
7. After not more than 4 hours of exposure, replace the lid of each settling plate, remove it from the sample location, and secure the lid with tape. During production, the passive plates should remain in place for the duration of the production.
8. TSA plates are first incubated at 30 to 35°C for 48 – 72 hours (as this temperature is suited to promote growth of bacteria if present on the plates), and then they will be moved to the incubator held at 20 - 25 °C for 5-7 days (suitable for the growth of fungi).
9. Following the incubation period, record the results obtained on the Viable Air Sampling Form (P2.15-A2 for batch sampling; P2.15-A4 for weekly sampling) and have the Quality Manager or Operations Manager verify the results.

4. Section 4: Non-Viable Air Sampling

1. For each batch, collect samples at the locations specified in Appendix 2 or 3 depending on the location of production. Samples are to be taken relative to critical processes.
    i. In the Laminar Airflow Work area, air samples will be taken within 12 inches of critical operations
    ii. In the Vial Filling Machine, air samples will be taken within 12 inches of the point of filling and withing 12 inches of the point of stopper insertion.
2. For weekly sampling, collect samples at the locations specified in Appendix 4.

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3. Don the appropriate garb for the area being sampled, including the use of sterile gloves when handling the air sampler.
4. To obtain an air sample, follow the instructions provided in Appendix 6 (Airy Technology Model P311 Handheld Laser Particle Counter Quick Start Guide).
5. If Sampling different classifications of air, begin with the cleanest room or area classification first and work progressively toward the lower room or area classifications (e.g., sample ISO Class 5 locations first, then ISO Class 7 locations, and then ISO Class 8 locations).
    i. For rooms of the same classification, the sampling order should follow the room pressurization scheme from the highest pressure area to the lowest pressure area.
6. The air sampler will provide data on 0. 5 micron and 5 micron particles.
7. For in-process sampling of ISO Class 5 LAFWs, samples shall be taken continuously for 10 minutes at each location designated in Appendix 2 during aseptic filling at a flow rate of 2.83 L/min.
8. For sampling of open areas within ISO Class 7 and ISO Class 8 areas, samples shall be taken continuously for 10 minutes at each location designated in Appendix 2 at a flow rate of 2.83 L/min during normal compounding activities prior to cleaning.
9. After sample collection, print the results and have it verified by the Pharmacy General Manager or Quality Control Manager.

5. Section 5: Growth Promotion Testing

1. Growth promotion tests demonstrate that growth media support recovery and growth of a wide range of microorganisms.
2. Qualification of the growth medium involves growth promotion testing of not less than three different lots of medium from each supplier. All growth promotion testing will be performed at an outside lab.
    i. If there is a Quality Agreement between the supplier and Eagle Pharmacy, Inc., then after the three lots have undergone growth promotion testing, no additional growth promotion samples are required.
    ii. If three lots have not already been tested for the supplier then have a third party conduct growth promotion testing.
3. Growth Promotion Testing
    i. The growth media will be inoculated with a representative sample from each organism classification including a gram positive, a gram negative, a spore forming, a mold, and a fungi to demonstrate its ability to detect a wide range of organisms.
    ii. Periodic growth promotion testing and other testing may be performed at the discretion of the Quality Control Manager to confirm that growth media meet specifications and conform to CoA.

6. Section 6: Positive and Negative Controls

1. A positive and negative control plate shall be created for each lot of media received into the facility.
2. Upon receipt of a shipment of a new lot of culture plates into the facility, the Environmental Monitoring Controls Form (Attachment 5) shall be reviewed to determine if control plates have been documented for the received lots.

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i. If control plates have already been tested for the received lot, then no additional control plates need to be run.
ii. If control plates have not already been tested for the received lot then follow the steps in section 6.3 and 6.4.

3. Positive Control Plate
   i. Expose the plate to a non-controlled environment or surface (e.g., floor surface, mouth swab) for 10 seconds.
   ii. Secure the lid on the plate with tape and label the outside of the plate with a permanent marker or a pre-printed translucent label, indicating the following: sampler initials, sampling date, control, the date, time, and control type (i.e., positive).
   iii. Incubate the plate as appropriate for the selected media.
4. Negative Control Plate
   i. Secure the lid of an unexposed sterile plate with tape and label the outside of the plate with a permanent marker or a pre-printed translucent label, indicating the following: sampler initials, sampling date, control, the date, time, and control type (i.e., negative).
   ii. Incubate the plate as appropriate for the selected media.
5. Complete the Environmental Monitoring Controls Form (P2.15-A5).
6. Following the incubation period, record the results obtained on the Environmental Monitoring Controls Form (P2.15-A5) and have verified by the General Pharmacy Manager or Quality Control Manager.

7. Section 7: Analysis of Results

1. Plates shall be read and documented during normal business hours. If the facility is not open for business when the incubation period ends, the plates shall be read on the following business day.
2. Any growth shall be brought to the attention of the Quality Control Manager or General Pharmacy Manager.
   i. For any samples that exceed the action level, an investigation shall be conducted and documented in an out-of-specification report with a product impact assessment. Affected batches shall be quarantined and may not be released until the investigation has been completed.
3. Any growth within ISO Class 7 or cleaner environments must be sent to an independent laboratory for identification to the species level. Growth within ISO Class 8 environments may be sent for identification periodically as determined by the General Pharmacy Manager or Quality Control Manager.
   i. If a plate contains more than 2 Colony Forming Units (CFUs), the laboratory may be instructed to identify only the two most prominent colonies.
   ii. Corrective actions and preventative actions (CAPAs) may be initiated following identification of the source(s) of contamination, if warranted.
4. All environmental monitoring not associated with sterile batches must be reviewed at least monthly.
5. Trending reports of room condition data shall be prepared at least quarterly and must be approved by the General Pharmacy Manager or Quality Control Manager.

Attachment 1

6. Excursions must be investigated and documented in an out-of-specification report, including a product impact assessment.

8. Section 8: Room Condition Monitoring

1. At least twice daily (beginning and end of working day), record the temperature, relative humidity, and differential pressures for all compounding areas on the applicable form (P2.13-A1, P2.13-A3, P2.13-A4).
2. At least twice daily (beginning and end of working day), record the temperature of the controlled drug storage areas on the applicable form (P2.13-A2)
3. All room condition data must be reviewed at least weekly.
4. Trending reports of room condition data shall be prepared at least quarterly and must be approved by the General Pharmacy Manager or Quality Control Manager.
5. Excursions shall be reported to the General Pharmacy Manager or Quality Control Manager immediately.
6. Excursions must be investigated and documented in an out-of-specification report, including a product impact assessment.

Attachment 1

CORRECTIVE ACTIONS

1. Any cfu count that exceeds it respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.
2. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices.
3. The source of the problem shall be eliminated, affected area cleaned, and resampling performed.
4. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory.
   a. Highly pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving compounded sterile products and must be immediately remedied with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.
   b. Any highly pathogenic organism recovered as part of environmental monitoring associated with batch processing will necessitate that the entire batch be discarded, regardless of whether sterility testing on the batch comes back negative.
   c. Corrective and preventative actions taken will be based on recommendations from the microbiologist or other competent personnel.
      i. Any environmental contamination discovered on weekly or batch processing monitoring will necessitate a complete clean down of the area with an agent proven to kill the identified bacteria/fungi. Highly pathogenic organism will warrant a triple clean procedure.
      ii. Any contamination noted on personnel monitoring will necessitate a reevaluation of hand washing/garbing competency, as well as, aseptic work practices.

REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION
1	04/20/15	07/24/16	
2	07/25/2016	04/03/17	Updated sampling diagrams and clarified sampling process.
3	04/04/2017	09/09/2018	Updated attachment numbers and made them easier to use; adjusted temperature range of incubator (INC002)
4	09/10/2018	11/2/2020	Added information for additional viable air sampler
5	11/3/2020	8/15/2021	Clarifired incubation times
6	08/16/2021		Adjusted EM Monitoring locations during batch production to better assess the environmental quality at critical areas

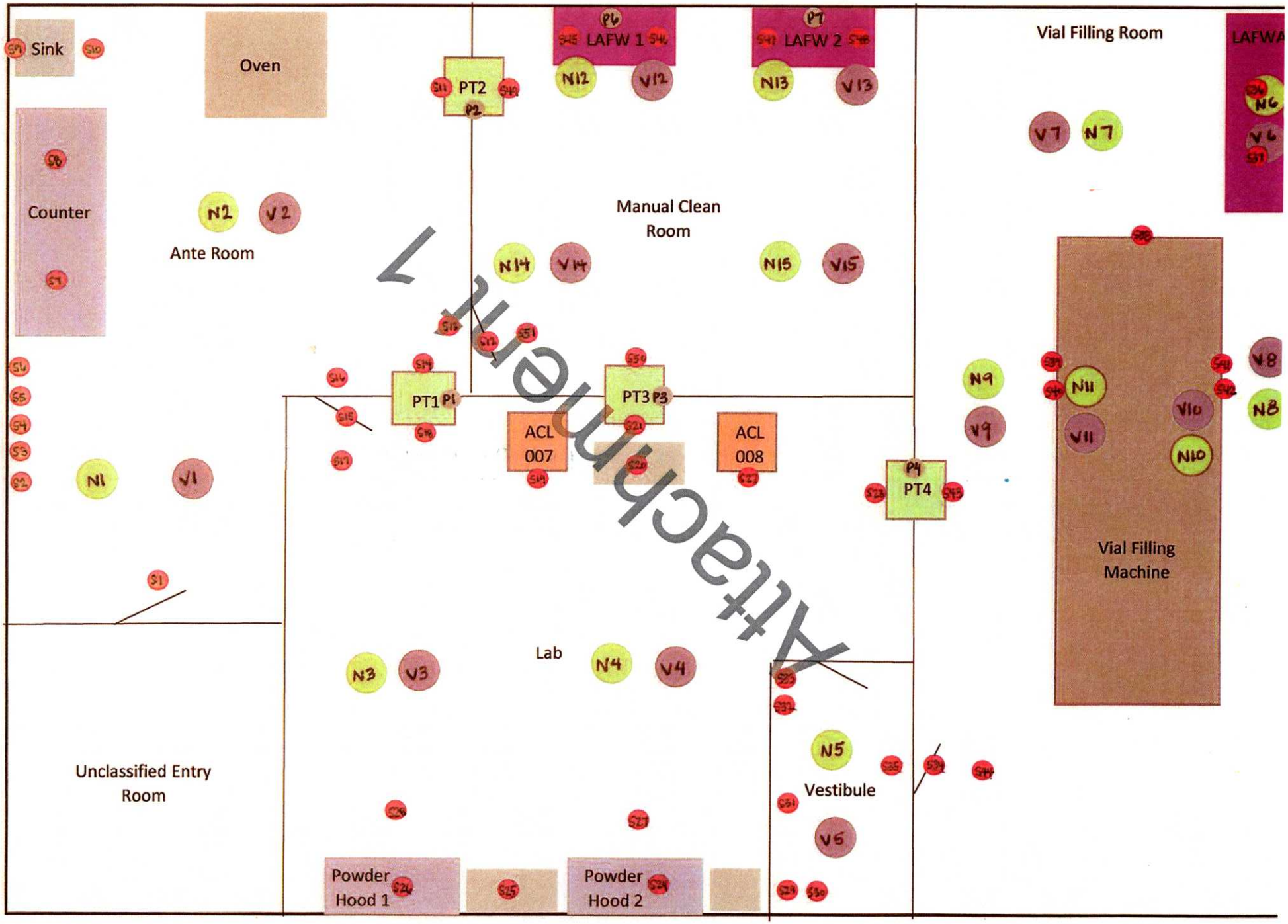
REFERENCES

ID	Document Title	Document Number	Author	Approval Date
1	Pharmaceutical Compounding, Sterile Preparations	Chapter 797	USP-NF	Yearly
2	Current Good Manufacturing Practice for Finished Pharmaceuticals	21 CFR Part 211	FDA	Yearly
3	Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing	N/A	FDA	2004
4	Guidance for Industry Current Good Manufacturing Practice —Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act	N/A	FDA	2020
5	Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness	ISO 14644-1	ISO	2015
6	Microbiological Control and Monitoring of Aseptic Processing Environments	Chapter 1116	USP-NF	Yearly

Attachment 1

APPENDICES

Appendix 1 - Controlled Room Environmental Monitoring Map



Appendix 2: Batch EM Monitoring Legend – Machine Filling Room

Surface Sampling

Location	Description	Justification
S36	Left Center of LAFWA surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S37	Right Center of LAFWA surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S38	Vial Rake surface	Area that comes into contact with sterile vials
S39	Big stopper door handle	Area touched by sterile compounder prior to placing sterile stopper bowl into vial filling machine
S40	Small stopper door handle	Area touched by sterile compounder when loading sterile stoppers
S41	Large crimp cap door handle	Area touched by sterile compounder when loading sterile tubing into filling machine
S42	Small crimp cap door handle	Area touched by sterile compounder prior to loading sterile crimp caps into filling machine
S43	Handle to Pass Thru	Area touched by sterile compounder when bring sterile supplies and product into the room
S44	Floor in front of entry door into room	Monitor garbing procedures and room cleanliness
FN	Swab of Filling Nozzle (sterile products)	Directly comes in contact with sterile product
SB	Swab of Stopper Bowl Interior	Stoppers directly contact sterile product and sterile vials

Viable Air Sampling (V)/Non-Viable Air Sampling (N)

Location		Description	Justification
V6	N6	Area in LAFWA where sterile produce is manipulated	Contamination could directly impact sterile product
V7	N7	Area directly in front of LAFWA where sterile compounder is working	Contamination in this area could be brought in the LAFWA or vial filling machine by sterile compounder
V8	N8	Area where sterile compounder loads tubing into the filling machine	Contamination in this area could be brought into the filling machine by the sterile compounder
V9	N9	Area where sterile compounder loads sterile stoppers into the filling machine	Contamination in this area could affect the sterility of the stoppers
V10	N10	Area in filling machine where product is filled into vials	Contamination of this area could directly affect sterility of product
V11	N11	Area in filling machine where sterile stoppers are inserted into vials	Contamination of this area could directly affect sterility of product

Passive Air Sampling (Viable)

Location	Description	Justification
P5	Area of LAFWA directly between compounding line and HEPA filter	Contamination of this area could directly impact sterile product

Attachment 1

KEY

Viable Air Sample	Surface Sample
Non-Viable Air Sample	Passive Air Sample

Appendix 3: Batch EM Monitoring Legend – Manual Filling Room

Surface Sampling

Location	Description	Justification
S45	Left Center of LAFW 1 surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S46	Right Center of LAFW 1 surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S47	Left Center of LAFW 2 surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S48	Right Center of LAFW 2 surface	Area where sterile compounding occurs; contamination directly affects final sterile product
S49	Handle of Pass Thru to Ante Room	Area touched by sterile compounder when retrieving sterile compounding supplies
S50	Handle of Pass Thru to Lab	Area touched by sterile compounder when retrieving sterile compounding supplies/pre-sterilized product
S51	Floor directly upon entering Manual Room	Assess proper garbing practices and cleaning procedures

Viable Air Sampling (V)/Non-Viable Air Sampling (N)

Location		Description	Justification
V12	N12	Area in LAFW1 where sterile product is manipulated	Contamination could directly impact sterile product
V13	N13	Area in LAFW2 where sterile product is manipulated	Contamination in this area could be brought in the LAFWA or vial filling machine by sterile compounder
V14	N14	Area directly in front of LAFW 1	Contamination in this area could be brought into the LAFW by the sterile compounder
V15	N15	Area directly in front of LAFW 2	Contamination in this area could be brought into the LAFW by the sterile compounder

Passive Air Sampling (Viable)

Location	Description	Justification
P6	Area of LAFW 2 directly between compounding line and HEPA filter	Contamination of this area could directly impact sterile product
P7	Area of LAFW 2 directly between compounding line and HEPA filter	Contamination of this area could directly impact sterile product

Attachment 1

KEY

Viable Air Sample	Surface Sample
Non-Viable Air Sample	Passive Air Sample

Appendix 4: Weekly EM Monitoring Legend
(Surface Sampling)

Location	Description	Justification
	ANTE ROOM	
S1	Floor upon entry into Ante Room	Monitor efficiency of entry procedures designed to minimize bioburden in ante room
S2	Top left garb bin lid	Area that is touched often to retrieve sterile garb
S3	Top middle garb bin	Area that is touched often to retrieve sterile garb
S4	Top right garb bin lid	Area that is touched often to retrieve sterile garb
S5	Bottom left garb bin lid	Area that is touched often to retrieve sterile garb
S6	Bottom right garb bin lid	Area that is touched often to retrieve sterile garb
S7	Left center of table surface	Area used during garbing procedures
S8	Right center of table surface	Area used during garbing procedures; next to sink
S9	Wall above sink	To monitor bioburden that could be introduced from water
S10	Floor in front of sink	To monitor bioburden that could be introduced from water
S11	Handle of Pass Thru leading to Manual Rm	Could result in contamination being brought into Manual Rm
S12	Door handle to Manual Rm	Could result in contamination being brought into Manual Rm
S13	Floor inside red line leading to Manual Rm	Monitor effectiveness of garbing procedures
S14	Handle of Pass Thru leading to Lab	Could result in contamination being brought into Lab
S15	Door Handle to Lab	Could result in contamination being brought into Lab
S16	Floor inside red line leading to Lab	Monitor effectiveness of garbing procedures
	LAB	
S17	Floor directly upon entrance to Lab	Monitor effectiveness of garbing procedures; contamination brought in from ante room
S18	Handle to Pass Thru from Ante Room	Contamination could result in contaminated supply pkgs.
S19	Handle to open autoclave ACL007	Contamination could transfer to sterile supply/product containers
S20	Worktable between autoclaves	Area where supplies are bagged to be autoclaved
S21	Handle to Pass Thru Leading to Manual Rm	Could result in contamination being introduced into Manual Rm
S22	Handle to open autoclave ACL008	Contamination could transfer to sterile supply/product containers
S23	Handle to Pass Thru Leading to Machine Rm	Could result in contamination being introduced into Machine Rm
S24	Center surface of Powder Hood 004	Contamination could inc. bioburden of presterilized product
S25	Center surface of table between Powder Hoods	Contamination could transfer to compounding supplies or presterilized product
S26	Center surface of Powder Hood 003	Contamination could inc. bioburden of presterilized product
S27	Floor in front of Powder Hood 004	Monitor cleaning and garbing procedures
S28	Floor in front of Powder Hood 003	Monitor cleaning and garbing procedures
	VESTIBULE	
S29	Lid to top garb bin on far wall	Area that is touched to retrieve sterile garb
S30	Lid to bottom garb bin on far wall	Area that is touched to retrieve sterile garb
S31	Center of garbing bench	Could directly impact sterile garb
S32	Lid to top garb bin on door wall	Area that is touched to retrieve sterile garb
S33	Lid to bottom garb bin on door wall	Area that is touched to retrieve sterile garb
S34	Door handle to Machine Room	Could result in contamination being introduced into Machine Rm
S35	Floor inside red line leading to Machine Rm	Monitor effectiveness of garbing procedures/ could result in contamination introduced into the Machine Room

Attachment 1

Weekly EM Monitoring Legend
(Air Sampling)

Viable Air Sampling - Active

Location	Description	Justification
	ANTE ROOM (ISO 8)	
V1	Area just upon entry into Ante Rm	Monitor air quality upon entry to Ante Room
V2	Area around entry to Lab and Manual Rm	Monitor air quality near entrance to ISO 7 Rooms
	LAB (ISO 7)	
V3	Left side of Lab	Monitor air quality in front of Powder Hood 003
V4	Right side of Lab	Monitor air quality in front of Powder Hood 004
	VESTIBULE (ISO 7)	
V5	Center of Vestibule	Monitor air quality of garbing rm prior to entry into ISO 5 Rm

Non-Viable Air Sampling (Particle Counts)

Location	Description	Justification
	ANTE ROOM (ISO 8)	
N1	Area just upon entry into Ante Rm	Monitor air quality upon entry to Ante Room
N2	Area around entry to Lab and Manual Rm	Monitor air quality near entrance to ISO 7 Rooms
	LAB (ISO 7)	
N3	Left side of Lab	Monitor air quality in front of Powder Hood 003
N4	Right side of Lab	Monitor air quality in front of Powder Hood 004
	VESTIBULE (ISO7)	
N5	Center of Vestibule	Monitor air quality of garbing rm prior to entry into ISO 5 Rm

Viable Air Sampling - Passive

Location	Description	Justification
	ANTE ROOM	
P1	Pass Thru between Ante Rm and Lab	Monitor air quality/cleaning of Pass Thru; contamination could affect compounding supplies
P2	Pass Thru between Ante Rm and Manual Rm	Monitor air quality/cleaning of Pass Thru; contamination could affect compounding supplies
	LAB	
P3	Pass Thru between Manual Rm and Lab	Monitor air quality/cleaning of Pass Thru; contamination could affect compounding supplies/pre-sterilized product
P4	Pass Thru between Machine Rm and Lab	Monitor air quality/cleaning of Pass Thru; contamination could affect compounding supplies/ sterile product

Attachment 1

KEY

	Viable Air Sample		Surface Sample
	Non-Viable Air Sample		Passive Air Sample

Appendix 5

1. **Buck Bio-Culture Model B30120 Instruction Manual** - This section contains basic startup and maintenance instructions. Refer to the user manual for complete instructions and user requirements.
    a. Operating Instructions
        i. Before beginning, ensure the battery is fully charged and that the "Low Battery" LED is not on. For greatest accuracy, the pump should be calibrated each day of use.
        ii. Clean entire machine with sterile prewetted 70% Isopropyl Alcohol wipe prior to each use.
        iii. Allow covered agar dish to reach room temperature before use.
        iv. Unscrew the sample head, remove cover from dish and position within the mounts. Then replace the head back on securely.
        v. Calibrate pump (see Calibration section below)
        vi. Push the "ON" button to power u the Buck Bio-Culture Pump and either: (a) continue to hold the "ON" button for four seconds to pout pump in "Continuous" mode, or (b) push one of the programmed time keys (1,2,5, or 10 minutes) for an automatic timed sample.
        vii. Set the time so that 500 liters of air is sampled.
        viii. At the end of programmed sample period, pump will automatically shut off and "Complete" LED will be lit; under "Continuous" mode, push and hold "OFF" button for 2 seconds to shut off pump.
        ix. Unscrew the head and remove the Agar Plate.
        x. Replace and secure the agar lid on the dish with tape or laboratory film and write sample number on the bottom of the dish.
        xi. Incubate the agar plate for the appropriate time and record the results on Attachment
    b. Cleaning
        i. Bio-Culture must be cleaned after each cycle to avoid cross contamination which would modify the reliability of the sampling.
        ii. Switch off the unit. Clean the surface of Bio-Culture using a sterile cloth wet with sterile 70% IPA.
        iii. After drying, the unit is ready for a new sampling cycle.
        iv. Between two samplings, spray sterile 70% IPA on both faces of the sampling head.
        v. Let dry at room temperature.
        vi. After drying, the sampling head is ready to use
    c. Calibration
        i. Replace sampling head with the Bio-Culture Calibrator which includes attached head and pressure gauge with flow chart on the side.
        ii. Push "ON", the press the "CAL" for 2 seconds to put pump into calibration mode.
        iii. Adjust the flow rate using the up and down arrow keys to the desired mm of water pressure per minute.
        iv. Correlate with the calibration chart on the side of the calibrator head.
        v. Fine adjustments are possible. Allow pump to stabilize.
        vi. When flow rate is achieved, push "CAL" to accept setting, then turn pump off.

Attachment 1

vii. Verify the flow at any time with the Calibrator by selecting a 1, 2, 5 or 10 minute timing routine. Press the OFF key to stop. If the verify flow was accurate, entering "Cal" is not necessary.

viii. Entering the "Cal" mode erases the previous setting for a new flow rate.

Calibration and Verification of Bio-Culture	
Flow Rate LPM	**Mm of Water Pressure**
150	5.6
120	3.8
100	2.7
90	2.2
60	1.1
30	0.30

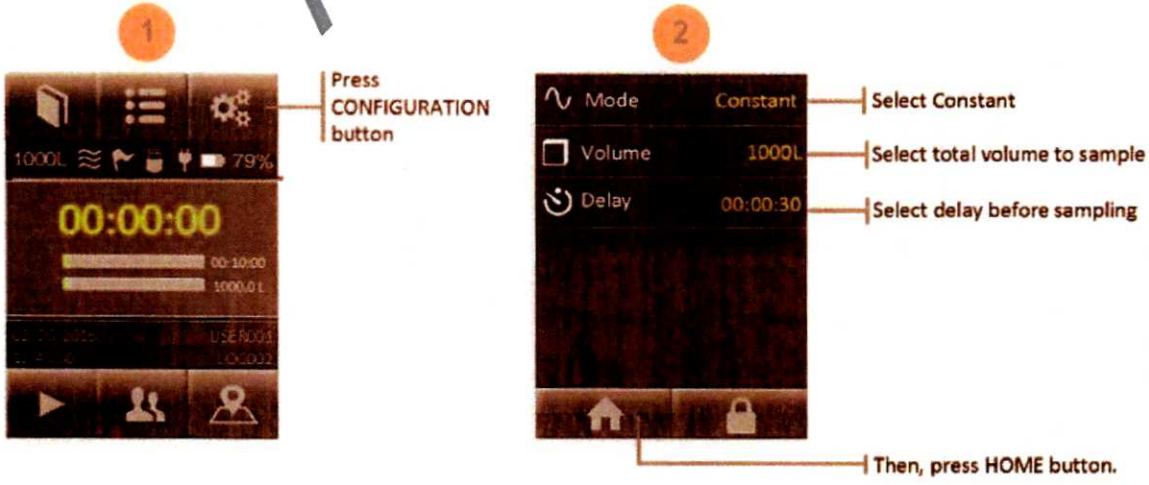
Attachment 1

2. Lifehouse Active Count C100H (Refer to user manual for in depth instructions)

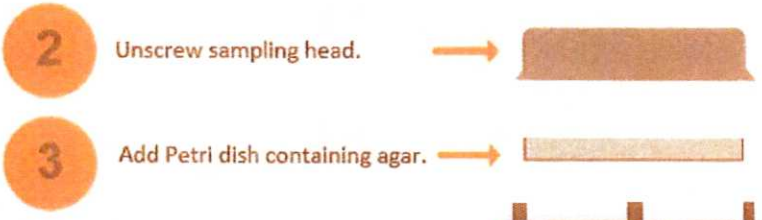
a. Prior to bringing the sampler into the controlled environment to be sampled, wipe down entire device with a sterile prewetted 70% isopropyl alcohol wipe.

b. Make sure the battery is sufficiently charged to perform the entire sampling process.

c. Set the amount of air to be sampled (500 Liters) as per diagram below (typically only needs to be done one time and then machine saves data until it is changed manually).



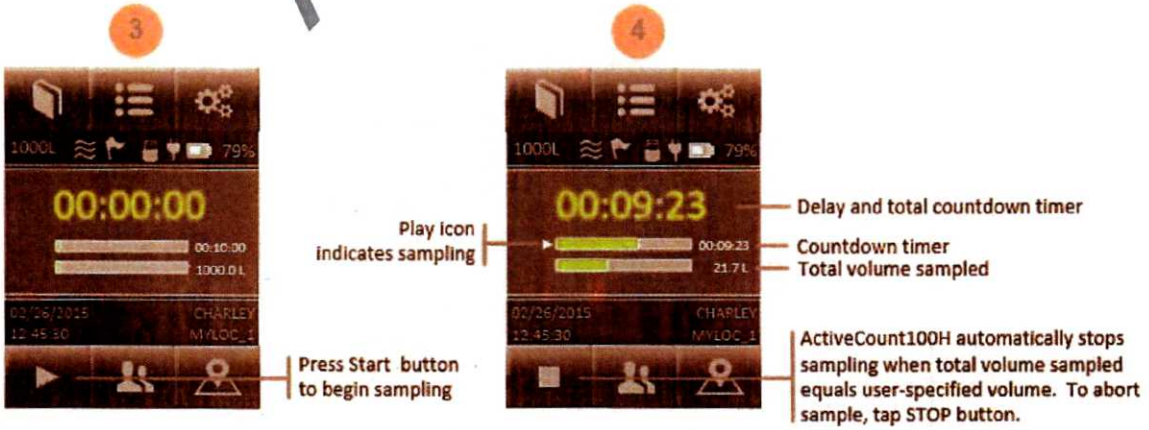
d. Place agar plate in sampler.



Front of ActiveCount100H

Attachment 1

e. To begin cycle, press the start button.



f. Sampling Status

The following table describes the Status LED color and blink feature.

Status	Color	Blink
Idle	Off	Off
Sampling	Blue	Solid
Delay/Pause	Green	Solid
Flow Error	Red	Blinking
Writing to USB	White	Solid
Service/Calibration Required	Yellow	Solid

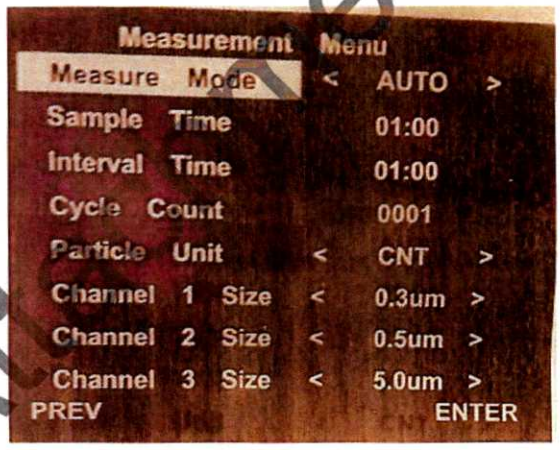
Status LED: Color and Blink table:

Attachment 1

Eagle Pharmacy	SOP CODE: P2.15.6 REVISION NUMBER: 6 ISSUE DATE: August 13, 2021 IMPLEMENTATION DATE: August 16, 2021
TITLE : Environmental Monitoring	
	Page 14 of 17

Appendix 6

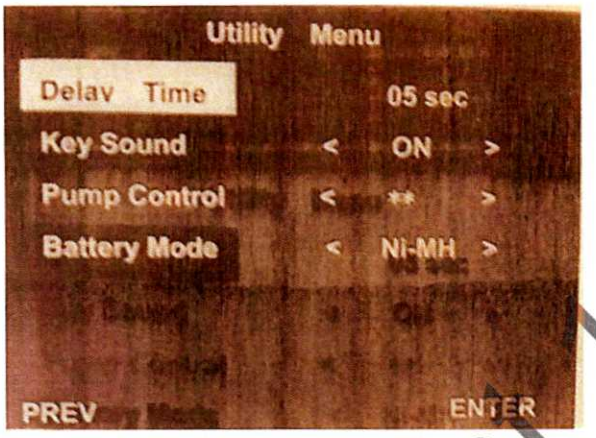
1. Airy Technology Model P311 Handheld Laser Particle Counter Quick Start Guide
    a. Operation
        i. When using AC power, must use the affiliated AC adapter, shown below. Connect Mini USB-B plug to the instrument.
        ii. If using the batteries, first remove the battery cover on the back of the shell, then insert four AA or Ni-MH type batteries.
        iii. Remove a rubber cap at the inlet and attach an Isokinetic inlet. In order to turn on the instrument, press the POWER key. After three seconds the default screen will appear. This means that the instrument is ready for operation.
        iv. From the default screen, press MENU key to go to the Main Menu. Press PREV key to go back to the Default Screen. At the Main Menu you can select the following settings.



Attachment 1

        v. From the Main Menu, select Measurement Setting.
        vi. Change settings (Below is an example setting).
        vii. Press PREV to return to the Main Menu.
        viii. Finally, select Utility Setting and set the battery mode (Standard is Ni-MH). DO NOT change the Pump Control.

Menu	Description
Measurement Setting	Set measure mode, sample time, interval time, cycle count, particle units, and channel size.
Data Process	Display data records, clear data records and transmit the data
System Setting	Set time and date, screen settings and location number
Utility Setting	Set delay time, key sound and pump speed



ix. Press PREV twice to return to the Default Screen.
x. Press START to run the sampling.

Attachment 1

Appendix 7 – Proper Swab Sampling Technique

1. Using aseptic technique, peel open the pouch containing the swab tube.

2. Determine the surface to be sampled.

3. Carefully remove the cap with the pre-moistened swab attached from the vial.

4. Hold swab at a 30° angle and wipe over the sample area in a back and forth motion. Rotate swab while wiping.

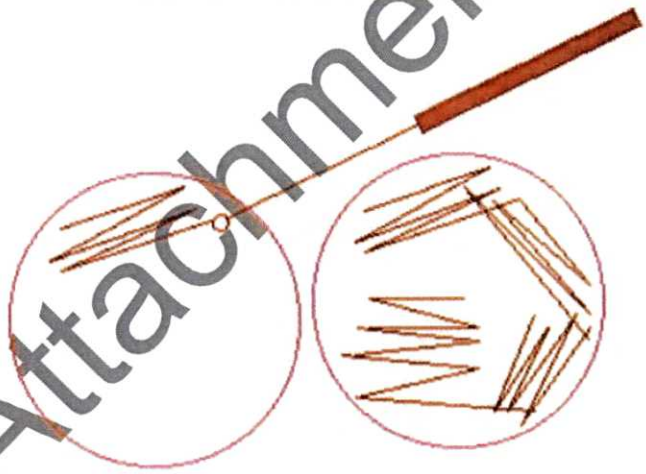
5. Return the swab to the vial containing the rinse solution and screw on the cap until tightly secured.

6. Immediately inoculate the contact plate using the swab in the manner described in Appendix 8.

Appendix 8 – Innoculation of Agar Plates using a Swab

A sterile swab must be used, care must be taken not to contaminate by touching other surfaces. Transfer to the growth media as quickly as possible. Depending on your purposes, you can inoculate the swab in a few ways. Described below is the Zigzag method of inoculation. The inoculation pattern is usually performed when the sample does not have a high cell density or with pure cultures when isolation is not necessary.

1. **With this method, a small amount of sample is placed on the agar plate (either with a swab, or as a drop from an inoculating loop if the sample is a liquid).**
2. **Hold the swab comfortably in one hand and lift the lid of the petri dish with the other. Use the lid of the petri dish to protect the agar from aerial contamination.**



Attachment 1

This is repeated 2-3 times, moving around the agar plate.

3. **Lightly drag the swab across the agar surface in a zigzag pattern.**
   Ex. ^^^^^^^^^^^^^^^^^^^^^^^^^^^^
   What should happen is that single bacterial cells get isolated by the streaking, and when the plate is incubated, forming discrete colonies that will have started from just one bacterium each.

1. Materials
    i. 60 mm TSA and Malt Extract Agar (or SDA) contact plates with lecithin and polysorbate 80
    ii. 100 mm TSA and MEA (or SDA) settling plates

2. Equipment
    i. Incubators
    ii. Viable Air Sampler
    iii. Non-Viable Air Sampler

Attachment 1

Documentation of Training on Updated Environmental Monitoring Procedures

Date: 8/16/2021
Trainer: Haleigh Wilkes, Quality Control Manager
Trainee: Rachel Crawford, Quality Control Technician

Training Topic: Environmental Monitoring Locations within ISO 5 Compounding Room
Description of Training:

- Reviewed updated policy Environmental Monitoring (P2.15.6)
- Reviewed updated sampling location sites (Appendices 1-4 in the Policy)
- Explained reasoning behind the sample sites – This helped quality technician understand that sampling sites need to represent what's happening at critical sites/operation points to represent final product quality.
- During the first Media Fill Process that occurred this day (8/16/2021), I demonstrated the sampling procedures, sites, and techniques to Rachel.
- During the second Media Fill Process that occurred on 8/16/2021, I allowed Rachel to perform the sampling procedures while I observed her.

Acknowledgement of understanding new procedures:
Rachel Crawford Date: 8/18/21

Trainer Signature to verify that trainee has demonstrated appropriate sampling technique and has good understanding of reasoning behind specific sampling practices.
Haleigh Wilkes Date: 8/18/21

Attachment 2

Standard Operating Procedure

Eagle Pharmacy	SOP CODE: P2.18.7	REVISION NUMBER: 7
	ISSUE DATE: August 17, 2021	
	IMPLEMENTATION DATE: August 18, 2021	

TITLE : Standard Operating Procedures for the Controlled Compounding Areas

DRAFTED BY:	**SIGNATORY:**	**Haleigh Wilkes**	Haleigh Wilkes SIGNATURE	8/17/21 DATE
☐ n/a	**TITLE:**	**Quality Control Manager**		
APPROVED BY:	**SIGNATORY:**	Zahir Hamid	SIGNATURE	8/17/21 DATE
	TITLE:	General Manager		

RELATED LOGS & FORMS

TYPE OF RECORD	FREQUENCY OF USE	Attachment Number	SPECIFICATION / DESCRIPTION

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE

Attachment 3

RESPONSIBILITIES

1. It is the responsibility of all compounding personnel to follow the Standard Operating Procedures (SOPs) for the controlled compounding environments set forth in this policy
2. It is the responsibility of the Pharmacy General Manager and Quality Control Manager to ensure that all compounding personnel are adequately trained in the SOPs.
3. It is the responsibility of the Pharmacy General Manager and Quality Control Manager to ensure that all compounding personnel correctly adhere to all SOPs for the controlled compounding environments.

PURPOSE

1. This policy describes the Standard Operating procedures for the controlled compounding Environments at Eagle Pharmacy.

SCOPE

1. This SOP applies to all personnel at Eagle engaged in aseptic processing of sterile drug products (SDPs).

DEFINITIONS

1. APS: Aseptic Process Simulation
2. FD&C: Federal Food, Drug, and Cosmetic Act
3. IPA: Isopropyl Alcohol

4. ISO: International Organization for Standardization
5. N/A: Not Applicable
6. PEC: Primary Engineering Control
7. SDP: Sterile Drug Product
8. SOP: Standard Operating Procedure
9. USP-NF: United States Pharmacopeia – National Formulary
10. Anteroom: An ISO Class 8 or better transition area between the non-sterile compounding area and the aseptic processing area in which sterile gowning occurs.
11. Aseptic Processing Area: An ISO Class 7 or better area containing Primary Engineering Controls (PECs).

SPECIAL CIRCUMSTANCE

1. Not Applicable

PROCEDURE

1. **Personnel**
   a. Compounded sterile products will be prepared either by a pharmacist or pharmacy technician under the supervision of a pharmacist.
   b. Personnel with weeping or shedding rashes, peeling sunburn, weeping sores, conjunctivitis, and active respiratory infections accompanied by fever, excessive coughing, sneezing, or runny nose will not prepare compounded sterile products or enter the compounding areas for any reason.
   c. Personnel preparing to enter any ISO Classified room shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of compounding garb.
   d. Personnel entering the Ante Room shall don attire and perform hand washing as described in the Personnel Cleansing and Garbing Policy (P2.01).

2. **Controlled Environments**
   a. Access to the controlled compounding areas is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.
   b. Traffic flow in and out of the Clean Room and Lab areas shall be minimized.
   c. Traffic in the area of the direct compounding environment is minimized and controlled.
   d. Certification of ISO Classified Rooms and Laminar Airflow Workbenches shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.
      i. HEPA filters and prefilters will be changed based on biannual evaluations performed during certification activities.
   e. Upon entering the Entry Room, all personnel must immediately don hair covers and put on Clean Room Designated Shoes. Prior to entering the Lab or Clean Room, garbing requirements set forth in Policy 2.01.2 Personnel Cleansing and Garbing.
   f. When performing sterile compounding operations in the Vial Filling Room, a minimum of 3 trained personnel are necessary to perform all required process (this includes the quality personnel performing environmental monitoring). A minimum of 3 trained personnel are

Attachment 3

necessary to perform sterile compounding operations in the Manual Filling Room, including the quality personnel performing the environmental monitoring. Additionally, the number of people in the clean room during sterile compounding operations should not exceed five.

g. Staging of Supplies Used in Compounding
   i. All supplies are removed from their shipping cartons prior to being brought into Compounding Supplies Storage Room.
   ii. The supplies are then decontaminated by wiping with Steri-Perox 6% wipes while they are being transferred to a clean and properly disinfected cart or area prior to being transferred into the Ante Room.
   iii. Passing Items from Ante Room into Lab
      1. Sterile water bags are removed from their outer wrapping as they are transferred into the Lab thru the pass thru window in the Ante Room. When transferring the sterile water bags from the pass thu window, they are sprayed with sterile 70% IPA prior to placing them on their storage shelf.
      2. The outermost bag of the sterile vials is removed prior to placing them in the pass thru for transfer into the Lab. As vial trays are transferred into the lab, each bag will be sprayed with sterile 70% IPA prior to placing them onto a cart.
      3. The outermost bag of the sterile stoppers is removed as they are placed in the pass thru window to the Lab. As the stopper bags are transferred into the Lab, each bag will be sprayed with sterile 70% IPA prior to placing them onto a cart.
      4. The outermost bag of sterile cleaners will be removed as it is placed into the pass thru window to the Lab. As the cleaners are transferred into the Lab they will be sprayed with sterile 70% IPA prior to being placed on storage shelves.
      5. Bagged items of compounding supplies will be sprayed with 70% IPA as they are placed in the pass thru window to the Lab. When transferring these items to the Lab they will be sprayed again with sterile 70% IPA prior to being place in storage location.
      6. All supply bins will be wiped with sterile 70% IPA prior to placing it in the pass thru window to the lab. When transferring the bins into the Lab they will be sprayed with 70% IPA prior to placing on shelves in the Lab or being transferred into the Clean Room.
      7. API containers will be wiped with sterile 70% IPA wipes prior to being placed in the pass thru window to the Lab. As they are being transferred into the Lab they will be wiped again using a sterile 70% IPA wipe.
      8. Double-wrapped depyrogenated beakers (for use in Lab) will be removed from the Depyrogenation oven in the Ante room, outer layer of aluminum foil removed, then transferred into the Lab thru the pass thru window.
      9. Triple-wrapped depyrogenated beakers (for use in the Clean Room) will be removed from the depyrogenation oven in the Ante Room, outer layer of foil removed, then transferred to the Lab.
   iv. Passing Items from the Lab to the Clean Rooms (Manual Room or Vial Filling Machine Room)
      1. Vial tray outermost bag will be cut off prior to placing into the pass thru to the Clean Room. As the bagged vial trays are transferred from the pass thru into the

Attachment 3

Clean Room they are sprayed with 70% IPA prior to being placed on a shelf in the Clean Room.

2. The outer most bag of the stoppers will be cut off prior to placing in the pass thru to the Clean Room. As the stoppers are transferred from the pass thru into the Clean Room, they are sprayed with 70% IPA prior to being placed on a shelf in the Clean Room.
3. All supply bins will be wiped with sterile 70% IPA prior to putting them into the pass thru window to the Clean Room. When transferring the bins into the clean room, they will be wiped or sprayed with sterile 70% IPA.
4. Bags containing sterile compounding supplies will be wiped with sterile 70% IPA wipes prior to being placed into the pass thru window to the Clean Room. When transferring these bags into the Clean Room they will be sprayed with sterile 70% IPA prior to being placed on storage shelves.
5. The 10 L depyrogenated beaker will have its 2nd layer of aluminum foil removed prior to passing it into the Clean Room. The last layer of foil is removed as it is being placed into the LAFWA.
6. The outside of the beakers containing non-sterile solutions of drug product will be wiped with a sterile 70% IPA wipe prior to being placed into the pass thru window into the Clean Room. The beakers are then transferred directly into the LAFWA.
7. The sterile bags containing the sterilized stopper bowl and vial tray rake will be wiped with sterile 70% IPA wipes prior to being put in the pass thru window to the Clean Room. As they are transferred into the Clean Room their bags will be sprayed with sterile 70% IPA.
8. Sterile disinfectants will have their final bag removed as they are being transferred into the Clean Room.

h. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the Ante Room.
i. Carts used to bring supplies from the storeroom cannot be rolled beyond the Entry Room. Carts used in the Lab and Clean Room must remain in these areas. If they are moved to a lesser ISO Classification, they must be recleaned prior to being brought back in.
j. Supplies required for the scheduled operations of the shift may be stored in the Lab and Clean Rooms.
k. Supplies that are required for back-up or general support of operations may be stored on designated shelving in the Clean Room and Lab, but excessive amounts of supplies are to be avoided.
l. Nonessential objects that shed particles shall not be brought into the Clean Room, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).
m. Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the Clean Room or Lab.
n. Chewing gum, drinks, candy, or food items shall not be brought into the controlled compounding areas (e.g., Ante Room, Lab, Vestibule, or Clean Room).

Attachment 3

o. Primary engineering controls shall be operated continuously. If for some reason a LAFH is turned off, it must be turn on and allowed to run for 1 hour prior to cleaning it and using it for compounding activities.
p. The pass thru windows should remain closed when not in use.
q. Cell phones, headphones, or other listening devices will not be permitted in ISO Classified areas.
r. Compounding worksheets used in medication preparation must be placed in a plastic sleeve and wiped down prior to being brought into the Lab. If the worksheet must be removed from the sleeve for purposes of recording information during the mixing process, it must be set on top of the plastic sleeve rather than directly on the tables in the Lab. If the worksheet must be taken back out of the Lab for checking purposes, then it must be put back in the plastic sleeve and re-sanitized prior to it going back in the Lab.

3. **Sterile Compounding Work Practices**
   a. At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are cleaned with sterile 70% isopropyl alcohol using a sterile non-shedding wipe.
   b. Supplies used in the direct compounding area for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% isopropyl alcohol or removing the outer wrap at the edge of the direct compounding area as the item is introduced into the aseptic work area.
   c. All supply items are arranged in the direct compounding area as to reduce clutter and provide maximum efficiency and order for the flow of work.
   d. After proper introduction into the direct compounding area of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures.
      i. No objects may be placed between the first air from the HEPA filters and an exposed critical site.
   e. All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with sterile 70% isopropyl alcohol.
   f. Calibration of the volume dispensed is specific to each batch produced and will be done immediately prior to beginning vial filling. Calibrations of dispense volume, as well as calibration re-checks will be performed using a graduated vial of appropriate size in relation to the required dispense volume.
   g. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the direct compounding area to minimize the risk of introducing contamination into the aseptic workspace.
   h. All batches will be complete (from mixing to sealed final product container) within one shift.
   i. If there is a loss of power or room pressurization during batch production, the entire batch will be discarded, and no production will occur in the rooms until normal operating conditions are restored and a complete clean down of the room is completed.
   j. For suspensions that are steam sterilized in beakers, the opening of the beaker will be wrapped with a single layer of autoclave paper and sealed with 3 rows of autoclave tape. The method will be consistent with each suspension processed in this manner, and compounding staff will be trained on this process and verified on their competency during APS validations.

Attachment 5

k. During the compounding process, if a pack of sterile vials is opened and found to have a shattered/crushed vial, the entire tray of vials will be discarded and not used during the compounding process. This is due to the fact that glass fragments from the shattered vial(s) may have come into contact with other vials in the tray.

l. During the compounding process, if a pack of sterile vials is opened and has vials that have been knocked over in the tray, these vials are to be left that way and not used during the filling process. Compounding staff is not to try and stand the vials back up for risk of contaminating other vials in the tray.

4. **Beyond Use Dates (BUDs)**

a. All Supplies autoclaved by Eagle Pharmacy in autoclave pouches will be assigned a 30-day sterile beyond use date (BUD).
   i. Once autoclaving is complete the exterior of the pouches will be labeled with the date autoclaved, the initials of the person who autoclaved the supplies, and the 30-day BUD.

b. All pharmaceutical ingredients used in the compounding of sterile drug products will be assigned a 1-year BUD upon initially opening the ingredient, unless the manufacturer assigned expiration date is shorter.
   i. Upon opening the pharmaceutical ingredient, the lid or label of the container will be initialed by the compounding personnel and notated with the date opened. Additionally, the BUD date will also be written on the lid/label – either 1 year from the date opened or the manufacturer expiration date, whichever is shorter.
   ii. After this 1-year BUD, the ingredients may no longer be used in compounding.

c. The BUD of sterile compounded drug products will be based on drug stability testing. The BUD cannot exceed the manufacturer provided expiration date of any of the product's active and inactive ingredients.

d. The manufacturer provided expiration date on the following items is considered a "sterile by date" and these items must be used prior to this date (this date is not a factor for determining the final BUD of a sterile compounded product):
   i. Sterile Water for Injection
   ii. Sterile Vials
   iii. Sterile Stoppers

e. All sterile compounding supplies received from the manufacturer that lack a supplier expiration date will be assigned a 2-year BUD.

f. All depyrogenated supplies which remain in a double layer of aluminum foil stored in the Lab will be assigned a beyond-use date of 30 days.

Attachment 3

Eagle Pharmacy	SOP CODE: P2.18.7	REVISION NUMBER: 7
	ISSUE DATE: August 17, 2021	
	IMPLEMENTATION DATE: August 18, 2021	

TITLE : Standard Operating Procedures for the Controlled Compounding Areas

REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION
1	04/27/15	8/7/16	
2	8/8/16	01/10/17	Added section on Beyond Use Dating
3	01/10/17	10/06/19	Added beyond use date for depyrogenated supplies
4	10/07/19	12/08/19	Clarified cleaning instruction on bringing supplies to Anteroom
5	12/09/19	08/23/20	Clarified BUD practices for ingredients used in sterile compounding. Clarified the wrapping of beakers during steam sterilization.
6	08/24/20	08/17/21	Added information regarding the certification of Controlled environments
7	08/18/21		Clarified the staging procedures for bringing supplies into the classified areas

Attachment 3

REFERENCES

ID	Document Title	Document Number	Author	Approval Date
	Pharmaceutical Compounding, Sterile Preparations	Chapter 797	USP-NF	Annual
	Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice		FDA	2004

Retraining of Compounding Personnel on the Staging of Supplies Entering the ISO Areas

Date of Training: 8/17/2021
Trainer: Haleigh Wilkes, Quality Control Manager
Trainees: All personnel who perform functions in ISO Classified Rooms
Dana Epps, Lead Sterile Compounding Technician
Jamie Latham, Sterile Compounding Technician
Kimberly Oliver, Sterile Compounding Technician
David Cole, Sterile Processing Technician
Rachel Crawford, Quality Control Technician

Training Documents:
Standard Operating Procedures for the Controlled Compounding Areas P2.18.7
Staging of Compounding Supplies Reference

Training Overview:
Reviewed Policy 2.18.7; Provide all personnel a copy of this policy for review
Provided all personnel a copy of the Staging of Compounding Supplies Reference

Discussed the staging for each item type that would be taken into the ISO Rooms and explained the reasoning for each process.

I observed these practices over the period of 8/17/21 to 8/20/21 to ensure understanding and compliance with practices.

Personnel Statements of Training and Understanding: I, (undersigned), have received the above mentioned training documents and understand all procedures for the staging of supplies that are to enter ISO Classified Environments.

Name	Signature	Date
Rachel Crawford	Rachel Crawford	8/20/21
Jamie Payton	Jamie Payton	8/20/21
David D. Cole III	David D. Cole III	8-20-21
Kim Oliver	Kim Oliver	8/20/21
Dana Epps	Dana Epps	8/20/21

I, Haleigh Wilkes, Quality Control Manager, have observed the above employees performing the staging of compounding supplies as they are being passed into the ISO Classified Rooms from 8/17/21 to 8/20/21. Each employee listed above has demonstrated proper procedures for cleaning and sanitizing items as they are being transferred into the ISO Classified Areas.

Haleigh Wilkes 8/20/21

Attachment 4

Staging of Compounding Supplies Reference

General Pharmacy Area
All supplies are removed from their shipping cartons prior to storage in the Compounding Supply Storage Room. When supplies are needed for compounding, they are first wiped down using a Steri-Perox 6% wipe and then placed on a cleaned cart indicated they are ready to be passed into the Ante Room.

Passing from Ante Room into Lab	
Sterile Water Bags	Remove the overwrap as they are placed into the Pass Thru Window to the Lab. Spray with sterile 70% IPA when transferring from Pass Thru Window to storage shelf in Lab.
Sterile Vials (Quadruple Bagged)	Cut off the outermost bag of the vials as they are placed into the Pass Thru Window to the Lab. Spray with sterile 70% IPA when transferring from the Pass Thru Window to a cart in the Lab
Sterile Stoppers (Quadruple Bagged)	Cut off the outermost bag of the stoppers as they are placed into the Pass Thru window to the Lab. Spray with sterile 70% IPA when transferring from Pass Thru Window to a cart in the Lab.
Sterile Disinfectants	Remove the outermost bag of the disinfectant bottles as they are placed into the Pass Thru Window to the Lab. Spray with sterile 70% IPA when transferring from the Pass Thru Window to storage shelf in the Lab
Bagged Compounding Supplies	Spray bag with sterile 70% IPA as they are placed into Pass Thru Window. Spray again with sterile 70% IPA as they are being transferred from the Pass Thru to storage shelving in the Lab.
Supply Bins	Wipe with sterile 70% IPA as they are placed into Pass Thru Window to Lab. Wipe again with sterile 70% IPA as they are transferred from the Pass Thru Window into the Lab
API containers	Wipe with sterile 70% IPA as they are placed into the Pass Thru Window to Lab. Wipe again with sterile 70% IPA as they are transferred from the Pass Thru to storage shelving in the Lab.
Depyrogenated Beakers	• Beakers for use in the Lab are Double wrapped. Remove from depyrogenation oven and remove outer wrap when placing into Pass Thru to Lab. Beakers are immediately transferred to storage shelving in the Lab • Beakers for use in the Clean Room are Triple Wrapped. Remove from the depyrogenation oven and remove outer wrap when placing into Pass Thru to Lab. Transfer beaker into Lab and immediately remove the 2nd wrap and transfer into the Clean Room (These beakers are to be stored in ISO 5 Environment)

Passing from Lab into Clean Room	
Sterile Vials (Quadruple Bagged)	Cut off the outermost bag of the vials as they are placed into the Pass Thru Window to the Clean Room. Spray with sterile 70% IPA when transferring from the Pass Thru Window to shelf in Clean Room.
Sterile Stoppers (Quadruple Bagged)	Cut off the outermost bag of the stoppers as they are placed into the Pass Thru window to the Clean Room. Spray with sterile 70% IPA when transferring from Pass Thru Window to a shelf in Clean Room.
Sterile Disinfectants	Remove the final bag of the disinfectant bottles as they are transferred to the Clean Room.
Bagged Compounding Supplies	Wipe bag with sterile 70% IPA as they are placed into Pass Thru Window. Spray with sterile 70% IPA as they are being transferred from the Pass Thru to storage shelving in the Clean Room.
Supply Bins	Wipe with sterile 70% IPA as they are placed into Pass Thru Window to Clean Room. Wipe again with sterile 70% IPA as they are transferred from the Pass Thru Window into the Clean Room
Sterile Stopper Bowl and Vial Tray Rake	Wipe the bag with sterile 70% IPA wipe and place into Pass Thru Window to Clean Room. As they are being transferred from Pass Thru into Clean Room, mist with 70% IPA.
Depyrogenated Beakers	• Once in the Lab, remove the 2nd layer of foil and immediately transfer the beaker into the Clean Room (These beakers are to be stored in ISO 5 Environment)

Attachment 4

Investigative Report – Out of Specification (Equipment)

Report ID: 001
Equipment ID: Vial Filling Machine

Date of Findings: 08/31/2021
Date Investigation Initiated: 08/31/2021
Date Investigation Completed: 08/31/2021
Person(s) Performing Investigation: Jeff Gloyer, Principal Engineer, Eagle Analytical

Statement of Findings:
Within the critical area of the Vial Filling Machine, there was turbulent airflow over the filling needle. Investigation determined that turbulent airflow caused by lack of airflow egress. Air could not flow out of the machine, causing it to push back against incoming air, causing eddy currents. Access doors were removed from both sides of the equipment to allow air to flow out of the machine. After the doors were removed, airflow characteristics improved significantly, allowing for laminar flow over the critical area.

Expected Results:
Airflow within the critical area of the Vial Filling Machine is unidirectional with sweeping action over and away from the product under dynamic conditions.

Actual Results:
Airflow within the critical area of the Vial Filling Machine is turbulent under dynamic conditions.

Investigation:
Smoke was introduced above the critical area to determine if the airflow was laminar over the critical area. Multiple air eddy currents were observed demonstrating turbulent airflow over the filling needle. Very little of the smoke seemed to be exiting the machine, instead staying inside the PEC, and interrupting the incoming airflow. Side doors were opened to simulate interventions into the PEC. While the side door was opened, smoke demonstrated airflow was becoming less turbulent. Due to this observation, both doors were then opened simultaneously to smooth out the airflow even more. While both doors were open, airflow over the critical area demonstrated sustained unidirectional airflow over the critical area.

Corrective/Preventative Action:
Both of the side doors to the Vial Filling Machine were permanently removed from the equipment.

Follow-Up to Test New Process and Confirm Resolution of Identified Problem:
A smoke study was performed under dynamic operating conditions to demonstrate that the equipment is now capable of providing unidirectional airflow under the worst case scenario.

Written by:
Jeff Gloyer, Principal Engineer, Eagle Analytical
08/31/2021

Reviewed/Approved By:

Haleigh Wilkes, Quality Manager
Haleigh Wilkes 8/31/21

Attachment 5

Zahir Hamid, Operations Manager (Sterile Compounding)

Attachment 5

EAGLE SCIENCE-BASED SOLUTIONS	QUALITY SYSTEM	EQUIPMENT
	DOCUMENT #: 3.700.20.F3	LEVEL: 3
	Effective Date: 12/10/2020	Revision #: 00
TITLE: Summary Report		Page 1 of 4

Summary Information	
Organization Name	Eagle Pharmacy
Site Location	2200 Riverchase Center #675, Hoover, AL 35244
Report Title	Summary Report of Smoke Study
Report Number	REP-21035
Revision Number	0.0

Attachment 6

Document Approval			
Department	**Name**	**Signature**	**Date**
Engineering *(Written By)*	Jeff Gloyer		08/31/2021
SME or System Owner *(Reviewed By)*	Zahir Hamid		8/31/21
Quality Unit *(Approved By)*	Haleigh Wilkes	Haleigh Wilkes	8/31/21

1. Objective

The objective of this summary report is to summarize the results obtained while executing the Smoke Study Protocol (PR-21035) at Eagle Pharmacy.

2. Executive Summary

The purpose of smoke studies is to demonstrate that airflow patterns within the critical areas minimize the risk of contamination, as outlined in FDA's *Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* and 21 CFR Part 211. The smoke study was performed successfully with no deviations.

3. Test Result:

A comprehensive summary is provided in Table 1: *Summary of Test Results*. More extensive summaries of the results obtained while executing the tests described in the protocol are provided in sections 3.1 through 3.7.

Attachment 6

Table 1: Summary of Test Results		
Test Function	**Results**	**Appendix**
Smoke Study	PASS	F

3.1. Appendix A – Identification of Executors and Training

Personnel involved in the execution of the protocol were trained on its content prior to engaging in protocol activities. A training record was attached to Appendix A. Personnel recorded their name, department, signature, initials, and date on the form in Appendix A verifying that they have been trained on the protocol.

3.2. Appendix B – Pre-Requisites Verification

There were no prerequisites to verify for this protocol.

3.3. Appendix C – Test Equipment Identification

Test equipment utilized during the execution of the protocol were documented and verified. Calibration statuses and certification were not required as smoke machines cannot be calibrated.

3.4. Appendix D – Qualification Deviation Log

There were no deviations that occurred during the execution of this protocol.

3.5. Appendix E – Qualification Deviation Form

There were no deviations that occurred during the execution of this protocol.

3.6. Appendix F – Smoke Study

A smoke study was performed under dynamic conditions on the Vial Filling Machine and the Laminar Airflow Workbench in the Vial Filling Room. The smoke tests are performed to demonstrate that the equipment is capable of maintaining unidirectional airflow and sweeping action over and away from the product under dynamic conditions. Dynamic conditions indicate a simulation of operation for the largest batch size. Sterile product is drawn from inside a beaker on the Laminar Airflow Workbench. It is then pumped into the Vial Filling Machine where the vial is filled, stoppered, capped, and crimped in an automated process.

Laminar Airflow Workbench

The smoke generator was positioned roughly six (6) inches from the face of the HEPA filter, in front of the technician preparing the sterile tubing that will be used in production. The smoke generator was positioned to demonstrate airflow over the critical area during the production activities. The sterile tubing was placed inside the beaker, under the protective covering. Smoke airflow patterns were observed to be unidirectional throughout the process. See video "*Vial Filling Room – LAFW Dynamic*"

Attachment 6

Vial Filling Machine

The smoke generator was positions roughly six (6) inches below the face of the HEPA filter, directly over the critical area where the vials are filled. The 1st technician connected the sterile tubing to the filling needle and then placed the filling needle into the equipment. The 2nd technician then loaded the vials into the equipment, which are then automatically taken towards the filling area. As the vial filling process began, the 2nd technician simulated an intervention of filling the stopper bowl with stoppers. The 1st technician then simulated an intervention of filling the cap bowl with caps. While the automated process was continuing, interventions into the room and the PEC were then simulated. Each simulated intervention was audibly spoken into the camera to demonstrate which intervention was occurring. The pass-through into the room was opened, the door to the room was opened, the small door to the Vial Filling Machine was opened, and then the large door to the Vial Filling Machine was opened. Throughout the entire process, the equipment demonstrated unidirectional airflow over the critical area to include all simulated interventions. See Video, "*Vial Filling Machine – Dynamic*".

3.7. Appendix L – Appendix Index

The appendices generated during the execution of the protocol and the corresponding number of pages were recorded

4. Success or Failure Statement:

The smoke study of the Vial Filling Machine was a success. The Smoke Study meets all acceptance criteria as defined by equipment manufacturer and relevant regulations.

5. Conclusions:

The smoke study on the Vial Filling Machine passed by demonstrating unidirectional airflow and sweeping action over and away from the product under dynamic conditions. The equipment is fit for use in production.

Attachment 6

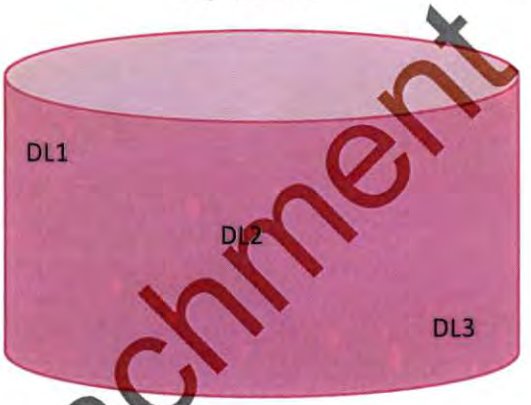
Load Pattern Configuration for Terminal Sterilization

A Max Load configuration of 952 vials will be tested to verify and document that the required biological kill can be achieved with this configuration. The vials will be arranged as follows: 476 vials in each of two baskets, in 3 single rows of upright vials, with 169 vials on the bottom layer, 169 vials on the middle layer, and 138 vials on the top layer. Biological indicators and data loggers will be placed in each row in a diagonal pattern, and in the cold spot (as determined in the OQ) per the diagram below (Diagram 1). Diagram 2 shows photos of the Top and Bottom Basket Vial Load Pattern with the data loggers in their locations. Diagram 3 shows how the baskets are placed in the autoclave for sterilization.

Diagram 1

DL = Data Logger
CS = Cold Spot

Top Basket



Attachment 7

Bottom Basket

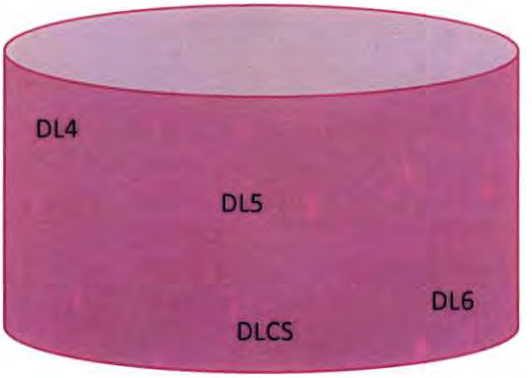
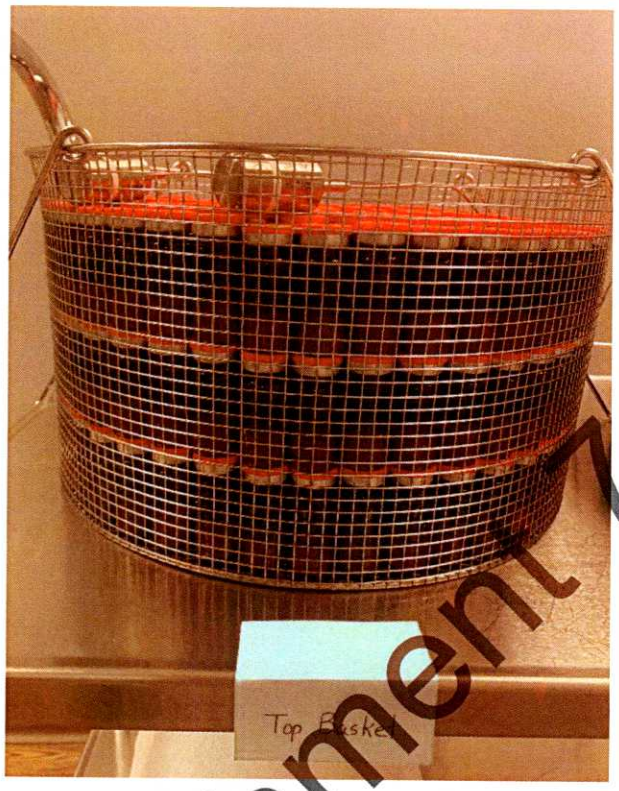
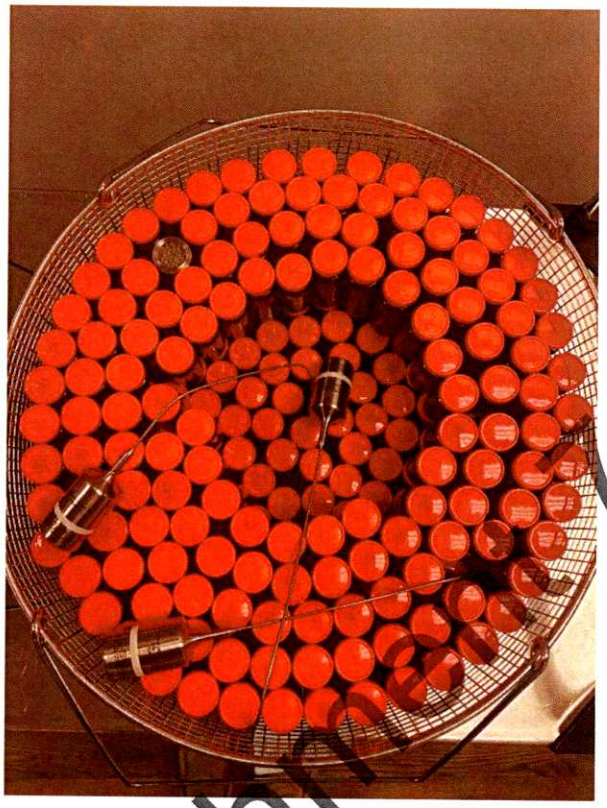


Diagram 3 (Top Basket Configuration)



Attachment 7

Diagram 2 (Bottom Basket)



Attachment 1

Diagram 3

NS Weekly Surface Sampling Form (P2.15-A3)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		S1	TSA with Neutralizers		NA					
		S2	TSA with Neutralizers		NA					
		S3	TSA with Neutralizers		NA					
		S4	TSA with Neutralizers		NA					
		S5	TSA with Neutralizers		NA					
		S6	TSA with Neutralizers		NA					
		S7	TSA with Neutralizers		NA					
		S8	TSA with Neutralizers		NA					
		S9	TSA with Neutralizers		NA					
		S10	TSA with Neutralizers		NA					
		S11	TSA with Neutralizers		NA					
		S12	TSA with Neutralizers		NA					
		S13	TSA with Neutralizers		NA					
		S14	TSA with Neutralizers		NA					
		S15	TSA with Neutralizers		NA					
		S16	TSA with Neutralizers		NA					
		S17	TSA with Neutralizers		NA					
		S18	TSA with Neutralizers		NA					
		S19	TSA with Neutralizers		NA					
		S20	TSA with Neutralizers		NA					
		S21	TSA with Neutralizers		NA					
		S22	TSA with Neutralizers		NA					
		S23	TSA with Neutralizers		NA					

Attachment 8

NS Weekly Viable Air Sampling Form (P2.15-A4)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000

Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		V1	TSA		NA					
		V2	TSA		NA					
		V3	TSA		NA					
		V4	TSA		NA					
		V5	TSA		NA					
		P1	TSA		NA					
		P2	TSA		NA					
		P3	TSA		NA					
		P4	TSA		NA					

P = Pass F = Fail

Attachment 8

Personnel Monitoring Form (P2.14-A1)

Date/Time Inserted into INC001: 00/00/0000 @ 0000
Date/Time Removed from INC001: 00/00/0000 @ 0000
Date/Time Inserted into INC003/INC004: 00/00/0000 @ 0000
Date/Time Removed from INC003/INC004: 00/00/0000 @ 0000

Sampler Initials	Sample Date	Compounding Personnel Initials	Post-Gowning or Post Process	Sampling Site	Plate Type	Plate Lot# Exp. Date	SDP or APS Lot #	Total CFU count	Result (Pass/Fail)	Verifier Initials	Investigation No.	Comments
				RH	TSA w/Neut							
				LH	TSA w/Neut							
				RF or LF	TSA w/Neut							
				Chest	TSA w/Neut							
				Face Mask	TSA w/Neut							

RH = Right Hand
LH = Left Hand
RF = Right Forearm
LF = Left Forearm
P = Pass
F = Fail

Attachment 8

Machine Batch Viable Air Sampling Form (P2.15-A2)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000

Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		V6	TSA							Area in LAFWA where sterile product is manipulated
		V7	TSA							Area directly in front of LAFW where sterile compounder is working
		V8	TSA							Area where sterile compounder loads tubing in filling machine
		V9	TSA							Areal where sterile compounder loads stoppers into filling machine
		V10	TSA							Area in filling machine where product is filled into vials
		V11	TSA							Area in filling machine where stoppers are inserted int vials
		P5	TSA							Area of LAFWA directly between the compounding line and HEPA filter

P = Pass F = Fail

Attachment 8

Machine Batch Surface Sampling Form (P2.15-A1)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000

Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		S36	TSA with Neutralizers							Left Center of LAFWA
		S37	TSA with Neutralizers							Rigt Center of LAFWA
		S38	TSA with Neutralizers							Vial Rake Surface
		S39	TSA with Neutralizers							Big Stopper Door Handle
		S40	TSA with Neutralizers							Small Stopper Door Handle
		S41	TSA with Neutralizers							Large Crimp Cap Door Handle
		S42	TSA with Neutralizers							Small Crimp Cap Door Handle
		S43	TSA with Neutralizers							Handle to Pass Thru
		S44	TSA with Neutralizers							Floor in front of entry door to room
		SB	TSA with Neutralizers							Stopper Bowl
		FN	TSA with Neutralizers							Filling Nozzle: Sampling only conducted on filling of sterile batches

P = Pass F = Fail

Attachment 8

Manual Batch Surface Sampling Form (P2.15-A1)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000

Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		S45	TSA with Neutralizers							Left center of LAFW1
		S46	TSA with Neutralizers							Right center of LAFW1
		S47	TSA with Neutralizers							Left center of LAFW2
		S48	TSA with Neutralizers							Right center of LAFW2
		S49	TSA with Neutralizers							Handle of Pass Thru to Ante Room
		S50	TSA with Neutralizers							Handle of Pass Thru to Lab
		S51	TSA with Neutralizers							Floor directly upon entering Manual Room

P = Pass F = Fail

Attachment 8

Manual Batch Viable Air Sampling Form (P2.15-A2)

Incubation Insertion date and time into INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC001 @ 30C to 35C for 2-3 days: 00/00/0000 @ 0000

Incubation Insertion date and time into INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000
Incubation Removal date and time from INC003/INC004 @ 20C to 25C for 5-7 days: 00/00/0000 @ 0000

Sampler Initials	Sampling Date	Sample ID	Plate Type	Plate Lot# and Exp	Batch Lot #	CFU	Result (Pass/Fail)	Investigation No (N/A or Number)	Verifier Initials	Comments
		V12	TSA							Area in LAFW1 wehre sterile product is manipulated
		V13	TSA							Area in LAFW2 where sterile product is manipulated
		V14	TSA							Area directly in front of LAFW1
		V15	TSA							Area directly in front of LAFW2
		P6	TSA							Area of LAFW1 directly between the compounding line and HEPA filter
		P7	TSA							Area of LAFW2 directly between the compounding line and HEPA filter

P = Pass F = Fail

Attachment 8

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	Label: _____ Initial/date
Lot #:	

Record Preparer: _____ **Date:** _____ **Signature:** _____

Signature Log (all personnel involved in the compounding process)

Print Name	Sign Name	Initials	Date

Raw Materials (Must be verified by a pharmacist)

Description	Manufacturer	Lot Number	Expiration Date	Verifier
Methylprednisolone Acetate, USP				
Base B (Polyglycol 3350), NF				
Sodium Phosphate, Monobasic, USP				
Sodium Phosphate Dried Dibasic, USP				
Sodium Chloride Granular, USP				
Polysorbate 80, NF				
Benzyl Alcohol, NF				
Sterile Water for Injection, USP				

Confirmation of Product (Must be verified by a pharmacist)

Step Description	Verified by/Date

Attachment 9

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

Confirm the product and batch number information for this batch: a. Product made: Methylprednisolone Acetate 80 mg/mL b. Verification of correct lot number:_____ c. Verification of the accuracy of all associated labels: _____ d. Target range of units to produce: 857-952 e. Target fill volume per unit: 10.5 mL	

Container Closure Components (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Stoppers				
Crimp Seals				

Consumables (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Filling Nozzle				
Syringes		Pre-sterilized		
Tubing		Pre-sterilized		
Sterile Vials				

Pre-Filters/Filter Connectors Used

Sterile Garb (Must be verified by a pharmacist)

Description	Lot Number	Exp. Date	Verifier init.
Sterile Gloves			
Sterile Coveralls			
Sterile Hood with Attached Mask			
Sterile Boot Covers			
Sterile Goggles			

Utensils (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Scoops				
Forceps				

Attachment O

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

1L Beaker				
5L Beaker				
10L Beaker				
Stainless Steel Beaker Cover				
Stir Bars				
Homogenizing Wand				
Stopper Bowl				
Rake				

Equipment & Instruments (Must be verified by a pharmacist) – Filled in Vial Machine Filling Room

Description	Calibration Date	Person Performing Calibration	Equipment Cleaned Prior to Use *Cleaned with sterile 70% IPA	Verifier init.
Electronic Balance				
Powder Containment Hood (PCH003)		ENV		
Powder Containment Hood (PCH004)		ENV		
Non-Viable Air Sampler (NVAS____)		Airy Technology		
Viable Air Sampler (VAS____)				
Laminar Airflow Work Area		ENV		
Machine calibrated to dispense: 10.5 mL				

Attachment Q

pH Testing (Must be verified by a pharmacist)

Step Description	Performed by/Date	Verified by/ Date
pH buffer 4 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ pH buffer 7 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ Final pH of product:_____ (Desired Range: 3.5 – 7.0)		

Autoclave Process (See Attached Data Log)

Autoclave ID	Calibration Date	Verified by/Date

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Liquid (45 min);121°C;15 PSI		

Timing of Process	**Documented By:**
Start time of Autoclave Process: Date: _____ Time: _____ Completion of Autoclave Process: Date: _____ Time: _____	

Autoclave Process (See Attached Data Log)

Autoclave ID	**Calibration Date**	**Verified by/Date**
Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Liquid (45 min);121°C;15 PSI		

Timing of Process	**Documented By:**
Start time of Autoclave Process: Date: _____ Time: _____ Completion of Autoclave Process: Date: _____ Time: _____	

Attachment 9

Aseptic Filling Process

Timing of Process	**Documented by/ Date**
Start time of Aseptic Filling Process: Date:_____Time:_____	
Completion of Aseptic Filling Process: Date:_____Time:_____	

Verification of Functioning ISO Class 5

Pressure Verification (Pressure reading must be greater than 0.02)	**Performed by/ Date**
Pressure verified every 30 min during compounding process (see attached record)	

In-Process Interventions (See Attachment)

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date: _____ Location: _____ Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Attachment 9

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: _____ Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Sterile Processing Steps

Step Description	Performed by/ Date
1. Weighing of ingredients	
2. Verification of ingredient weight (pharmacist only)	
3. Mixing of ingredients	
4. Main Technician	
5. Helper Technician	

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

6. Auxiliary Technician	
7. Air Sampling	

Visual Inspection (Can only be performed by a pharmacist)

Step Description	Performed by/ Date
1. Verify that the visual inspection area is clear and free of any other product or labels.	
2. Ensure the total number of units received for visual inspection is equal to the total number of units filled. Number of units received: _____ (A)	
3. Number of units filled falls within the expected range for filled units (90-100%)	
4. Perform visual inspection on each unit for Critical, Major, and Minor defects as categorized in the table below.	

CRITICAL	Chipped Vials/Glass in Vials	
	Particulates in Vial	
	Cracked/Broken Vials	
	Missing Stopper	
	Discoloration or Cloudiness	
MAJOR	Uncrimped/partially crimped vials	
	Overfills / Underfills	
MINOR	Dents in Aluminum Seal	
	Scratches on Glass Vials	

5. Remove any units with critical or major defects from the batch Number of units removed: _____ (B)	
6. Number of units used for syringability test: _____ (C)	
7. Total Number of units to be included in final batch: Total number of units = (A) – (B) – (C) = _____	

Attachment 9

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

Vial Labeling

Vial Labeling Verification (To be initialed by the person who performs the function)	**Initial/ Date**
Labels are verified to match the product that you are labeling	
Lot number on label matches the lot number on product	
Compound date on label matches the compound date on the product	
Expiration date on label matches the expiration date of the product	
Vials are clean and free of drug residue prior to labeling	
Did any of the flip caps come off during labeling? If so, how many _____	
Did any vials break during labeling? If so, how many _____	
Vial Label Reconciliation (must be verified by a pharmacist)	
Total no. of labels printed: _____ (a + b) a. No. of labels printed initially for batch: _____ Initial: _____ Date: _____ b. No. of additional label printed if needed: _____ Initial: _____ Date: _____	
No. labels used on batch records: _____	
No. labels used for product labeling: _____	
No. labels deemed unusable: _____	
No. labels discarded (unusable + extra): _____	
Total no. labels printed is equal to (labels used + labels discarded: _____	

Attachment 9

Final Product Testing

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

Step Description	Performed by/ Date
No. of vials sent out for sterility/potency/endotoxin testing: _____ Date sent for testing: _____	
No. of vials sent out for particle size distribution testing: _____ Date sent for testing: _____	
After the testing period is complete, the lab will release all results. Date of Release: _____	
No. of units to be included in final batch available for dispensing. (#7 from above) – (no. of units sent for testing) = _____	

Batch Testing Results (attach all documentation forms) – must be verified by a pharmacist

Test	Pass/Fail	Verified by/ Date
Potency of Methylprednisolone Acetate falls within 90 – 110% of expected 80 mg/mL		
Potency of Benzyl Alcohol falls within 80-120% of expected 0.9% v/v		
Sterility (No Growth)		
Endotoxin Limit (Less than116.8 EU/mL)		
Viable Air Sampling Results (0 cfu/plate)		
Non-Viable Air Sampling Results (≤ 3,520 particles ≥ 0.5 um/m^3)		
Surface Sampling Results(0 cfu/plate)		
Personnel Sampling Results (0 cfu/plate)		
Particle Size Distribution: Average Mean Diameter (10-20 µm)		

Attachment 9

AQL Inspection at Batch Release (3% of Total Vial Count for Batch)

AQL # : _____ (Total # of vials in batch) **X 0.03 =** _____ (Number of vials to inspect prior to release)

Were any defects noted on AQL inspection (other than minor dents indicated in initial check)?	Yes/ No	Initial/Date:

Eagle Pharmacy **Batch Record – Methylprednisolone 80 mg/mL**	
Lot #:	

If applicable, list type and number of defects discovered:

Quality Manager to be notified of defects found during AQL inspection: _____
Quality Manager Signature

NOTE: Quality Manager to perform investigation (if applicable) and attach results to batch record

Attachment 9

Batch Record Review and Release (Must be performed by at least 1 pharmacist)

Reviewer	Signature	Date
1st Quality Check		
2nd Quality Check		

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	Label: _____ Initial/date
Lot #:	

Record Preparer: _____ **Date:** _____ **Signature:** _____

Signature Log (all personnel involved in the compounding process)

Print Name	Sign Name	Initials	Date

Raw Materials (Must be verified by a pharmacist)

Description	Manufacturer	Lot Number	Expiration Date	Verifier
Triamcinolone Acetonide, USP				
Sodium Chloride Granular, USP				
Carboxymethylcellulose (Medium Viscosity), USP				
Benzyl Alcohol, NF				
Polysorbate 80, NF				
Sterile Water for Injection, USP				

Attachment 10

Confirmation of Product (Must be verified by a pharmacist)

Step Description	Verified by/Date
Confirm the product and batch number information for this batch: a. Product made: Triamcinolone Acetonide 80 mg/mL b. Verification of correct lot number: _____ c. Verification of the accuracy of all associated labels: _____ d. Target range of units to produce: 857-952 e. Target fill volume per unit: 10.5 mL	

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Container Closure Components (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Stoppers				
Crimp Seals				

Consumables (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Filling Nozzle				
Syringes		Pre-sterilized		
Tubing		Pre-sterilized		
Sterile Vials				

Pre-Filters/Filter Connectors Used

Sterile Garb (Must be verified by a pharmacist)

Description	Lot Number	Exp. Date	Verifier init.
Sterile Gloves			
Sterile Coveralls			
Sterile Hood with Attached Mask			
Sterile Boot Covers			
Sterile Goggles			

Utensils (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Scoops				
Forceps				
10L Beaker				
Stainless Steel Beaker Cover				
Stir Rod				
Stir Bars				
Homogenizing Wand				
Stopper Bowl				
Rake				

Attachment 10

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Equipment & Instruments (Must be verified by a pharmacist) – Filled in the Vial Filling Machine Room

Description	Calibration Date	Person Performing Calibration	Equipment Cleaned Prior to Use *Cleaned with sterile 70% IPA	Verifier init.
Electronic Balance				
Powder Containment Hood (PCH003)		ENV		
Powder Containment Hood (PCH004)		ENV		
Non-Viable Air Sampler (NVAS____)		Airy Technology		
Viable Air Sampler (VAS____)				
Laminar Airflow Work Area		ENV		
Machine calibrated to dispense: 10.5 mL				

pH Testing (Must be verified by a pharmacist)

Step Description	Performed by/Date	Verified by/ Date
pH buffer 4 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ pH buffer 7 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ Final pH of product:_____ (Desired Range: 5.0 – 7.5)		

Attachment 10

Aseptic Filling Process

Timing of Process	Documented by/ Date
Start time of Aseptic Filling Process: Date:_____Time:_____	
Completion of Vial Stoppering: Date:_____Time:_____	

Verification of Functioning ISO Class 5

Pressure Verification (Pressure reading must be greater than 0.02)	Performed by/ Date
Pressure verified every 30 min during compounding process (see attached record)	

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

In-Process Interventions: See Attachment

Autoclave Process (See Attached Data Log)

Autoclave ID	Calibration Date	Performed by/Date
Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Normal (30 min)		

Timing of Process	Documented By:
Start time of Autoclave Process: Date: _____ Time: _____ Completion of Autoclave Process: Date: _____ Time: _____	

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: Top basket – cold spot Pass/Fail: _____ Location: Bottom basket - center Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Inside Vial Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: Center vial top basket Pass/Fail: _____ Location: Center vial bottom basket Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Attachment 10

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Sterile Processing Steps

Step Description	Performed by/ Date
1. Weighing of ingredients	
2. Verification of ingredient weight (pharmacist only)	
3. Mixing of ingredients	
4. Main Technician	
5. Helper Technician	
6. Auxiliary Technician	
7. Air Sampling	

Visual Inspection (Can only be performed by a pharmacist)

Step Description	Performed by/ Date
1. Verify that the visual inspection area is clear and free of any other product or labels.	
2. Ensure the total number of units received for visual inspection is equal to the total number of units filled. Number of units received: _____ (A)	
3. Number of units filled falls within the expected range for filled units (90-100%)	
4. Perform visual inspection on each unit for Critical, Major, and Minor defects as categorized in the table below.	

CRITICAL	Crimped Vials/Glass in Vials	
	Particulates in Vial	
	Cracked/Broken Vials	
	Missing Stopper	
	Discoloration or Cloudiness	
MAJOR	Uncrimped/partially crimped vials	
	Overfills / Underfills	
MINOR	Dents in Aluminum Seal	
	Scratches on Glass Vials	

5. Remove any units with critical or major defects from the batch Number of units removed: _____ (B)	
6. Number of units used for syringability test: _____ (C)	
7. Total Number of units to be included in final batch: Total number of units = (A) – (B) – (C) = _____	

Attachment 10

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Vial Labeling

Vial Labeling Verification (To be initialed by the person who performs the function)	**Initial/ Date**
Labels are verified to match the product that you are labeling	
Lot number on label matches the lot number on product	
Compound date on label matches the compound date on the product	
Expiration date on label matches the expiration date of the product	
Vials are clean and free of drug residue prior to labeling	
Did any of the flip caps come off during labeling? If so, how many _____	
Did any vials break during labeling? If so, how many _____	
Vial Label Reconciliation (must be verified by a pharmacist)	
Total no. of labels printed: _____ (a + b) a. No. of labels printed initially for batch: _____ Initial: _____ Date: _____ b. No. of additional label printed if needed: _____ Initial: _____ Date: _____	
No. labels used on batch records: _____	
No. labels used for product labeling: _____	
No. labels deemed unusable: _____	
No. labels discarded (unusable + extra): _____	
Total no. labels printed is equal to (labels used + labels discarded: ____	

Attachment 10

Final Product Testing

Step Description	**Performed by/ Date**
No. of vials sent out for sterility/potency/endotoxin testing: _____ Date sent for testing: _____	
No. of vials sent out for particle size distribution testing: _____ Date sent for testing: _____	
After the testing period is complete, the lab will release all results. Date of Release: _____	
No. of units to be included in final batch available for dispensing. (#7 from above) – (no. of units sent for testing) = _____	

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Batch Testing Results (attach all documentation forms) – must be verified by a pharmacist

Test	Pass/Fail	Verified by/ Date
Potency of Triamcinolone Acetate falls within 90 – 115% of expected 50 mg/mL		
Potency of Benzyl Alcohol falls within 80-120% of expected 0.9% v/v		
Sterility (No Growth)		
Endotoxin Limit (Less than 220 EU/mL)		
Viable Air Sampling Results (0 cfu/plate)		
Non-Viable Air Sampling Results (Levels fall below USP specified limits)[1]		
Surface Sampling Results(0 cfu/plate)		
Personnel Sampling Results (0 cfu/plate)		
Particle size distribution: Average Mean Diameter (5-15 µm)		

Attachment 10

AQL Inspection at Batch Release (3% of Total Vial Count for Batch)

AQL # : _____ **X 0.03 =** _____
Total # of vials in batch — Number of vials to inspect prior to release

Were any defects noted on AQL inspection (other than minor dents indicated in initial check)?	Yes/ No	Initial/Date:
If applicable, list type and number of defects discovered:		

Quality Manager to be notified of defects found during AQL inspection: _____
Quality Manager Signature

NOTE: Quality Manager to perform investigation (if applicable) and attach results to batch record

Eagle Pharmacy **Batch Record – Triamcinolone Acetonide 80 mg/mL**	
Lot #:	

Batch Record Review and Release (Must be performed by at least 1 pharmacist)

Reviewer	Signature	Date
1st Quality Check		
2nd Quality Check		

Attachment 10

Timeline for Establishing Dissolution Studies to Completion

- December 2019: Eagle Pharmacy, Inc regulatory meeting with the FDA in which it was addressed for the first time that Eagle Pharmacy needed to determine particle size distribution range for all suspension products as a component of batch release and part of a stability study program
- December 2019: Began discussions with ARL Labs to see if they could perform testing. Several months of communication only to determine they could not perform the testing
- March 2020: Hired Valsource consulting to help determine appropriate particle size specifications for our suspension products or help with finding a lab that could perform these studies. This consultant provided information on 4/15/2020 confirming that the testing did need to be completed but was unable to provide any information regarding testing labs.
- October 2020: After contacting several labs (made more difficult due to shutdowns from Covid), we found EuTech Scientific Services to conduct the necessary dissolution studies for our suspension products.
- November 2020: Method Development Studies were started at EuTech
- January 2021: Schedule for Initiation of Testing at EuTech was sent as follows:
    - **Methylprednisolone**--Validation to begin the second week of January 2021. *(Estimated time 15 days)*
      To Do:
      Scientech--Forward Protocol to Eagle. Due Date: January 5, 2021
      Eagle--Review/Revise Protocol
      Method Validation Report Completed February 22, 2021; signed by Eagle 2/24/2021
      Eagle sent samples for Dissolution Study (18-month stability study) on 4/15/2021, studies started on 4/19/2021 with estimated completion date of October 2022.

    - **Triamcinolone**--Validation to begin the fourth week of January 2021. *(Estimated time 30 days)*
      To Do:
      Scientech--Tweaking the Method as discussed. Due Date: January 8, 2021
      Eagle--Review/Revise Method.
      Scientech--Forward Protocol to Eagle. Due Date: January 22, 2021
      Eagle--Review/Revise Protocol.
      Method Validation Report Completed March 25, 2021; signed by Eagle 3/30/2021
      Eagle sent samples for Dissolution Study (18-month stability study) on 5/13/2021, studies started on 5/18/2021 with estimated completion date of November 2022.

Attachment 11

- **Betamethasone**--Method Development to begin the fourth week of January. (*Estimated time 10 days)*
  To Do:
  Eagle--Ship samples and placebos. Due Date: January 25, 2021
  Method Validation Report Completed May 26, 2021; signed by Eagle 5/26/2021
  Eagle sent samples for Dissolution Study (18-month stability study) on 7/20/2021, studies started on 7/23/2021 with estimated completion date of January 2023.

- **Dexamethasone**--Method Development to begin the second week of February 2021. (*Estimated time 14 days)*
  To Do:
  Eagle--Ship samples and placebos. Due Date: January 25, 2021
  Method Validation Report Completed June 18, 2021; signed by Eagle 6/21/2021
  Eagle sent samples for Dissolution Study (18-month stability study) on 6/23/2021, studies started on 6/28/2021 with estimated completion date of December 2022.

Attachment 11

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	Label: _____ Initial/date
Lot #:	

Record Preparer: _____ **Date:** _____ **Signature:** _____

Signature Log (all personnel involved in the compounding process)

Print Name	Sign Name	Initials	Date

Attachment 12

Raw Materials (Must be verified by a pharmacist)

Description	Manufacturer	Lot Number	Expiration Date	Verifier
Betamethasone Acetate, USP				
Betamethasone Sodium Phosphate, USP				
Sodium Phosphate Dibasic Heptahydrate, USP				
Sodium Phosphate Monobasic, USP				
Benzalkonium Chloride Soln. 50%, NF				
Edetate Disodium, USP				
Sterile Water for Inj., USP				
Sodium Hydroxine, NF				

Confirmation of Product (Must be verified by a pharmacist)

Step Description	Verified by/Date
Confirm the product and batch number information for this batch: a. Product made: Betamethasone 7mL b. Verification of correct lot number:_____ c. Verification of the accuracy of all associated labels: _____ d. Target range of units to produce: 685-761 vials e. Target fill volume per unit: 10.5 mL	

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Container Closure Components (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Stoppers				
Crimp Seals				

Consumables (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Filling Nozzle				
Machine Tubing		Pre-sterilized		
Syringes		Pre-sterilized		
Pump Tubing		Pre-sterilized		
Sterile Vials				
Filter Connector		Pre-sterilized		

Sterile Garb (Must be verified by a pharmacist)

Description	Lot Number	Exp. Date	Verifier init.
Sterile Gloves			
Sterile Coveralls			
Sterile Hood with Attached Mask			
Sterile Boot Covers			
Sterile Goggles			

Utensils (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Scoops				
Forceps				
1.5L Beaker				
5L Beaker				
10L Beaker				
Stainless Steel Beaker Cover				
Stir Bars				
Homogenizing Wand				
Stopper Bowl				
Rake				

Attachment 12

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Equipment & Instruments (Must be verified by a pharmacist) – Filled in Vial Machine Filling Room

Description	Calibration Date	Person Performing Calibration	Equipment Cleaned Prior to Use Cleaned with sterile 70% IPA	Verifier init.
Electronic Balance				
Powder Containment Hood (PCH003)		ENV		
Powder Containment Hood (PCH004)		ENV		
Non-Viable Air Sampler (NVAS____)		Airy Technology		
Viable Air Sampler (VAS____)				
Laminar Airflow Work Area		ENV		
Machine calibrated to dispense: 10.5 mL				

pH Testing (Must be verified by a pharmacist)

Step Description	Performed by/Date	Verified by/ Date
pH buffer 7 lot #: _____ Exp. Date: _____ pH meter calibrated to: _____ pH buffer 10 lot #: _____ Exp. Date: _____ pH meter calibrated to: _____ Final pH of product: _____ (Desired Range: 6.8 – 7.2)		

Attachment 12

Autoclave Process (See Attached Data Log)

Autoclave ID	Calibration Date	Verified by/Date
Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Liquid (45 min); 121°C; 15 PSI		
Timing of Process		**Documented By:**
Start time of Autoclave Process: Date: _____ Time: _____		
Completion of Autoclave Process: Date: _____ Time: _____		

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Aseptic Filling Process

Timing of Process	Documented by/ Date
Start time of Aseptic Filling Process: Date:_____Time:_____	
Completion of Aseptic Filling Process: Date:_____Time:_____	

Verification of Functioning ISO Class 5

Pressure Verification (Pressure reading must be greater than 0.02)	**Performed by/ Date**
Pressure verified every 30 min during compounding process (see attached record)	

In-Process Interventions: See Attachment

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: _____ Pass/Fail: _____ Date and Time Inserted (Incubator): _____ Performed by:_____ Date and Time Removed (Incubator): _____ Performed by:_____	

Bubble-point Testing (Aqueous Solutions only) – Must be verified by pharmacist

Bubble-point Testing of Filter	Verified by/ Date
Filter Lot#: _____ Exp. Date: _____	
Product specific bubble point value must be at least: 43.80 Actual bubble point value of the sterilizing filter: _____ Bubble-point testing performed by: _____ Pass/Fail: _____ Pressure Gauge #_____ Pressure Gauge Calibration Date:_____	

Attachment 12

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Sterile Processing Steps

Step Description	Performed by/ Date
1. Weighing of ingredients	
2. Verification of ingredient weight (pharmacist only)	
3. Mixing of ingredients	
4. Main Technician	
5. Helper Technician	
6. Auxiliary Technician	
7. Air Sampling	

Visual Inspection (Can only be performed by a pharmacist)

Step Description	Performed by/ Date
1. Verify that the visual inspection area is clear and free of any other product or labels.	
2. Ensure the total number of units received for visual inspection is equal to the total number of units filled. Number of units received: _____ (A)	
3. Number of units filled falls within the expected range for filled units (90-100%)	
4. Perform visual inspection on each unit for Critical, Major, and Minor defects as categorized in the table below.	

CRITICAL	Chipped Vials/Glass in Vials	
	Particulates in Vial	
	Cracked/Broken Vials	
	Missing Stopper	
	Discoloration or Cloudiness	
MAJOR	Uncrimped/partially crimped vials	
	Overfills / Underfills	
MINOR	Dents in Aluminum Seal	
	Scratches on Glass Vials	

5. Remove any units with critical or major defects from the batch Number of units removed: _____ (B)	
6. Number of units used for syringability test: _____ (C)	
7. Total Number of units to be included in final batch: Total number of units = (A) – (B) – (C) = _____	

Attachment 12

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Vial Labeling

Vial Labeling Verification (To be initialed by the person who performs the function)	**Initial/ Date**
Labels are verified to match the product that you are labeling	
Lot number on label matches the lot number on product	
Compound date on label matches the compound date on the product	
Expiration date on label matches the expiration date of the product	
Vials are clean and free of drug residue prior to labeling	
Did any of the flip caps come off during labeling? If so, how many _____	
Did any vials break during labeling? If so, how many _____	
Vial Label Reconciliation (must be verified by a pharmacist)	
Total no. of labels printed: _____ (a + b) a. No. of labels printed initially for batch: _____ Initial: _____ Date: _____ b. No. of additional label printed if needed: _____ Initial: _____ Date: _____	
No. labels used on batch records: _____	
No. labels used for product labeling: _____	
No. labels deemed unusable: _____	
No. labels discarded (unusable + extra): _____	
Total no. labels printed is equal to (labels used + labels discarded: ____	

Attachment 12

Final Product Testing

Step Description	**Performed by/ Date**
No. of vials sent out for sterility/potency/endotoxin testing: _____ Date sent for testing: _____	
No. of vials sent out for particle size distribution testing: _____ Date sent for testing: _____	
After the testing period is complete, the lab will release all results. Date of Release: _____	
No. of units to be included in final batch available for dispensing. (#7 from above) – (no. of units sent for testing) = _____	

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Batch Testing Results (attach all documentation forms) – must be verified by a pharmacist

Test	Pass/Fail	Verified by/ Date
Potency of Betamethasone Acetate falls within 90-115% of expected 3mg/mL		
Potency of Betamethasone Sodium Phosphate falls within 90-115% of expected 4mg/mL		
Potency of Benzalkonium Chloride falls within 80-120% of 0.02% v/v		
Sterility (No Growth)		
Endotoxin Limit (Less than 204.4 EU/mL)		
Viable Air Sampling Results (0 cfu/plate)		
Non-Viable Air Sampling Results (< 3,520 particles ≥ 0.5 µm/m³)		
Surface Sampling Results(0 cfu/plate)		
Personnel Sampling Results (0 cfu/plate)		
Particle Size Distribution: Average Mean Diameter (10-15 µm)		

Attachment 12

AQL Inspection at Batch Release (3% of Total Vial Count for Batch)

AQL #: _____ X 0.03 = _____
Total # of vials in batch — Number of vials to inspect prior to release

Were any defects noted on AQL inspection (other than minor dents indicated in initial check)?	Yes/ No	Initial/Date:

If applicable, list type and number of defects discovered:

Quality Manager to be notified of defects found during AQL inspection: _____
Quality Manager Signature

NOTE: Quality Manager to perform investigation (if applicable) and attach results to batch record

Eagle Pharmacy **Batch Record – Betamethasone 7 mg/mL**	
Lot #:	

Batch Record Review and Release (Must be performed by at least 1 pharmacist)

Reviewer	Signature	Date
1st Quality Check		
2nd Quality Check		

Attachment 12

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	Label: _____ Initial/date
Lot #:	

Record Preparer: _____ **Date:** _____ **Signature:** _____

Signature Log (all personnel involved in the compounding process)

Print Name	Sign Name	Initials	Date

Raw Materials (Must be verified by a pharmacist)

Description	Manufacturer	Lot Number	Expiration Date	Verifier
Dexamethasone Acetate Anhydrous, USP				
Sodium Chloride Granular, USP				
Edetate Disodium, USP				
Sodium Bisulfite, FCC				
Carboxymethylcellulose Sodium (Medium Viscosity), USP				
Polysorbate 80, NF				
Benzyl Alcohol, NF				
Sterile Water for Injection, USP				
Sodium Hydroxide, NF				

Attachment 13

Confirmation of Product (Must be verified by a pharmacist)

Step Description	Verified by/Date
Confirm the product and batch number information for this batch: a. Product made: Dexamethasone Acetate 8 mg/mL b. Verification of correct lot number:_____ c. Verification of the accuracy of all associated labels: _____ d. Target range of units to produce: 857-952 vials e. Target fill volume per unit: 10.5 mL	

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Container Closure Components (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Stoppers				
Crimp Seals				

Consumables (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Filling Nozzle				
Syringes		Pre-sterilized		
Tubing		Pre-sterilized		
Sterile Vials				

Pre-Filters/Filter Connectors Used

Sterile Garb (Must be verified by a pharmacist)

Description	Lot Number	Exp. Date	Verifier init.
Sterile Gloves			
Sterile Coveralls			
Sterile Hood with Attached Mask			
Sterile Boot Covers			
Sterile Goggles			

Utensils (Must be verified by a pharmacist)

Description	Lot Number	Steriliz. Date	Exp. Date	Verifier init.
Scoops				
Forceps				
1L Beaker				
10L Beaker				
Stainless Steel Beaker Cover				
Stir Bars				
Homogenizing Wand				
Stopper Bowl				
Rake				

Attachment 13

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Equipment & Instruments (Must be verified by a pharmacist) – Filled in Vial Machine Filling Room

Description*	Calibration Date	Person Performing Calibration	Equipment Cleaned Prior to Use *Cleaned with sterile 70% IPA	Verifier init.
Electronic Balance				
Powder Containment Hood (PCH003)		ENV		
Powder Containment Hood (PCH004)		ENV		
Non-Viable Air Sampler (NVAS____)		Airy Technology		
Viable Air Sampler (VAS____)				
Laminar Airflow Work Area		ENV		
Machine calibrated to dispense: 10.5 mL				

pH Testing (Must be verified by a pharmacist)

Step Description	Performed by/Date	Verified by/ Date
pH buffer 4 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ pH buffer 7 lot #: _____ Exp. Date:_____ pH meter calibrated to: _____ Final pH of product:_____ (Desired Range: 5.0 – 7.5)		

Attachment 13

Autoclave Process (See Attached Data Log)

Autoclave ID	Calibration Date	Verified by/Date
Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Liquid (45min); 121°C; 15 PSI		

Timing of Process	Documented By:
Start time of Autoclave Process: Date: _____ Time: _____ Completion of Autoclave Process: Date: _____ Time: _____	

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Autoclave Process (See Attached Data Log)

Autoclave ID	Calibration Date	Verified by/Date
Verification of Correct Cycle	**Verify by:**	**Verify by:**
Sterilize Liquid (45min); 121°C; 15 PSI		

Timing of Process	Documented By:
Start time of Autoclave Process: Date: _____ Time: _____ Completion of Autoclave Process: Date: _____ Time: _____	

Aseptic Filling Process

	Documented by/ Date
Start time of Aseptic Filling Process: Date:_____Time:_____	
Completion of Aseptic Filling Process: Date:_____Time:_____	

Verification of Functioning ISO Class 5

Pressure Verification (Pressure reading must be greater than 0.02)	**Performed by/ Date**
Pressure verified every 30 min during compounding process (see attached record)	

In-Process Interventions (See Attachment)

Attachment 13

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: _____ Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Biological Indicator Results (for terminal sterilization only) – must be verified by a pharmacist

Biological Indicator	Verified by/ Date
Manufacturer: _____ Lot#: _____ Exp. Date:_____ Location: _____ Pass/Fail: _____ Date and Time Inserted (Incubator):_____ Performed by:_____ Date and Time Removed (Incubator):_____ Performed by:_____	

Attachment 13

Sterile Processing Steps

Step Description	Performed by/ Date
1. Weighing of ingredients	
2. Verification of ingredient weight (pharmacist only)	
3. Mixing of ingredients	
4. Main Technician	
5. Helper Technician	
6. Auxiliary Technician	
7. Air Sampling	

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Visual Inspection (Can only be performed by a pharmacist)

Step Description	Performed by/ Date
1. Verify that the visual inspection area is clear and free of any other product or labels.	
2. Ensure the total number of units received for visual inspection is equal to the total number of units filled. Number of units received: _____ (A)	
3. Number of units filled falls within the expected range for filled units (90-100%)	
4. Perform visual inspection on each unit for Critical, Major, and Minor defects as categorized in the table below.	

CRITICAL	Chipped Vials/Glass in Vials	
	Particulates in Vial	
	Cracked/Broken Vials	
	Missing Stopper	
	Discoloration or Cloudiness	
MAJOR	Uncrimped/partially crimped vials	
	Overfills / Underfills	
MINOR	Dents in Aluminum Seal	
	Scratches on Glass Vials	

5. Remove any units with critical or major defects from the batch Number of units removed: _____ (B)	
6. Number of units used for sympatability test: _____ (C)	
7. Total Number of units to be included in final batch: Total number of units = (A) – (B) – (C) = _____	

Attachment 15

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Vial Labeling

Vial Labeling Verification (To be initialed by the person who performs the function)	**Initial/ Date**
Labels are verified to match the product that you are labeling	
Lot number on label matches the lot number on product	
Compound date on label matches the compound date on the product	
Expiration date on label matches the expiration date of the product	
Vials are clean and free of drug residue prior to labeling	
Did any of the flip caps come off during labeling? If so, how many _____	
Did any vials break during labeling? If so, how many _____	
Vial Label Reconciliation (must be verified by a pharmacist)	
Total no. of labels printed: _____ (a + b) a. No. of labels printed initially for batch: _____ Initial: _____ Date: _____ b. No. of additional label printed if needed: _____ Initial: _____ Date: _____	
No. labels used on batch records: _____	
No. labels used for product labeling: _____	
No. labels deemed unusable: _____	
No. labels discarded (unusable + extra): _____	
Total no. labels printed is equal to (labels used + labels discarded: ____	

Attachment 13

Final Product Testing

Step Description	**Performed by/ Date**
No. of vials sent out for sterility/potency/endotoxin testing: _____ Date sent for testing: _____	
After the testing period is complete, the lab will release all results. Date of Release: _____	
No. of units to be included in final batch available for dispensing. (#7 from above) – (no. of units sent for testing) = _____	

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

AQL Inspection at Batch Release (3% of Total Vial Count for Batch)

AQL # : _____ **X 0.03 =** _____
Total # of vials in batch — Number of vials to inspect prior to release

Were any defects noted on AQL inspection (other than minor dents indicated in initial check)?	Yes/ No	Initial/Date:

If applicable, list type and number of defects discovered:

Quality Manager to be notified of defects found during AQL inspection: _____
Quality Manager Signature

NOTE: Quality Manager to perform investigation (if applicable) and attach results to batch record

Attachment 13

Batch Testing Results (attach all documentation forms) – must be verified by a pharmacist

Test	Pass/Fail	Verified by/ Date
Potency of Dexamethasone Acetate falls within 90-110% of expected 8mg/mL		
Potency of Benzyl Alcohol falls within 80-120% of expected 0.9% v/v		
Sterility (No Growth)		
Endotoxin Limit (Less than 173.6 EU/mL)		
Viable Air Sampling Results (0 cfu/plate)		
Non-Viable Air Sampling Results (< 3,520 particles ≥ 0.5 um/m^3)		
Surface Sampling Results(0 cfu/plate)		
Personnel Sampling Results (No Growth)		
Particle Size Distribution: Average Mean Diameter (17-23 µm)		

Eagle Pharmacy **Batch Record – Dexamethasone Acetate 8 mg/mL**	
Lot #:	

Batch Record Review and Release (Must be performed by at least 1 pharmacist)

Reviewer	Signature	Date
1st Quality Check		
2nd Quality Check		

Attachment 13

Lot#: _____

In-Process Interventions **Start Time:**_____ **End Time:**_____

Location	Time/Description
Door to Clean Room	
Pass-Thru Window	
Large Stopper Door	
Small Stopper Door	
Large Reject Door	
Small Reject Door	

Attachment 14

Lot#: _____

Vial Outfeed Door	
Crimper Door	
Large Crimp Cap Door	
Small Crimp Cap Door	
Other	

Attachment 14

Total # Interventions: _____

DEAPSBETA080221

In-Process Interventions **Start Time:** 1351 **End Time:** 1419

Location	Time/Description
Door to Clean Room	1419 - ZH entering 1434 - JP entering
Pass-Thru Window	1353 - Get Drug out - 15L Beakers 1401 - Put empty Beakers in 1404 - get stock out 1406 - get 5L Beaker out 1437 - get ~~bags~~ out 1446 - getting stock 14
Large Stopper Door	
Small Stopper Door	1455 - Putting stoppers in
Large Reject Door	1505 - adjusting crimper
Small Reject Door	1453 - Pulling vial w/no stopper 1456 - Pulling rejects 1500 - Pulling rejects 1503 - Pulling rejects 1504 - Pulling rejects 1512 - Pulling rejects 1514 - Pulling rejects 1516 - Pulling rejects

Attachment 15

Vial Outfeed Door	
Crimper Door	1455- Putting Crimp caps in 1501- putting crimp caps in 1507- Putting crimp caps in ~~[illegible]~~ 1516 - Putting crimp caps in
Large Crimp Cap Door	1433- insert Beaker 1439- putting needle/nozzle on 1447- Priming nozzle 1446- Putting in grad. cyl.- checking filling level 1450- Putting in 2nd. grad. cyl. 1451 - checking adjusted filling level
Small Crimp Cap Door	
Other	

Attachment 15

Investigative Report – Deviation from Lab Testing Protocol

Lipo B Plus Lot#1022
Compound Date: 7/31/2019
Date of Findings: N/A
Person(s) Completing Report:
Haleigh Cawood, Quality Control Manager

Statement of Findings:
Stability study testing completed on days 0, 270, 365

Expected Results:
Original protocol stated that stability study testing timepoints would be on days 0, 30, 60, 90, 180.

Actual Results:
The testing timepoints per the stability study protocol were altered by Eagle Pharmacy after the initial study and extended to 0, 270, and 365.

Investigation:
Because Eagle Pharmacy had already conducted an initial study confirming passing results for all timepoints, we wanted to test for extension of the 180-day Beyond Use Date. We conducted the study with testing time points at 0, 270, and 365 days. If there were any failing results at the day 270 timepoint or later, Eagle Pharmacy would have retained the original 180 day beyond use date. All time points through the 365-day mark were passing, so there were no negative implications from extending these dates.

Were Other Products Effected?
No

Corrective/Preventative Action:
Because all results from the extended time-points were passing, there are no corrective/preventative actions necessary. Additionally, the BUD on the Lipo B Plus was not extended to 12 months until the passing results of the 365-day time point were received and reviewed by the Quality Manager.

Follow-Up:
An additional lot of Lipo B Plus Lot#1024 was also placed on Stability study on 9/3/2019 to have a second lot with extended testing results.

Signature of Quality Control Manager:
Haleigh Wilkes 8/23/21

Signature of Pharmacy Manager:
8/25/21

Attachment 16

INFINITY LABORATORIES

PHARMACEUTICAL
Test Request Form

Laboratory Use Only
Accession Number _____
Logged By/Date/Time _____
Temp. when Received _____
MOC ☐ With sample ☐ Other: _____

Purchase Order #:	Quote #:

Customer Information	
Contact: Zahir Hamid	
Company: Eagle Pharmacy, Inc.	
Phone: 205-682-7999	
Email: eaglepharmacy@gmail.com	
Address: 2200 Riverchase Center Ste 675	
City: Hoover	State: AL
Zip: 35244	Country: USA

Billing Information Same as Customer ☐	
Contact: Lisa Russell	
Company: Eagle Pharmacy, Inc.	
Phone: 205-682-7999	
Email: lisar.eaglepharmacy@gmail.com	
Address: 2200 Riverchase Center Ste 675	
City: Hoover	State: AL
Zip: 35244	Country: USA

Sample Information

Please use exact wording to be included on final report

Sample Description: LIPO B Plus

Part Number:	Testing priority: ☐ Standard ☐ RUSH (*extra charge*)
Lot Number: LIPO1022	Sample Storage: ☐ Light Sensitive ☐ %RH _____
Date of Origin: 7/31/2019 Batch Size:	☐ -25 to -15°C ☐ 2-8°C ☐ 20-25°C
Total Quantity Submitted for Testing: 93	Hazardous Material: ☐ Yes ☐ No
☐ BUD Testing, Days: 0, 270, 365 ☐ Accelerated	Investigate Out of Specification Result: ☐ Yes ☐ No

Additional Information: **PHASE 2 TO BE COMPLETED ONLY**
** SEE ATTACHED SHEET **

Test Information

Test Requested (*Name of Test*)	# of Samples for Test	Method to be Followed (*USP, Customer Protocol, etc.*)	Acceptance Criteria

Customer Signature: Jamie Latham Date: 7/31/19

Client agrees to Infinity Laboratories' terms and conditions.

Attachment 16

Lipo B Plus

Phase I (Method Development and Suitability) – NEED SUITABILITY ONLY (Method Development Completed on Vitachrom formulation)

Method Development		
Active Pharmaceutical Ingredient	**Standard**	**Total # Samples**
Methionine	USP <1225>	2
Inositol		
Choline Chloride		
Thiamine Hydrochloride		
Cyanocobalamin		
Anti-Microbial Evaluation		
Preservative	**Standard**	**Total # Samples**
Benzyl Alcohol	USP <341>	2

Method Suitability	
Standard/Procedure	**Total # Samples**
USP <71>	10

Phase II (Stability Study)

Stability Study				
Test Performed	**Standard**	**Time Points**	**# Samples Each Time Point**	**Total # Samples**
Appearance	Visual	0, 270, 365	1	3
Potency	USP <621>	0, 270, 365	1	3
Sterility	USP <71>	0, 270, 365	10	30
Endotoxin	USP <85>	0, 270, 365	1	3
Particulates	USP <788>	0, 270, 365	10	30
pH	USP <791>	0, 270, 365	1	3
Container Closure		365	10	10
Antimicrobial Effectiveness	USP <51>	0, 365	6, 5	11

Total # Samples: 93 (Phase II only)

* Note: for potency need for each active plus benzyl alcohol at all time points.

Attachment 16

Investigative Report – Deviation from Lab Testing Protocol

Lipo B Plus Lot#1024
Compound Date: 9/3/2019
Date of Findings: N/A
Person(s) Completing Report:
Haleigh Cawood, Quality Control Manager

Statement of Findings:
Stability study testing completed on days 0, 270, 365

Expected Results:
Original protocol stated that stability study testing timepoints would be on days 0, 30, 60, 90, 180.

Actual Results:
The testing timepoints per the stability study protocol were altered by Eagle Pharmacy after the initial study and extended to 0, 270, and 365.

Investigation:
Because Eagle Pharmacy had already conducted an initial study confirming passing results for all timepoints, we wanted to test for extension of the 180-day Beyond Use Date. We conducted the study with testing time points at 0, 270, and 365 days. This study was the second for Lipo B Plus to be conducted with the testing timepoints. If there were any failing results at the day 270 timepoint or later, Eagle Pharmacy would have retained the original 180 day beyond use date. All time points through the 365-day mark were passing, so there were no negative implications from extending these dates.

Were Other Products Effected?
LIPO1022 was also tested with these extended timepoints and had passing results.

Corrective/Preventative Action:
Because all results from the extended time-points were passing, there are no corrective/preventative actions necessary. This second study confirms the 365-day BUD.

Follow-Up:
N/A

Signature of Quality Control Manager:
Haleigh Wilkes 8/23/21

Signature of Pharmacy Manager:
8/25/21

Attachment 16

INFINITY LABORATORIES

PHARMACEUTICAL Test Request Form

Laboratory Use Only

Accession Number _____

Logged By/Date/Time _____

Temp. when Received _____

MOC ☐ With sample ☐ Other: _____

Purchase Order #:	Quote #:

Customer Information	
Contact: Zahir Hamid	
Company: Eagle Pharmacy, Inc.	
Phone: 205-682-7999	
Email: eaglepharmacy@gmail.com	
Address: 2200 Riverchase Center Ste 675	
City: Hoover	State: AL
Zip: 35244	Country: USA

Billing Information Same as Customer ☐	
Contact: Lisa Russell	
Company: Eagle Pharmacy, Inc.	
Phone: 205-682-7999	
Email: lisar.eaglepharmacy@gmail.com	
Address: 2200 Riverchase Center Ste 675	
City: Hoover	State: AL
Zip: 35244	Country: USA

Sample Information

Please use exact wording to be included on final report

Sample Description: Lipo B Plus

Part Number:	Testing priority: ■ Standard ☐ RUSH (*extra charge*)
Lot Number: LIP01024	Sample Storage: ☐ Light Sensitive ☐ %RH _____
Date of Origin: 9/3/19 Batch Size: 149-166	☐ -25 to -15°C ☐ 2-8°C ■ 20-25°C
Total Quantity Submitted for Testing: 72	Hazardous Material: ☐ Yes ■ No
☐ BUD Testing, Days: 0,270,365 ☐ Accelerated	Investigate Out of Specification Result: ☐ Yes ■ No

Additional Information: **ONLY PHASE 2 TO BE COMPLETED/SEE ATTACHED SHEET**

Attachment 16

Test Information

Test Requested (*Name of Test*)	# of Samples for Test	Method to be Followed (*USP, Customer Protocol, etc.*)	Acceptance Criteria

Customer Signature: Jamie Latham Date: 9/3/19

Client agrees to Infinity Laboratories' terms and conditions.

Lipo B Plus

Phase I (Method Development and Suitability) – COMPLETE

Method Development		
Active Pharmaceutical Ingredient	**Standard**	**Total # Samples**
Methionine	USP <1225>	2
Inositol		
Choline Chloride		
Thiamine Hydrochloride		
Cyanocobalamin		
Anti-Microbial Evaluation		
Preservative	**Standard**	**Total # Samples**
Benzyl Alcohol	USP <341>	2

Method Suitability	
Standard/Procedure	**Total # Samples**
USP <71>	10

Phase II (Stability Study)

Stability Study				
Test Performed	**Standard**	**Time Points**	**# Samples Each Time Point**	**Total # Samples**
Appearance	Visual	0, 270, 365	1	3
Potency (Actives and Preservative)	USP <621>	0, 270, 365	1	3
Sterility	USP <71>	0, 270, 365	10	30
Endotoxin	USP <85>	0, 270, 365	1	3
Particulates	USP <788>	0, 270, 365	3	9
pH	USP <791>	0, 270, 365	1	3
Container Closure		0, 365	5	10
Antimicrobial Effectiveness	USP <51>	0, 365	6, 5	11

Total # Samples: 72

Phase II Only

Attachment 16

INFINITY LABORATORIES

Customer Quality Agreement

PARTIES INVOLVED:

This Agreement is entered into on July 29, 2021 by and between:

1. **Infinity Laboratories, LLC, having a principal location at: 1585 S Perry St, Suite B, Castle Rock, CO 80104**

(referred to in this Agreement as "Infinity")

And

2. **Eagle Pharmacy Inc., having a principal location at: 2200 Riverchase Ctr., Suite 675 Hoover, AL 35244**

(referred to in this Agreement as "Customer")

Attachment 17

1.0 Scope

This Agreement sets forth the mutual expectations between Customer and Infinity regarding, product testing, overall quality systems, responsibilities of each party, and confidentiality.

2.0 Compliance with Laws

Infinity agrees and acknowledges its obligation to act in accordance with the terms of this Agreement, and its independent duty to comply with all applicable laws and regulations in which products are distributed. Infinity and Customer mutually agree to fully cooperate in ensuring compliance with all applicable provisions within the scope and duties and responsibilities established by this Agreement.

The validity, construction, and enforceability of this Agreement is governed by the laws of the State of Delaware.

3.0 Certifications, Registrations and Licenses

Infinity shall maintain the following accreditations, ISO/IEC 17025, FDA registration, DEA license, and any other accreditations required by applicable laws. Infinity shall provide Customer with documentation of such accreditation upon request. Infinity shall notify Customer of any material change in status to the following accreditations: ISO/IEC 17025, FDA registration, and DEA license.

4.0 Quality Management

Infinity shall maintain a Quality Management System that is appropriate for the supported work of the Customer. Infinity shall provide adequate management support, oversight, resources, and infrastructure in support of its Quality Management System. Infinity shall have documented and controlled procedures for test methods, preparatory methods, and any applicable procedures that are used to support test methods and protocols.

5.0 Equipment

Infinity shall have documented procedures in place for the maintenance of equipment used in the receiving, handling, storing, and testing of Customer samples. Furthermore, Infinity shall maintain in reasonable working condition any equipment used in the process of analytical testing for Customer.

6.0 CAPA System

Infinity shall maintain an appropriate Corrective Action and Preventative Action (CAPA) system as required per ISO/IEC 17025. As applicable and if required, Infinity shall communicate test issues to

INFINITY LABORATORIES

Customer Quality Agreement

Customer with root cause and preventive/corrective action required. Infinity shall monitor complaints and corrective actions for trends and other relevant patterns, making adjustments as necessary.

7.0 Nonconforming Results

Infinity shall establish and maintain procedures to control nonconforming results. A nonconforming result may also include Out of Specification (OOS) results. In cases where a nonconforming result has been generated, established procedures and protocols will be followed to determine root cause. If a product nonconformity is observed and a laboratory investigation determines that all laboratory protocols, procedures, and system quality checks were within acceptable criteria, it is the responsibility of Customer to determine root cause per their own quality procedures.

8.0 Audits and Inspections

Infinity shall provide Customer and any third-party consultant approved by Customer, with reasonable access to inspect, review and audit Infinity. Customer shall provide at least 30 days' notice prior to a requested audit, except when special circumstances warrant a shorter notice time. Audit terms such as date, scope, number of participants, and duration of the audit visit shall be mutually agreed upon by both Infinity and Customer and Customer will be responsible for all costs of such audits.

Infinity and Customer understands the FDA shall have access to and the right to inspect or audit any pertinent test results, test procedures and protocols, and the overall laboratory facility of Infinity. Customer acknowledges that FDA inspectors may arrive at Infinity at any time and without notice. Infinity shall notify Customer of such visits if their products are inspected and if Infinity is not prohibited from notifying the Customer.

9.0 Records

Infinity shall maintain a record retention policy as required by applicable law for all records, both written and electronic. When requested by Customer, record retention may be extended at the cost of the Customer. Records may include, but are not limited to: test results, test methods, training records, quality manuals, protocols and procedures, and requisition forms.

10.0 Responsibilities of the Customer

Customer agrees to specific responsibilities in order to achieve quality data. This includes:

a) Provide test samples with instruction detailing the appropriate contact person, test(s) to be performed, quantity of samples submitted, sample description, part number, lot number, test specifications, and any special instructions.
b) Package and deliver samples to Infinity under appropriate conditions to maintain sample integrity and protect samples from outside contamination.
c) Cooperate with laboratory to provide samples in a form which maximizes the probability of an accurate and reliable test.
d) Submit samples within a reasonable period of time to complete the test and meet any testing deadlines. Samples requiring priority testing may incur additional charges.
e) Cooperate with laboratory in providing Customer product information that may assist in method development and test procedures/protocols (e.g. formula worksheets).
f) Notification of a product or design change that may directly impact testing procedures (e.g. formulation change).
g) Notification prior to sending potentially harmful or toxic test material (e.g. chemotherapy drugs).

Attachment 17

INFINITY LABORATORIES

Customer Quality Agreement

11.0 Subcontractors

Infinity shall not subcontract test product(s) unless written permission/approval from Customer has been obtained. Infinity shall not be liable for testing services provided by outside organizations.

12.0 Term of Agreement

This Agreement is effective on the Effective Date and shall remain in effect so long as Customer provides test products to Infinity.

13.0 Confidentiality

Any information disclosed by Infinity and/or Customer, either directly or indirectly in writing, orally or by inspection, including, without limitation, scientific or technical information, information about planned facilities, and all information regarding intellectual property including test results and product trade secrets, financing or personnel matters, suppliers, prices, customers, computer systems, sales, employees, investors or business strategy shall be held in strict confidentiality and not released to any third party unless received prior written approval by entity which holds information as such.

14.0 Amendments

This Agreement may not be amended except in writing signed by Infinity and Customer.

15.0 Conflicts

In the event a conflict arises between this Agreement and any statement of work, quotation, service agreement or master service agreement, the statement of work, the statement of work, quotation, service agreement or master service agreement, the statement of work will govern.

16.0 Counterparts

This Agreement may be executed in one or more counterparts, each of which will be deemed an original and all of which, when taken together, will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

Attachment 17

INFINITY LABORATORIES, LLC	EAGLE PHARMACY INC.
Signature [signature]	Signature Haleigh Wilkes
Name Dan Henderson	Name Haleigh Wilkes
Title CEO	Title Quality Manager
Date July 29, 2021	Date 7/29/21

Standard Operating Procedure

	SOP CODE: P1.11.4 REVISION NUMBER: 4 ISSUE DATE: August 18, 2021 IMPLEMENTATION DATE: August 18, 2021

TITLE : Adverse Drug Experience Reporting.

DRAFTED BY:	**SIGNATORY:**	Zahira Hamid	SIGNATURE	8/18/21 DATE
☐	**TITLE:**	General Manager		
APPROVED BY:	**SIGNATORY:**	Haleigh Wilkes	Haleigh Wilkes SIGNATURE	8/18/21 DATE
	TITLE:	Quality Manager		

RELATED LOGS & FORMS

TYPE OF RECORD	FREQUENCY OF USE	NUMBER OF RECORDS	SPECIFICATION / DESCRIPTION
Form	As needed	P1.11-A1	Adverse Drug Experience Form

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
P2.27	Patient/Customer Complaint/Problems

Attachment 18

RESPONSIBILITIES

1. Pharmacy managers and staff pharmacists to oversee this SOP.
2. All staff has a duty to follow this policy by reporting any complaint(s), adverse occurrence or event(s) immediately to the supervising pharmacist.
3. Pharmacy managers and/or staff pharmacists have the responsibility to document and report adverse drug experience to FDA.

PURPOSE

1. Eagle Pharmacy acknowledges that safe use of medicines is an essential component of patient safety.
2. Eagle pharmacy recognizes that accurate reporting, documentation, response and communication of an Adverse Drug Experience and allergies are required in order to reduce potential harm to patients from the use of medicines.

SCOPE

1. Applies to Eagle Pharmacy sterile compounded drug product.
2. Applies to all procured manufactured drugs.

DEFINITIONS

1. Expected adverse drug experiences: one that is reasonably consistent with applicable product information or characteristics of drug.
2. Unexpected adverse drug experiences: any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity.
3. Unexpected: refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling), rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.
4. Medical events: an unexpected reaction to a drug which could have or did lead to unintended or unexpected harm, loss or damage. The onset of a drug adverse reaction could be sudden or develop over time. Examples of medical events:
    1. Allergic bronchospasm requiring intensive treatment in an emergency room or at home.
    2. Blood dyscrasias or convulsions that do not result in inpatient hospitalization.
    3. The development of drug dependency or drug abuse.
5. Serious adverse drug experience: event (events relating to drugs or devices) as one in which the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly/birth defect, or required intervention to prevent permanent impairment or damage.

FREQUNECY

1. With each adverse drug experience.

SPECIAL CIRCUMSTANCE

1. Not applicable.

Attachment 18

PROCEDURE

1. Any non-pharmacist staff member at Eagle Pharmacy upon receiving information or notification of any adverse reaction, has to report it immediately to a pharmacist.
2. The pharmacist upon receiving notification of an adverse reaction from a health care provider or a patient, is required to obtain contact information of the person reporting the adverse reaction and complete the Adverse Drug Experience Form.
3. Staff pharmacist upon receiving and handling an adverse drug experience from a health care provider and/or patient, is required to immediately notify the pharmacist-in-charge.
4. Pharmacist-in-charge/pharmacists are required to submit adverse drug experience report (all serious events, whether expected or unexpected) to FDA as soon as possible, but no later than 15 calendar days of initial receipt of the information along with a copy of the drug product's current labeling. In addition, all serious, expected and unexpected adverse drug experiences that are the subject of these reports 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 FDA.

5. Eagle Pharmacy will investigate the following four data elements
   i. An identifiable patient: Collect enough information to indicate the existence of a specific patient. One or more of the following would qualify a patient as identifiable. Patients should not be identified by name or address when reporting to FDA. Instead, Eagle Pharmacy should assign a unique code number for each patient.
      1. Age or age category (e.g., adolescent, adult, elderly)
      2. Gender
      3. Initials
      4. Date of birth
      5. Name
      6. Patient identification number
   ii. An identifiable reporter: Person who initially notifies Eagle Pharmacy about an adverse event. Initial reporter can be a patient, consumer, family member, doctor, pharmacist, other health care professional, or other individual. Eagle Pharmacy should obtain, if possible, sufficient information to indicate that the reporter is an identifiable person who purports to have knowledge about the patient, adverse event, and drug involved. One or more of the following would qualify a reporter as identifiable:
      1. A personal identifier (e.g., name)
      2. A professional identifier (e.g., doctor, nurse, pharmacist)
      3. Contact information (e.g., e-mail address, phone number)
   iii. A suspect drug: A suspect drug product that the initial reporter suspected was associated with the adverse event. Adverse event report should describe the known product attributes (e.g., active ingredient(s), dosage form, strength, color, lot number). If compounded drug contains multiple components (e.g., excipients, drug substances, finished dosage forms), Eagle Pharmacy should list each component and its manufacturer. Eagle Pharmacy to should list any other known medical product(s) the patient was taking at the time he or she experienced the adverse event and the manufacturer of that product(s).
   iv. A serious adverse event: When reporting an unexpected adverse event to FDA that results in one or more of the following patient outcomes:
      1. Death
      2. A life-threatening adverse drug experience
      3. Inpatient hospitalization or prolongation of existing hospitalization: inpatient hospitalization includes initial admission to the hospital on an inpatient basis (even if released same day)
      4. A persistent or significant disability or incapacity, or
      5. A congenital anomaly or birth defect

Attachment 18

6. Follow-Up Reports:
    i. If unable to include all four of the data elements mentioned above during initial reporting, Eagle Pharmacy will exercise its due diligence to obtain information about any remaining elements and should keep records of its efforts to obtain this and other relevant information.
    ii. Eagle Pharmacy will report to FDA any new information it obtains about the initial report regarding adverse event.
7. Report attachments and additional information:
    i. A copy of the current labeling for the compounded drug product that is the subject of the report.
    ii. If available:
        1. Hospital discharge summaries.
        2. Autopsy reports/death certificates.
        3. Relevant laboratory data.
        4. Other critical clinical data.
        5. Information on the event(s) that led to the death.
8. How to report adverse events
    i. FDA website (https://www.fda.gov/safety/medical-product-safety-information/forms-reporting-fda) provides two options for electronic submission of initial and follow up adverse event reports to FDA:
        1. Submission through the Safety Reporting Portal (SRP).
        2. Submission through the Electronic Submissions Gateway (ESG).
    ii. Prior to submitting an adverse event to FDA, Eagle Pharmacy should notify the FDA Adverse Event Reporting System (FAERS) Electronic Submission Coordinator of its intent at fareseub@fda.hhs.gov
    iii. Each report should have a unique case identification number (to avoid duplicate adverse event reports in the FAERS database, each report should have a unique case identification number, regardless of how it is transmitted to the FDA).
9. Expected adverse drug events will be reviewed, signed and trended by pharmacy manager(s). All serious (expected and unexpected) adverse events will be reviewed, signed and submitted to the FDA by pharmacy manager(s).
10. Recordkeeping: All adverse drug experiences records/reports must be maintained for 10 years, including raw data and any correspondence relating to the adverse event, and allow FDA access to review, copy, and verify these records.
11. Failure to report adverse events by an entity that is registered in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FD&C Act.12 Violations relating to this provision are subject to regulatory and enforcement action.

Attachment 18

REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION
1	05/07/2015	04/28/2016	
2	04/28/2016		Changed pharmacy manager terminology
3	09/02/2019		Made policy more detailed
4	08/18/2021		Added serious (expected and unexpected) adverse events

REGULATORY COMPLIANCE GUIDELINES

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
FDA		08/22/2014		Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Attachment 18

Adverse Drug Experience Form (P1.11-A1):

Questionnaire

Patient Information:

1. Patient identification number:_____
2. Age or Date of Birth:_____
3. Gender: ☐ Male ☐ Female
4. Weight: ☐ lb ☐ kg
5. Ethnicity: ☐ Hispanic/Latino
   ☐ Not Hispanic/Latino
6. Race: ☐ Asian ☐ Black or African American ☐ White
   ☐ Native Hawaiian or other Pacific Islander ☐ American Indian or Alaskan Native

Reporter:

Last name:_____ First name:_____

Address:_____

City:_____ State:_____ Zip Code:_____

Phone number:_____ e-mail address:_____

Health care professional: Yes_____ No_____

Occupation:_____

Suspect Drug:

Name and strength:_____ Dose or Amount:_____

Frequency:_____ Route:_____

Color:_____ Lot #:_____

NDC #:_____ Dates of use:_____

Diagnosis or Reason for Use:_____

Manufacturer/Compounder:_____

Product manufactured or compounded date:_____ Expiration Date:_____

Attachment 18

Adverse Event:

☐ Death - include date(dd/mmm/year):_____

☐ Life Threatening

☐ Inpatient hospitalization – initial or prolonged

☐ Persistent or significant disability

☐ Congenital anomaly or Birth defect

Date of Event (dd/mmm/year):_____

Date of this Report (dd/mmm/year):_____

Describe Event:_____

_____

_____

_____

Preexisting Medical Conditions (Allergies, pregnancy, smoking, alcohol use, liver/kidney problems, etc.):

_____

_____

_____

_____

List of medication currently taking:_____

_____

_____

_____

Attachment 18

16B

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: Empower Pharmacy

Physical Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip Code: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Toll Free Number: (877) 562-8577 (Required per NAC 639.708)

E-mail: shaunnoorian@gmail.com Website: empowerpharmacy.com

Supervising Pharmacist: Jordan Cuccia Nevada License #: ~~Pending~~ 20531 ✓ 10/31/21

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

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3011887629

Please provide the name of the facility as registered with the FDA and the registration number:
Empower Pharmacy / 3011887629

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Empower Pharmacy

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Jordan Cuccia Nevada License Number: 20531

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

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

Shaun Noorian
Print Name of Authorized Person

5/18/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Texas

Parent Company if any: Empower Clinic Services, LLC

Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Contact Person: Shaun Noorian

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Shaun Noorian 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1

3) What was the price paid per share? $25,000

4) What date did the corporation actually receive the cash assets? 1/14/2009

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

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

EMPOWER PHARMACY
5980 W SAM HOUSTON PKY N STE 300
HOUSTON TX 77041

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

EMPOWER CLINIC SERVICES LLC DBA
EMPOWER PHARMACY
5980 W SAM HOUSTON PKY N STE 300
HOUSTON, TX 77041

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

PRESCRIPTION DRUG MANUFACTURER

License # 1001983
Expires: July 6, 2022

NON-TRANSFERABLE

Commissioner

513228

Re: Ownership

Company Name: Empower Clinic Services, LLC
Doing Business As: Empower Pharmacy

Name: Shaun Noorian
DOB: 05/13/1983
Titles: CEO, Business owner, LLC manager, LLC officer, Sole shareholder
Residential Address: [redacted] Kelliwood Oaks Dr, Katy, TX 77450
Business Address: 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041
Business Phone: (832) 678-4417
Home Phone: [redacted]
Ownership: 100%

Franchise Tax Account Status

As of : 05/07/2021 13:18:57

This page is valid for most business transactions but is not sufficient for filings with the Secretary of State

EMPOWER CLINIC SERVICES, L.L.C.

Texas Taxpayer Number	32038504513
Mailing Address	5980 W SAM HOUSTON PKWY N STE 300 HOUSTON, TX 77041-5251
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	12/12/2008
Texas SOS File Number	0801062724
Registered Agent Name	SHAUN NOORIAN
Registered Office Street Address	5980 W SAM HOUSTON PKWY N STE 300 HOUSTON, TX 77041

Maria Herrera

From: Shaun Noorian <[redacted]
Sent: Friday, May 7, 2021 1:40 PM
To: Maria Herrera
Subject: Re: Nevada Board of Pharmacy - Application (Empower Pharmacy)
Attachments: Taxable Entity Search Results.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Hello Maria,

I spoke with a representative from the Texas Secretary of State and they confirmed that they no longer use Certificates of Account Status. This document has been replaced with the Taxable Entity Search. I attached an additional document showing the results of this public Taxable Entity Search that shows that we are current with all state franchise taxes. Please let me know if there's anything else I can get for you.

Thanks,

Shaun Noorian Founder & CEO
Mobile: [redacted]
Empower Pharmacy *Expanding Access.*

On Fri, May 7, 2021 at 10:02 AM Maria Herrera <m.herrera@pharmacy.nv.gov> wrote:

Hi Shaun,

Mark asked me to finalize a few applications to get them set on the scheduled June Board Meeting, and I came upon yours. The only thing we were not sure of is the Certificate of Good Standing you provided has "Certificate of Fact" written on it and it does not state "Certificate of Good Standing" or that all documents and fees have been paid with the Secretary of State? is this one in the same in Texas? Can you provide something from the state of Texas stating that this is One in the same?

Thank you,

Maria Herrera

Licensing Specialist

Nevada State Board of Pharmacy

MEMBERSHIP LISTING

	NAME OF MEMBER	PLACE OF RESIDENCE	TIME BECAME OWNER	CERTIFICATES ISSUED		FROM WHOM CERTIFICATES WERE TRANSFERRED (If Original Issue Enter As Such)	
				CERTIF. NOS.	MEMBERSHIP %		
	Shaun Noorian	[redacted] Kelliwood Oaks Dr Katy, TX 77450	12/12/08	00	100	Original	
A							
B							
C							
D							
E							
F							
G							

CERTIFICATE No. 00

ISSUED TO

RECEIVED CERTIFICATE No. _____ NAME _____

DATED Jan 14, 2009 FOR 100 PERCENTAGE INTEREST ADDRESS _____

ON _____

00 | ORGANIZED UNDER THE LAWS OF THE STATE OF TEXAS | PERCENTAGE INTEREST 100

Percentage Interest

Empower Clinic Services, L.L.C.

A LIMITED LIABILITY COMPANY

This Certifies That Shaun Noorian *is the owner*

of 100 *Percentage Interest of the above Limited Liability Company transferable only on the books of the Limited Liability Company by the holder hereof in person or by duly authorized attorney upon surrender of this Certificate properly endorsed, and is entitled to the full benefits and privileges of such membership subject to the duties and obligations, as more fully set forth in the Company's Certificate of Formation/Operating Agreement/Regulations for this Limited Liability Company. Transfer of this Percentage Interest is subject to restrictions in the books of the Limited Liability Company.*

In Witness Whereof, *The said Limited Liability Company has caused this Certificate to be executed by its duly authorized Member(s)/Manager(s) and its Limited Liability Company Seal to be hereunto affixed, this* 14th *day of* Jan *A.D.,* 2009

Shaun Noorian

Shaun Noorian

©FASTKIT

This Document Contains Security Features See back For Details

2763

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

Date of this notice: 12-19-2008

Employer Identification Number:
26-3899110

Form: SS-4

Number of this notice: CP 575 A

EMPOWER CLINIC SERVICES LLC
SHAUN NOORIAN MBR
1402 KELLIWOOD OAKS DR
KATY, TX 77450

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 26-3899110. 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 941	04/30/2009
Form 940	01/31/2010
Form 1065	04/15/2009

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.

(IRS USE ONLY) 575A 12-19-2008 EMPO B 9999999999 SS-4

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* and Publication 4248, *EFTPS (Brochure)*. If you need to make a deposit before you receive your Welcome Package, please visit an IRS taxpayer assistance center to obtain a Federal Tax Deposit Coupon, Form 8109-B. To locate the taxpayer assistance center nearest you, visit the IRS Web site at http://www.irs.gov/localcontacts/index.html. Note: You will not be able to obtain Form 8109-B by calling 1-800-829-TAXFORMS (1-800-829-3676).

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 (payroll service providers) are available to assist you. Visit the IRS Web site at www.irs.gov for a list of companies that offer IRS e-file for business products and services. The list provides addresses, telephone numbers, and links to their Web sites.

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.

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.**
* 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.

If you have questions about your EIN, you can call us at the phone number or write to us at the address shown at the top of this notice. If you write, please tear off the stub at the bottom of this notice and send it along with your letter. If you do not need to write us, do not complete and return the stub. Thank you for your cooperation.

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: 12-19-2008
EMPLOYER IDENTIFICATION NUMBER: 26-3899110
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

EMPOWER CLINIC SERVICES LLC
SHAUN NOORIAN MBR
1402 KELLIWOOD OAKS DR
KATY, TX 77450

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Empower Pharmacy (99-7594)	)	**Case No. 1510**
5980 W. Sam Houston Pkwy, Ste 300	)	
Houston, TX 77041	)	

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on June 13, 2018, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams, and Whitehead were present. President Whitehead presided. John M. Settle, Assistant Attorney General, served as prosecutor for the Board. Respondent appeared and was represented by legal counsel, Doug Rice of Derryberry & Naifeh, LLP.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of the right to contest the allegations of the Complaint herein, to cross-examine witnesses, and to present witnesses and evidence in defense of the allegations of the Complaint. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent is licensed as a non-resident pharmacy in the State of Oklahoma and is located at 5980 W. Sam Houston Pkwy, Ste 300, Houston, TX 77041. Souchinda Nanthavongdouangsy, D.Ph. #15854, is Respondent's pharmacist-in-charge.

2. Respondent compounded the following products that the Board alleges are commercially available or essentially copies of commercially available FDA-approved drug products under Oklahoma law:

HCG 11,000 units/vial & units/vial kits	#287 prescriptions
HCG 5,000 units/vial & units/vial kits	#85 prescriptions

HCG injection in 5,000 units per vial is commercially available. HCG injection in 11,000 units per vial is essentially a copy of the HCG 10,000 units/vial.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondent has neither admitted nor denied violating OAC 535:15-10-53(a) by compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product, as set forth in Counts 1 through 372 of the First Amended Complaint.

4. Pursuant to 59 O.S. §353.7(12), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

AGREED ORDER

1. Respondent, Empower Pharmacy, a non-resident pharmacy in the State of Oklahoma and holder of non-resident pharmacy license number 99-7594, neither admits nor denies guilt on all Three Hundred Seventy-two (372) Counts. In order to resolve this dispute outside of a hearing on the merits, however, Respondent agrees as follows:

2. Respondent is hereby fined One Hundred and no/100 Dollars ($100.00) for each Count 1 through 372 of the Complaint for a total fine on said Counts 1 through 372 of Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00).

3. The total amount of fines due from Respondent is Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00). This fine is due on June 13, 2018.

4. This Agreed Order is not considered "discipline" by the Board, but instead is a deferral of the same pending a probationary period of two years. After a period of two years, any discipline by the Board shall be suspended unless Respondent has violated this Agreed Order, or any Oklahoma Board of Pharmacy rule. This deferred penalty is intended to ensure continued compliance with the Oklahoma Board of Pharmacy rules.

5. Failure of Respondent to abide by any of the terms of this Agreed Order could result in disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

6. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

Kyle Whitehead, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 13th day of June, 2018.

[SEAL]

Melissa Reichert
Notary Public

My Commission Expires: 3/13/22

Commission No: 18002597

I, Shaun Noorian, Founder and Chief Executive Officer, of Empower Pharmacy, have read the above Agreed Findings of Fact, Conclusions of Law and Agreed Order. I understand that by its terms Empower Pharmacy, will be waiving certain rights accorded under Oklahoma Law. I also understand that Empower Pharmacy, must comply with the terms and conditions of the Agreed Order or discipline will be imposed on Empower Pharmacy. On behalf of Empower Pharmacy, LLC., I agree to the above Agreed Order.

Dated this 11 **day of** June **, 2018.**

Shaun Noorian
Founder & Chief Executive Officer
Empower Pharmacy Respondent

State of Texas)
) ss.
County of Harris)

Subscribed and sworn before me on this the 11 day of June, 2018.

[SEAL]

SUSAN VAN BERGEN
Notary Public, State of Texas
Comm. Expires 02-10-2020
Notary ID 130533332

Notary Public

My Commission Expires: 02-10-2020

Commission No: 130533332

AGREED AND APPROVED:

Douglas A. Rice, OBA #16927
DERRYBERRY & NAIFEH, LLP
4800 North Lincoln Boulevard
Oklahoma City, OK 73105
Telephone: (405) 528-6569
Facsimile: (405) 528-6462
Attorney for Respondent

Notification of Stipulation and Consent Order for Informal Disposition

Empower Pharmacy entered into a Stipulation and Consent Order for Informal Disposition with the Idaho State Board of Pharmacy regarding allegations involving Empower Pharmacy's filling of prescriptions for three patients from an out-of-state prescriber that allegedly did not attain appropriate licensure from the Idaho Medical Board as defined in the Idaho Telehealth Access Act, and allegedly did not have the requisite prescriber-patient relationship prior to issuing a prescription.

In the attached Stipulation and Consent Order for Informal Disposition with Idaho, Empower did not admit or deny violating any law or the Board's rules. The Informal Disposition also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Informal Disposition is not considered discipline in Idaho. The Idaho State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the disposition with the Idaho State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Informal Disposition.

Please note, this Stipulation and Consent Order for Informal Disposition was included and communicated to The Nevada State Board of Pharmacy on 10/25/2019 regarding a new Out-of-State Pharmacy License application. The Board questioned Empower regarding this Stipulation and Consent Order for Informal Disposition during the Board's scheduled license approval meeting and had no concerns once explained, and our new Out-of-State Pharmacy License (PH04169) was approved on 12/16/2019.

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License of:	)	
	)	Case No. BOP 18-053
EMPOWER PHARMACY,	)	
Mail Service Pharmacy License No. 36411MS,	)	**STIPULATION AND**
	)	**CONSENT ORDER FOR**
Respondent.	)	**INFORMAL DISPOSITION:**
	)	**I.C. § 67-5241(1) ("Stipulation")**
	)	

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that could constitute grounds for the initiation of an administrative case against Empower Pharmacy ("Respondent"); and,

WHEREAS, the Parties wish to expeditiously settle this matter of possible administrative violations relating to non-resident pharmacies dispensing controlled substances to Idaho residents, by Informal Disposition pursuant to Idaho Code § 67-5241(1);

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED between the undersigned Parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent is a licensee of the Board and holds Mail Service Pharmacy License No. 36411MS. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho

Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

B. STIPULATED FACTS

1. Board staff's review of the PMP reports and records provided by Respondent revealed the following:

A. Idaho resident D.B. received from Respondent delivery of four (4) prescriptions fills for testosterone, a Schedule III controlled substance, which were issued in December 2016 through October 2017, by prescriber, J.S., located in Tampa, Florida.

B. Idaho resident J.S. received delivery of four (4) prescription fills for testosterone from Respondent, which were issued in October 2016 through September 2017 by prescriber, J.S., located in Tampa, Florida.

C. Idaho resident J.H. received delivery of six (6) prescription fills for testosterone from Respondent, which were issued in December 2016 through February 2018 by prescriber, J.S., located in Tampa, Florida.

2. Allegations arose from concerns of the Board that Respondent issued prescription drugs, including Schedule III controlled substances, to the above three (3) patients, based upon prescriptions which may have been invalid, the patients not having been seen in a face-to-face encounter by prescriber, J.S., in accordance with 21 U.S.C. § 829(e) prior to prescribing, and the prescriber not having been in compliance with the Idaho Telehealth Access Act, Title 54, Chapter 56, Idaho Code. Specifically, Idaho Code § 54-5703(4) requires telehealth providers to be licensed in the state of Idaho; Idaho Code § 54-5707(1) requires telehealth providers to have an established provider-patient relationship in order to issue prescription drug orders; and Idaho Code § 54-5705 requires two-way audio and visual interaction between the provider and patient.

In addition, 21 U.S.C. § 802(54) states that if telemedicine is being practiced, the patient must be in the presence of an onsite practitioner who possesses a valid DEA controlled substance registration and state license, and Idaho Code § 37-2716(a) requires the distant provider to hold a state controlled substance registration in the state where the patient is located.

3. Respondent asserts that the prescriber, J.S., advised Respondent that he had seen these three (3) patients in Florida, prior to prescribing for them, in accordance with 21 U.S.C. § 829(e).

4. Respondent admits that its business practices are subject to the following statutes and rules: Idaho Code §§ 54-1726(1)(f) and (2), 54-1728(1)(f) and (2), 37-2718(a)(4), 37-2719(c), 37-2722(c), 37-2723, 37-2730A(2), 37-2733(a)(1); and IDAPA 27.01.01.110 and 27.01.01.501.

5. Without Respondent admitting or denying that facts support a basis for discipline, and in lieu thereof, the Parties agree to an Informal Disposition pursuant to Idaho Code § 67-5241(1), as settlement and compromise, which shall not be deemed admitting to any acts or omissions which may be alleged, and Respondent agrees, the Board may enter its final Order as set forth in Section C below.

C. STIPULATED, AGREED SETTLEMENT

1. Respondent shall pay a monetary sum of fifteen thousand dollars ($15,000).

2. This monetary sum shall become payable after the Board approves and executes its Order approving this Settlement, to be paid to the Board within 180 days of the date the Order is executed.

3. Commencing the date the Stipulation is executed by the Board, Respondent shall verify that all prescribers issuing prescriptions to Idaho residents to be filled by Respondent shall

have the required prescriber licenses and controlled substance registrations which allow the prescribers to issue prescriptions to Idaho residents. Documentation of such verifications shall be retained by Respondent for two years from the date they are obtained and shall be provided to the Board upon its written request.

4. Further, Respondent shall designate a representative of its management to whom the Board may direct its communications and inquiries and who shall be responsible for responding to such inquiries. This representative shall be designated in writing within thirty (30) days of the date the Order incorporating this Stipulation is executed.

5. Failure to comply with any of the terms of this Stipulation may result in administrative action being taken against Respondent's mail service pharmacy license.

6. All costs associated with Respondent's compliance with the terms of this Stipulation shall be borne solely by Respondent. Nothing relating to this Stipulation shall be considered a restriction of Respondent's licensure.

D. COMPLIANCE WITH STIPULATION

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority of its Order upon appeal to a district court. Thereafter, if there shall be reason to believe Respondent may have violated any terms or conditions of this Stipulation, the Executive Director of the Board may file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on such administrative complaint, any allegations of non-compliance may be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may

then be subject to discipline, up to and including suspension or revocation. Accordingly, the Board retains jurisdiction over this proceeding, until all matters are finally resolved, as set forth in this Stipulation.

3. Any additional costs and/or attorney fees incurred by the Board in any future enforcement action based upon any allegation of this Stipulation shall be borne solely by Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. The Board has jurisdiction to proceed in this matter.

2. Respondent has read the above Stipulation fully and has had the opportunity to review it with legal counsel. Respondent understands and acknowledges that, by its terms, it is waiving certain rights provided under Idaho law.

3. Respondent acknowledges that, should the Board have brought a formal complaint in this matter, Respondent would have had certain rights, including but not limited to: the right to a full and complete hearing, pursuant to the Idaho Administrative Procedure Act; the right to confront and to cross examine witnesses; the right to present evidence, to call witnesses and to testify on its own behalf; the right to administrative reconsideration; the right to appeal any findings to the district court; and, any and other rights provided pursuant to the Idaho Administrative Procedure Act, statutes and rules governing the practice of pharmacy in Idaho, and otherwise as may be applicable pursuant to law. By entering into this Stipulation, Respondent agrees to forgo such rights and process and to waive same as part of the resolution of any allegations which may obtain.

4. Respondent understands that in signing this Stipulation, it agrees to the above terms without further process.

5. Respondent understands that, if approved as proposed, the Board shall execute and issue this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), according to the aforementioned terms, and Respondent agrees to the above Stipulation for settlement of all allegations, which allegations are contested and which Respondent denies. If the Board approves this Stipulation subject to changes, and those changes are acceptable to Respondent, Respondent acknowledges the Stipulation shall take effect, and an order modifying the terms of the Stipulation shall be issued. If the changes are unacceptable, or the Board rejects this Stipulation, this Stipulation shall be of no force or effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation shall not be admissible at any subsequent administrative hearing.

6. In the event this Stipulation is rejected by the Board, or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative proceedings, based on that the Board had considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the Parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or

otherwise.

10. This Stipulation shall be presented by the Executive Director of the Board and the Deputy Attorney General responsible for this matter to the Board with a recommendation for approval at the next regularly scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective, until it has been approved by a majority of the Board, and a Board member signs the attached Order.

12. Each Party shall bear its own costs and fees associated with this matter.

DATED this 2nd day of July, 2019.

EMPOWER PHARMACY

By: _____

Printed: Shaun Noorian

Its: CEO

Authorized Representative for Respondent

I concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend that the Board adopt the same by its Order.

DATED this 3 day of July, 2019.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

STEVEN L. OLSEN
Deputy Attorney General

I also concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend the Board adopt the same by its Order.

DATED this 9th day of July, 2019.

IDAHO BOARD OF PHARMACY

By: Nicole Chopski
Nicole Chopski, PharmD
Executive Director

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), and it is hereby Ordered that the Parties shall comply with said terms and conditions.

DATED this 15 day of August, 2019.

Holly Henggeler, PharmD
Board Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of [illegible], 2019, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER FOR INFORMAL DISPOSITION: I.C. § 67-5241(1) ("Stipulation") by the following method to:

Ms. Souchinda Nanthavongdouangay
Empower Pharmacy
5980 W. Sam Houston Pkwy N, Suite 300
Houston, TX 77041

- ☒ U.S. Mail
- ☐ Hand Delivery
- ☒ Certified Mail, Return Receipt Requested
- ☐ Overnight Mail
- ☐ Facsimile:

Steven L. Olsen
Deputy Attorney General
Civil Litigation Division
P. O. Box 83720
Boise, ID 83720-0010

- ☐ U.S. Mail
- ☐ Hand Delivery
- ☐ Overnight Mail
- ☐ Facsimile:
- ☒ Email: steven.olsen@ag.idaho.gov
  colleen.funk@ag.idaho.gov

[signature]
Ellen Mitchell
Investigations Support Coordinator

Notification of Agreed Order

Empower Pharmacy entered into an Agreed Order with the Oklahoma State Board of Pharmacy regarding allegations involving the compounding of what the Oklahoma State Board of Pharmacy considered essential copies under Oklahoma law. Please note that our home state Board, the Texas State Board of Pharmacy, did not consider these compounds essential copies (see attached). FDA also did not consider these compounds essential copies by their final guidance issued in January 2018 (see attached) and evidenced through FDA's most recent inspection of Empower Pharmacy in January 2018.

In the attached Agreed Order with Oklahoma, Empower did not admit or deny violating any law or the Board's rules. The Agreed Order also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Agreed Order is not considered discipline in Oklahoma. The Oklahoma State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the agreement with the Oklahoma State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Agreed Order.

Please note, this Agreed Order was included and communicated to The Nevada State Board of Pharmacy on 10/25/2019 regarding a new Out-of-State Pharmacy License application. The Board questioned Empower regarding this Agreed Order during the Board's scheduled license approval meeting and had no concerns once explained, and our new Out-of-State Pharmacy License (PH04169) was approved on 12/16/2019.

TEXAS STATE BOARD OF PHARMACY

December 19, 2018

Empower Pharmacy
c/o Souchinda Nanthavongdouangsy, R.Ph.
Pharmacist-in-Charge
5980 W Sam Houston Pkwy N, Ste 300
Houston, TX 77041

RE: Empower Pharmacy, License #26444
Complaint #2019-00426

The Texas State Board of Pharmacy (Board) received a copy of the Agreed Findings of Fact, Conclusions of Law and Final Order of the Oklahoma State Board of Pharmacy entered June 13, 2018, which imposed a non-disciplinary deferral of probation against the license and a $37,200 fine. The Order of the Oklahoma State Board of Pharmacy references allegations the pharmacy compounded commercially available medication and medication that was essentially a copy of a commercially available product. This violation is addressed in Section 565.002(a)(3) of the Texas Pharmacy Act, Tex. Occ. Code Ann., Title 3, Subtitle J; and Section 291.133(d)(1)(C) and (D) of the Texas Pharmacy Board Rules, 22. Tex. Admin. Code.

Following Board staff's review of this matter, this complaint was closed with this letter specifically notifying you of applicable Texas pharmacy law and rules. A copy of the referenced pharmacy laws and rules are attached for your review. Board staff encourages you to develop and implement policies and procedures to ensure compliance with pharmacy compounding requirements. If additional information indicates you may have violated Texas laws, the laws of another state, or the United States, you may be subject to further review and action by the Board.

A reply to this letter is not required. If you choose to reply, please include the complaint number listed above in your written reply.

Sincerely,

David Meryman
Compliance Analyst

DM/hh

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Componnding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. For policies pertaining to repackaged drug products, see FDA's guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:[3]

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."[4]

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."[5]

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

[3] In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

[4] See section 503A(b)(1)(D).

[5] See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription.[6] Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

[6] Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.[7] This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is *essentially a copy of a commercially available drug product:* if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.[8]

[7] See section 503A(b)(1)(D).

[8] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) *commercially available drug product*, (2) *essentially a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed[9] or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.[10] A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

---

However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

[9] FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

[10] See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

- the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are *essentially* copies of a commercially available drug product – not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed.[11]

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[12] When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product *essentially a copy,* unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient.

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

[11] U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[12] Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3.

CGMP requirements).[13] In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose.[14]

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).[15] In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

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[13] *See* note 11.

[14] If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

[15] See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.[16]

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.[17]

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. Documentation of Shortage

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked.[18]

4. Regularly or in Inordinate Amounts

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

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[16] Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products." *See* the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[17] See section IV of this guidance.

[18] See section IV of this guidance.

product.[19] FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered *commercially available* if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient.
Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a prescription for the drug product that is essentially a copy without making a determination that there is a change that will produce a significant difference for a patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

[19] See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.[20] As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.[21]

FDA recommends that compounders maintain the records described above for a period of at least three years.

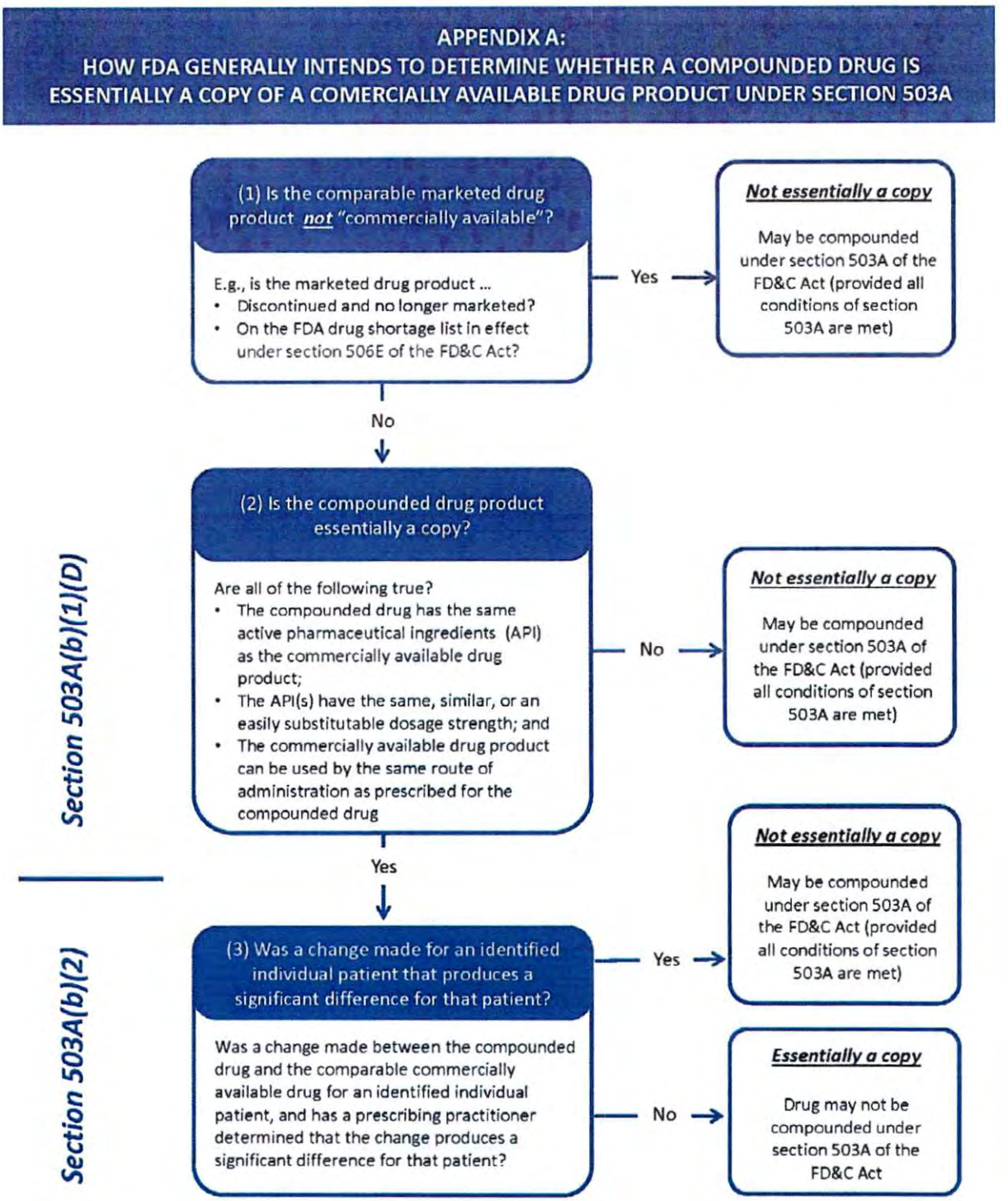
IV. PAPERWORK REDUCTION ACT

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

[20] For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

[21] See section IV of this guidance.

APPENDIX A.


APPENDIX A:
HOW FDA GENERALLY INTENDS TO DETERMINE WHETHER A COMPOUNDED DRUG IS ESSENTIALLY A COPY OF A COMERCIALLY AVAILABLE DRUG PRODUCT UNDER SECTION 503A
(1) Is the comparable marketed drug product not "commercially available"?
E.g., is the marketed drug product ...
• Discontinued and no longer marketed?
• On the FDA drug shortage list in effect under section 506E of the FD&C Act?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Section 503A(b)(1)(D)
(2) Is the compounded drug product essentially a copy?
Are all of the following true?
• The compounded drug has the same active pharmaceutical ingredients (API) as the commercially available drug product;
• The API(s) have the same, similar, or an easily substitutable dosage strength; and
• The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug
No
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
Yes
Section 503A(b)(2)
(3) Was a change made for an identified individual patient that produces a significant difference for that patient?
Was a change made between the compounded drug and the comparable commercially available drug for an identified individual patient, and has a prescribing practitioner determined that the change produces a significant difference for that patient?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Essentially a copy
Drug may not be compounded under section 503A of the FD&C Act

DEPARTMENT OF STATE HEALTH SERVICES
P.O. Box 149347
Austin, Texas 78714-9347

No. 06-1307

Date: 11/07/18

Firm Name Empower Pharmacy

Classification Prescription Drug Manufacturer/503B Outsourcing Facility

Person Contacted Mr. Arta Shaun Noorian Title Founder & CEO

City Houston Address 5980 W Sam Houston Pkwy N, Suite 300

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

1. Routine calibration and inspection of electronic equipment is not performed according to a written program designed to assure proper performance. For example,
   a. Your firm lacks a written program designed to ensure proper performance of the LyoMac Freeze Dryer system (Model #LyoPro-2-CIP-SIP, Serial #2015-001) that is used in lyophilization of drug products such as the following: Sermorelin Acetate and Ipamorelin Acetate.
   b. Non-critical equipment is not calibrated annually by contract providers. Specifically, the following pieces of equipment were last calibrated 10/25/17 and were due for calibration in October 2018:
      i. Reliance 680PG Pharmaceutical Grade Washer, Serial Number 3630411001
      *calibration in process of completion as of 11/07/18
      ii. Finn-Aqua Autoclave, 999-N-D-B-BPS-A, Serial Number COA43185
      *corrected and verified
      iii. Finn-Aqua Pure Steam Generator T-Series, 450 T-AB, Serial Number COA42465
      *corrected and verified

2. The roles and responsibilities applicable to the quality control unit (QCU) are not in writing.

Signature of Firm Representative

State Food and Drug Inspector(s)
Elizabeth Richter/Tricia Green

CEO
Title

Sample No. N/A
(If collected)

DEPARTMENT OF STATE HEALTH SERVICES
P.O. Box 149347
Austin, Texas 78714-9347

No. 06-1307

Date: 11/07/18

Firm Name Empower Pharmacy

Classification Prescription Drug Manufacturer/503B Outsourcing Facility

Person Contacted Mr. Arta Shaun Noorian Title Founder & CEO

City Houston Address 5980 W Sam Houston Pkwy N, Suite 300

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

3. Written procedures are not established for quality standard evaluations for each drug product to determine the need for changes in product specifications and/or control procedures. Specifically, your firm manufactures and distributes compounded sterile products, included but not limited to the following, and there is no documentation that product reviews are periodically completed:
   a. Cyanocobalamin 2,000MCG/ML injectable (30ML)
   b. Testosterone Cypionate in Grapeseed Oil 200MG/ML (30ML)

Signature of Firm Representative

State Food and Drug Inspector(s)
Elizabeth Richter/Tricia Green

CEO
Title

Sample No. N/A
(If collected)

TEXAS STATE BOARD OF PHARMACY

December 19, 2018

Empower Pharmacy
c/o Souchinda Nanthavongdouangsy, R.Ph.
Pharmacist-in-Charge
5980 W Sam Houston Pkwy N, Ste 300
Houston, TX 77041

RE: Empower Pharmacy, License #26444
Complaint #2019-00426

The Texas State Board of Pharmacy (Board) received a copy of the Agreed Findings of Fact, Conclusions of Law and Final Order of the Oklahoma State Board of Pharmacy entered June 13, 2018, which imposed a non-disciplinary deferral of probation against the license and a $37,200 fine. The Order of the Oklahoma State Board of Pharmacy references allegations the pharmacy compounded commercially available medication and medication that was essentially a copy of a commercially available product. This violation is addressed in Section 565.002(a)(3) of the Texas Pharmacy Act, Tex. Occ. Code Ann., Title 3, Subtitle J; and Section 291.133(d)(1)(C) and (D) of the Texas Pharmacy Board Rules, 22. Tex. Admin. Code.

Following Board staff's review of this matter, this complaint was closed with this letter specifically notifying you of applicable Texas pharmacy law and rules. A copy of the referenced pharmacy laws and rules are attached for your review. Board staff encourages you to develop and implement policies and procedures to ensure compliance with pharmacy compounding requirements. If additional information indicates you may have violated Texas laws, the laws of another state, or the United States, you may be subject to further review and action by the Board.

A reply to this letter is not required. If you choose to reply, please include the complaint number listed above in your written reply.

Sincerely,

David Meryman
Compliance Analyst

DM/hh

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* For policies pertaining to repackaged drug products, see FDA's guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.*

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Contains Nonbinding Recommendations

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:[3]

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."[4]

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."[5]

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

[3] In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

[4] See section 503A(b)(1)(D).

[5] See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription.[6] Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

[6] Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.[7] This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is *essentially a copy of a commercially available drug product:* if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.[8]

[7] See section 503A(b)(1)(D).

[8] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) *commercially available drug product*, (2) *essentially a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed[9] or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.[10] A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

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However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

[9] FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

[10] See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

- the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are *essentially* copies of a commercially available drug product – not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed.[11]

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[12] When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product *essentially a copy,* unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient.

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

[11] U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[12] Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3.

CGMP requirements).[13] In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose.[14]

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).[15] In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

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[13] *See* note 11.

[14] If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

[15] See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.[16]

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.[17]

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. *Documentation of Shortage*

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked.[18]

4. *Regularly or in Inordinate Amounts*

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

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[16] Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products." *See* the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[17] See section IV of this guidance.

[18] See section IV of this guidance.

product.[19] FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered *commercially available* if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient.
Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a prescription for the drug product that is essentially a copy without making a determination that there is a change that will produce a significant difference for a patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

[19] See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.[20] As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.[21]

FDA recommends that compounders maintain the records described above for a period of at least three years.

IV. PAPERWORK REDUCTION ACT

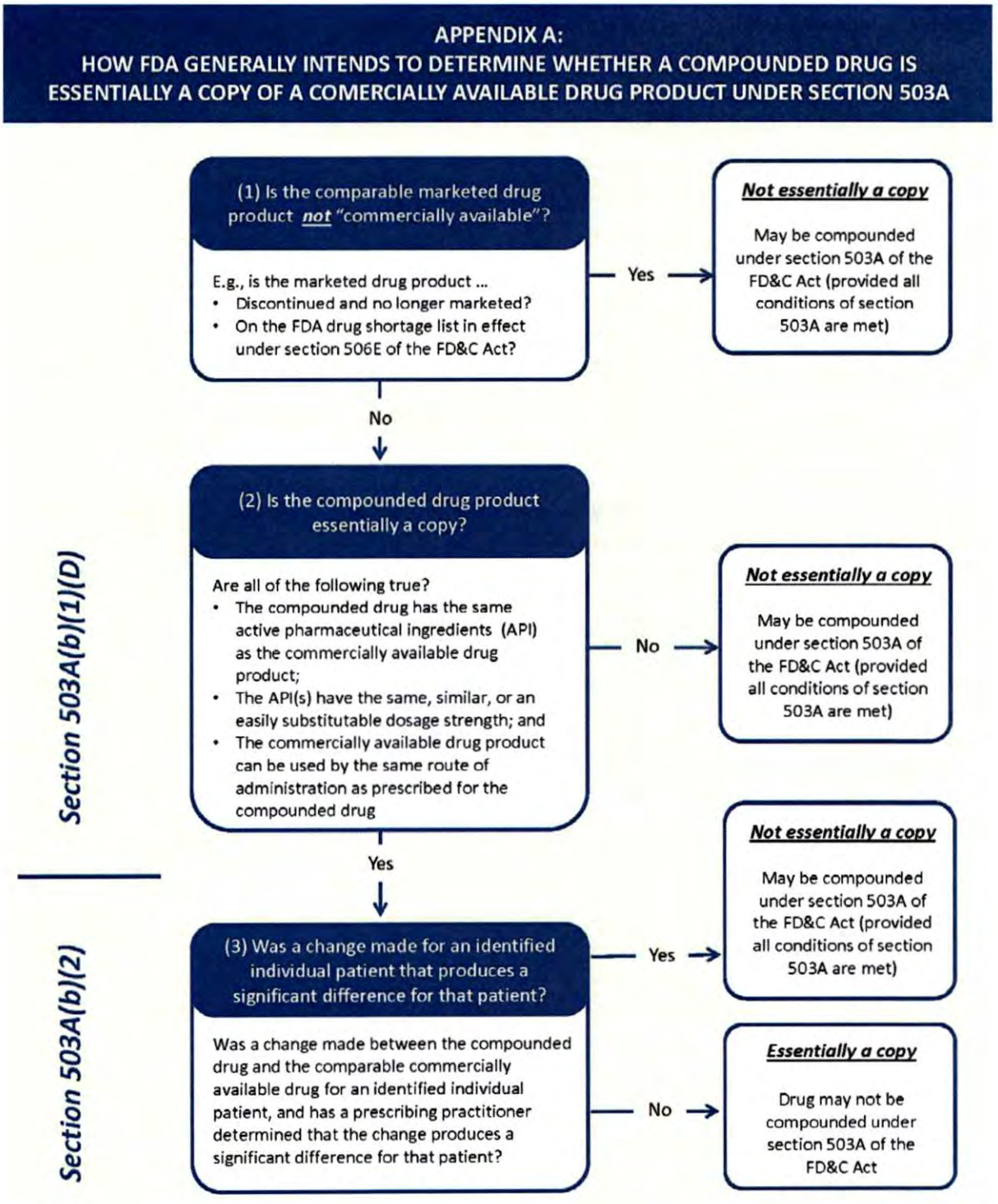
This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

[20] For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

[21] See section IV of this guidance.

Contains Nonbinding Recommendations

APPENDIX A.



TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

2820

CLASS: A (A-S) B C C-S (BEDS____) D Other_____

Name of Pharmacy EM Power Pharmacy
Pharmacist in Charge Souchi NANTHAVONGDOUANGSY
Personnel

TSBP License # 26444
Lic 425 24 Exp 4/30/20
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline. √ items in Column Two receive a Warning Notice (W/N).

For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4	✓	Balance Failed
	5		Equipment Inspection 21 Bromocas
	6		Inadequate Library
	7		Improper security
	8		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	47		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	61		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	76		No PIC
	34		Notification Violation
	79		Nametags
	60		Improper documentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory 5-11-18 Cont
	15		No PIC inventory
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	17		Incomplete inventory
	18		Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24		Theft/Loss not reported N/D
	30		Invoices not dated/initialed
	86		Absence of RPh pick up records
	19		Rx lacks proper information
	25		No documentation of refill authorization
	32		Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80		No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21		Computer records incomplete
	22		Computer system noncompliance
	82		PMR Incomplete
	83		PMR Absent
	84		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	(71)		Incomplete P&P manual
	72		Improper procedures for IV preparation
	81		Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87		Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	63		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Remarks

Advised to update written security P5 & P55

It Appears that the three broken balances were removed from operation to be sent for Repair.

Action Taken

(1) ✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

April 12, 2019
Date

_____
Time of Exit

Souchinda Nanthavongdouangsy, PIC, 42524
Printed Name and Title of Authorized Individual

Texas State Board of Pharmacy

Inspection Report for Pharmacies Compounding Sterile Preparations

Circle One: **Class A-S** Class B Class C-S

Name of Pharmacy EMPOWER PHARMACY TSBP License # 26444

Deficiency key: Circled items need improvement (N/I); Refer to Legal Division (R/L) for review and possible discipline; and Warning Notices (W/N) require corrective action within a designated timeframe. For an explanation of specific violations noted, refer to remarks section of inspection report. Note: "M" = Multiple Codes

R/L	Code	W/N	
			Environment
	M		Is cleanroom clean/free of objects that shed particles? (109) Contain only appropriate supplies? (119) Used only for sterile preps? (110)
	M		Does ante-area provide at least ISO Class 8 under dynamic conditions? (101) Contain a hands-free sink with hot/cold running water? (115)
	M		Does buffer area provide at least ISO Class 7 under dynamic conditions? (102) Area free from sources of water (e.g., sink/floor drains)? (106)
	108		Is there hands-free access to the buffer area?
	113		Are floors, walls, ceilings & fixtures smooth/impervious and free from cracks & crevices? Does floor covering enable regular disinfection (112)?
	118		Are supplies stored above the floor to permit adequate floor cleaning?
	127		Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area/room and ante-area/room and between the ante-area/room and the general environment? Pressure between ISO 7 & general environment shall not be less than 0.02" water column.
	M		Are temperature and humidity monitored (documented) and within required range? (116) Thermometer available for cleanroom and refrigerator? (167)
			Primary Engineering Control (PEC) Device - i.e., Laminar Air Flow Hood, BSC, CAI, or CACI
	126		Is the Laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02-0.05" water?
	121		Is the PEC able to maintain at least ISO Class 5 conditions, while compounding sterile preparations?
	M		Are hazardous drugs prepared in a Class II or III vertical flow **BSC** or **CACI** located in an ISO 7 area physically separated from other areas? (246) Does the BSC or CACI have not less than 0.01" negative pressure adjacent to the positive pressure ISO 7 environment? (247)
	M		Does the **CAI** provide unidirectional flow? (105) If the **CAI** or **CACI** is used for high risk compounded sterile preparations, then is the CAI/CACI placed in an ISO 8 environment? (104)
	122		If the CAI is not required to be placed in an ISO 7 environment, does the pharmacy maintain documentation from the manufacturer?
	M		PEC certified by independent contractor every 6 months & when relocated? (124) Are prefilters inspected periodically & replaced as needed? (125)
	128		Are differential pressures monitored and documented at least every work shift (minimum daily) or by a continuous recording device?
			Equipment and Supplies
	M		Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? (174) Does the pharmacy have lint-free towels or wipes? (177) Does the pharmacy have masks, caps, gowns with tight cuffs, shoe covers, and beard covers? (180)
	M		Does pharmacy have handwashing agents w/ bactericidal action? (176) Disinfectant cleaning solutions and dedicated cleaning supplies? (175)
	M		Does the pharmacy have hazardous spill kits, if applicable (179)? Appropriate disposal containers for needles and syringes? (171)
	170		Does the pharmacy have sterile IPA, sterile gloves, and waterless alcohol-based surgical hand scrub?
	178		Does the pharmacy have appropriate filters and filtration equipment?
	181		If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy on a daily basis-Is it documented?
	172		Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?
			High-Risk Sterile Preparations (CSPs)
	103		If high-risk CSPs are compounded, does buffer area provide physical separation from other compounding areas?
	M		Is sterility testing performed under the following conditions: CSPs prepared in groups > 25? (231); MDV prepared for multiple pts or when exposed > 12 hrs at 2-8°C before sterilized? (232); Exposed > 6 hrs at warmer than 8° C before sterilized? (233)
	237		Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen free water, and then thoroughly drained or dried immediately before use for high-risk compounding?
	238		Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2 micron filter to remove particulate matter? Sterilization by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer pore size filter within an ISO Class 5 environment or better.
	165		Are filter integrity tests being performed and documented (e.g., bubble point)?
	239		Are pre-sterilization procedures (weighing & mixing) completed in an ISO Class 8 environment or better?
			Library
	M		Does the pharmacy have: Reference on injectable drugs (154), Specialty Reference (155), Applicable USP Chapters (156)?

R/L Code W/N

			Hazardous Sterile Preparations
	M		Do personnel wear protective apparel (242); use safety/containment techniques (243); dispose of waste appropriately (244); affix proper label (245)?
	248		If using a BSC or CACI, does pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?
	249		Does pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment?
	250		Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?
			Personnel Cleansing, Garbing and Hand Hygiene
	M		Does hand sanitizing and gowning occur in the ante-area (outside the buffer area)? (202) Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around wrist and enclosed at the neck. Is the order of garbing appropriate? (180)
	M		Do personnel remove: cosmetics (194); hand, wrist, and body jewelry or piercings (195); Are natural nails kept neat and trim (no artificial nails)? (196) Do personnel remove debris underneath fingernails using nail cleaner under warm water? (200)
	192		Are personnel with apparent illness or open lesions compounding sterile preparations?
	241		When personnel temporarily exit the ISO 7 environment, are re-donning procedures properly followed?
	M		Do personnel engage in proper hand hygiene? (201) Do personnel dry hands and forearms using lint-free disposable towels or hand-dryer? (203)
	204		Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside buffer area & prior to donning sterile gloves?
	206		Is sterile IPA applied to gloves throughout the day & when non-sterile surfaces are touched?
			Cleaning and Disinfection Procedures
	182		Does pharmacy have written procedures regarding cleaning & disinfecting (e.g., beginning of shift; every 30 minutes; before each batch; & spills)?
	230		Is cleaning performed by trained personnel using approved agents (described in written SOPs)?
	228		Are supplies and equipment that are removed from shipping cartons wiped with a disinfecting agent - such as sterile 70% IPA?
	M		Are all areas properly cleaned? Daily (floors, DCA)? (226) Weekly, Monthly (walls, ceilings, shelving)? (227) Does pharmacy maintain documentation of cleaning procedures [i.e., date/time of cleaning, type of cleaning, and name(s) of person(s) carrying out the cleaning]? (229)
			Environmental Sampling
	M		Is surface sampling conducted in all ISO classified areas on a periodic basis? Are these results evaluated and addressed? (270) i.e. Action Levels followed? (271)
	M		Is viable air sampling performed? (272) And documented by properly trained individuals for all risk levels every 6 months? (273)
			Records of Compounded Sterile Preparations
	252		Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?
	M		Do records include: date (253); formula (254); who prepared (255); who checked (256); quantity (257); container used and number of units prepared (258); criteria for BUD (259); and documentation of performance of quality control procedures? (260) Other?
	M		Are batch compounding records complete? (261) Are master worksheets developed and approved by RPh (262)?
			General Operational Requirements
	166		Is RPh available at all times (24/7)?
	M		Are written SOPs followed to ensure accountability, accuracy, quality, safety, and uniformity? (187) Does pharmacy have all required written procedures (e.g., pharmaceutical care services, viable air sampling plan, and recalls)? Does pharmacy follow recall procedures? (188)
	158		If pharmacy compounds commercially available products, does pharmacy meet requirements for such compounding?
	275		Does pharmacy dispense prescriptions to patients in other states without proper licensure in those states?
			Office Use Compounding/Distribution
	163		Does pharmacy have written agreement with prescriber? Does written agreement meet all requirements?
	162		If pharmacy is distributing compounded sterile preparations to another pharmacy, does pharmacy meet requirements for such distribution?
			Quality Control and Verification of Compounding Accuracy
	M		Does a RPh review all compounding records for accuracy and perform final check? (207) Are periodic in-process checks defined in written procedures? (185)
	191		Are all drug components manufactured in an FDA-registered facility? Are Certificates of Analysis available, if applicable?
			Label
	M		Is CSP properly labeled to include: generic name (209); compounded by pharmacy (210); BUD (211) If prepared in batch, do labels contain: unique lot# (213); quantity (214); cautionary statements (215); and device-specific instructions, if applicable (216)?
	220		Are CSPs assigned a beyond-use-date that is based upon the specified labeling for the drug, appropriate literature sources, and/or direct testing?
			Training and Competency Testing
	129		Has each pharmacist completed the required education and training prior to engaging in sterile compounding?
	130		Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?
	142		Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g., media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?
	144		Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel?

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, Texas 78701
(512) 305-8000

WARNING NOTICE OF VIOLATION(S) REQUIRING CORRECTION

Name of Pharmacy	Empower Pharmacy
Pharmacy License Number 26444	Date of Inspection April 17, 2019

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.

Signed: [signature] **Date:** 4/17/2019

1. ***Law/Rule:*** 291.10(c)(2) ***Code:*** 4

Explanation of Violation and Correction Needed:
Failure to properly maintain prescription balances. Either remove or replace or have reversed by the authorized person, immediately.

Due Date for Completed Correction: May 17, 2019

2. ***Law/Rule:*** _____ ***Code:*** _____

Explanation of Violation and Correction Needed:

Due Date for Completed Correction: _____

TEXAS STATE BOARD OF PHARMACY

Pharmacist-in-Charge Attestation:

I hereby attest the following statements are true and accurate (*initial each statement below*):

SN I am the Pharmacist-in-Charge (PIC) of Empower Pharmacy (*Name of Pharmacy*) pharmacy license number 26444 (*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 April 17, 2019 (*Date of Inspection*);

SN I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector;

SN I reviewed the document titled *Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF* (on the reverse side of this attestation);

SN If applicable, the Warning Notice issued contains 1 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;

SN 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: _____ (*Signature of PIC*) **Date:** 4/17/2019

Printed Name: Suchinda Nuntharongdouangsy **License No.:** 42524

EmpoweRx PHARMACY

Via Email and UPS

MARCH 27, 2020

Edmundo Garcia
District Director
Food and Drug Administration, Dallas District
4040 N Central Expressway, Suite 300
Dallas, TX 75204
Email: edmundo.garcia@fda.hhs.gov
ORAPHARM2_RESPONSES@fda.hhs.gov
Attn: Monica Maxwell, Acting Program Division Director

Re: Form FDA 483 - Inspectional Observations Issued 03/06/2020

To Whom It May Concern:

This letter is in response to the Form FDA 483 – Inspectional Observations issued on March 6, 2020 at Empower Clinic Services, LLC (the Company) located at 5980 W Sam Houston Parkway N, Suite 300, Houston, TX 77041. See **Attachment # 1** for a copy of the issued Form FDA 483.

We appreciate the investigator's time in conducting a comprehensive cGMP audit of our facility over a four-week period (13 days) and welcome the opportunity to respond to the listed findings. The Company is committed to quality and regulatory compliance, taking its responsibility as a manufacturer of compounded products very seriously.

We have evaluated the issued observations and the following response reflects our current business practices and steps we will take to address FDA's observations, as applicable. This response also contains content provided to the investigator's questions during the inspection but was not included within the cited observation(s).

Respectfully,

Shaun Noorian
Founder & CEO

Enclosures

BUILDING AND FACILITIES
Observation # 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm's procedure, T06.04 Lighthouse Environmental Monitoring System, Revision 02, requires that operators document differential pressure, relative humidity, and temperature monitoring before and during sterile drug production. Your procedure fails to require the recording and/or documentation of these results as part of your firm batch record. The Sterile Temperature, Pressure, and Humidity Monitoring Logs dated 2/4/2019 through 2/28/2020 demonstrated that your firm did not always document the differential pressure, relative humidity, and temperature before and during drug production in each ISO classified area. You failed to maintain adequate environmental controls during sterile drug production.

Response to Observation # 1

This observation corresponds to 21 CFR § 211.42(c)(10)(iv) regarding Environmental Monitoring Systems:

> "(10) Aseptic processing, which includes as appropriate... (iv) A system for monitoring environmental conditions."

Per FDA's updated guidance released January 2020 titled, "Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act," lines 319 – 322:

> "An adequate control system includes monitoring for pressure differentials, humidity, and temperature during production and taking prompt action to correct adverse conditions, which are necessary activities to prevent contamination during aseptic processing."

As indicated in the observation and discussed during the inspection, the Company utilizes the Lighthouse Environmental Monitoring System as a measure to maintain adequate environmental controls before and during sterile drug production.

Per SOP T06.04, under the Introduction and Scope section:

> The Lighthouse Monitoring system is a real-time recording system that measures temperature, pressure, humidity, and non-viable particulates in real-time in the cleanroom, non-sterile compounding area, and drug storage areas. All the data is saved, and it is centrally connected to a designated Lighthouse Server.

This system is monitored by the Company's Facilities and Engineering team and reviewed by the Company's Quality Unit to ensure readings align with those documented on the Company's Sterile Temperature, Pressure, and Humidity Monitoring Log. During the inspection, examples of the pressure differential readings taken during production were provided to the investigator for review per his request. The examples were shown to be all within specification and had no issues; **thus demonstrating the Company maintains "adequate environmental controls during sterile drug production."**

With regards to the Sterile Temperature, Pressure, and Humidity Monitoring Log, this log serves as the primary method in which operators document the environmental factors and note any immediate issue within their designated area(s); however, neither this log information nor the data from Lighthouse were ever required to be included within the batch record, but instead be readily available for reference purposes only.

To address this observation, however, we have re-evaluated the requirements in our SOPs addressing the contents of batch records and made the decision to revise batch records to include the environmental factors

before and during compounding, as well as revise SOP T06.04 to specify how to document and incorporate the data captured by Lighthouse before and during compounding operations within the batch record.

See **Attachment # 2** for a copy of the revised SOP titled, "T06.04 Lighthouse Environmental Monitoring System."

See **Attachment # 3** for a copy of the revised batch record that includes the environmental factors to be recorded before, during, and immediately after filling.

See **Attachment # 4** for a copy of a Training Register addressing Observation # 1, with regards to the revised SOP and revised batch record.

==========

PRODUCTION AND PROCESS CONTROL
Observation # 2

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, your firm failed to establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products. For example, the table below shows the date production process steps were performed for selected batch records.

Drug Product Description	Lot #	Formulation Date	Sterile Filter Date 1	Sterile Filter Date 2	Fill Date (s)
Leuprolide 10mg/ml	64738	2/11/20	2/12/2020	2/15/2020	2/15/20
Glycine 50mg/ml	64619	2/10/20	2/10/20	2/14/20	2/14/20
Testosterone Cyp. In GSO (5 ml) 200 mg/ml Injectable	64579	2/11/20	2/11/20	2/14/20	2/14/20 & 2/15/20
Testosterone Cyp. In GSO (5 ml) 50 mg/ml Injectable	56796	8/21/19	8/21/19	8/28/19	8/28/19
Pyridoxine HCL (Vit B6) (30 ml) 100 mg/mL Injectable	62303	12/23/19	12/23/19	1/7/20	1/7/20

Your firm's management reported the firm has not estoblished a written hold-time procedure.

Response to Observation # 2

This observation directly corresponds to the first part of 21 CFR § 211.111, which states,

> When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product.

Based on our current process, sterilization is immediately conducted via a continuous process, specifically with a filtration step before filling into the final product container (as seen in the table above). Since this step occurs as close to filling into the final product container as is feasible, the Company determined that establishing time limits and hold times is "not appropriate" or necessary for this phase of production.

In addition, the Company also determined that it was "not appropriate" to establish time limits (or hold times) for the first filtration step since documented historical data and analytical test results for each of the finished products' specifications regarding potency, endotoxin, and sterility (which are performed for each lot

produced) have shown repeatedly to fall well within their respective acceptable tolerances and specifications, thereby validating sterility assurance of the finished product.

Regardless, to address this observation, we will develop a procedure to establish storage (or hold) times for the relevant intermediate steps by validating our first filtration step to further assure control of the microbiological content (bioburden) articles and components that are to be subsequently sterilized.

See **Attachment # 5** for a copy of the new protocol establishing in-process time limits (hold times) for relevant intermediate steps during compounding operations.

See **Attachment # 6** for a copy of a Training Register addressing Observation # 2.

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QUALITY
Observation # 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, your firm failed to adequately write and fully follow the following procedures applicable to your firm's quality unit:

A. *Your firm failed to adequately implement your firm's change control procedure, T01.05 Good Documentation Practices, Revision 03 for changes made to approved protocols. For example;*
    1. *During a review of your firm's performance qualification report, PennTech Vial Washer, Model RW-250 Performance Qualification Report, Version V 3.0 dated 6/27/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, PennTech Vial Washer, Model RW-250 Performance Qualification Protocol, Version V 3.0 dated 6/27/2019.*
    2. *During a review of your firm's performance qualification report, PennTech Tunnel Performance Qualification Report, Asset# E1078, Revision V.3 dated November 2019, Approved 11/12/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, PennTech Tunnel Performance Qualification Protocol, Asset# E1078, Revision V.3 dated November 2019, Approved 11/12/2019.*

B. *Your firm failed to adequately implement your firm's written, procedure T08.19 Investigation of Non-conformance and CAPA Issuance procedure, Revision 03. For example, during a review of your firm's performance qualification report, PennTech Tunnel Performance Qualification Report, Asset# E1078, Revision V.3 dated November 2019, Approved 11/12/2019, I found as a result of investigations into documented deviations, your firm's quality unit made changes to the acceptance criteria documented within the original protocol without obtaining your firm's management approval prior to its implementation and ultimate approval of the performance qualification.*

Response to Observation # 3
This observation directly corresponds to 21 CFR § 211.22(d), stating, "The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed."

The Company's "responsibilities and procedures applicable to the Quality Control Unit" are in writing as illustrated by the standard operating procedures and protocols provided to the investigator during the audit.

Please note that the investigator neither stated nor clearly identified the "changes" he allegedly observed within the protocols listed in both #1 and #2 of Part A of this observation. Based on the conversations with the investigator during the audit, we initiated a CAPA addressing what we understood to be the changes he meant to convey during the audit. However, after evaluating these identified "changes", we understood the adjustments made to the final report to be simple format differences to appropriately manage the results in the reporting section. Please note we understand and believe that formatting to allow for proper results documentation does not warrant a change control. However, as mentioned, to address Part A of the observation, a CAPA was initiated to review and evaluate these adjustments.

With regards to Part B, when a change to a Protocol occurs, a verbal approval is given to deviate from the Protocol template, and the specific changes made are to be appropriately documented using the Protocol's Deviation form. The Company understands and believes based on industry practice that Protocol changes allow for certain minor deviations to occur, which do not fall within the scope of a Company's deviation procedure or change control procedure.

In addition, our review of the attached Protocol shows that the acceptance criteria were not altered or changed, and the deviation from the original protocol was properly documented on the appropriate Deviation Form attached to the Protocol. Since the investigator did not provide any specific examples of the acceptance criteria "changed," and the Company did not find any change in the acceptance criteria, there is no need for change control or non-conformance to be initiated per T08.19.

To address Part B, the Company has re-evaluated our Protocol structure and included a section in the Protocol's Deviation Form requiring approval prior to implementing any change and/or deviation to a Protocol.

See **Attachment # 7** for a copy of the CAPA Executive Summary Report addressing Observation # 3, Part A.
See **Attachment # 8** for a copy of revised Deviation Form attached to the Protocols addressing Part B
See **Attachment # 9** for a copy of a Training Register addressing Observation # 3.

==========

Observation # 4

Your firm compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, a) you compound drug products that are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that ore essentially a copy of one or more approved drugs include:

A. *Human Chorionic Gonadotropin*
B. *Menotropins Injection*
C. *Leuprolide Acetate Injection*

D. Pyridoxine HCL Injection

[The investigator designated this observation to be a repeat observation.]

Response to Observation # 4

This observation directly corresponds to the Guidance for Industry dated January 2018 titled, "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

With regards to the observation, in general, the formulations listed above have each been requested for compounding by physicians/providers/purchasing agents based on a clinical need and determination of clinical difference between the commercially available drug product and the compounded formulation.

FDA's Essentially Copies Final Guidance describes this issue as follows:

> If an outsourcing facility compounds a drug, the component of which is a bulk drug substance that is a component of an approved drug, there must be a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner.

Each of the compounded formulations listed above were specifically requested by a prescriber. The Company's clinical team communicates with health care practitioners and/or their purchasing agents to obtain "Clinical Difference Statements" from the prescribers when requesting the compounded products. Empower will modify its documentation practices concerning receiving prescriptions or orders. Empower will ensure that each prescription or order (that may be otherwise considered "essentially a copy") will include a statement of clinical difference from the practitioner. The order will also include a statement or notation that the compounded formulation will be used by the practitioner for those patients with that clinical need.

Empower will further ensure that the documentation "clearly identifies the relevant change and the clinical difference that the change will produce for patient(s), as determined by the prescriber."

Most importantly, contrary to the investigator's observation, this is NOT a "repeat observation." FDA has not made this observation during or after any FDA inspection prior to this inspection.

We kindly request that the statement regarding this observation being a "repeat observation" be removed from this form FDA 483.

See **Attachment # 10** for a copy of SOP T03.36 regarding essential copy documentation procedure for 503A products.
See **Attachment # 11** for a copy of SOP T08.36 regarding essential copy documentation procedure for 503B products.

==========

Observation # 5

The containers of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a) *Information to facilitate adverse event reporting:* www.fda.gov/medwatch and 1-800-FDA-1088; *Examples of your container labels that do not contain this information:*

3. *Testosterone Cypionate 200 mg/ml Injection*
4. *Testosterone Cypionate 50mg/ml Injection*
5. *HCG 12000 IU*
6. *HCG 6000 IU*
7. *FSH 1500 IU*
8. *Menotropins (HMG) 500 IU*
9. *Ascorbic Acid Preserved 500mg/ml*
10. *Leuprolide Acetate 40MCG/0.2ml*
11. *Pyridoxine HCL (Vit B6) 100mg/ml*
12. *BCAA 30ml 15/10/40 MG/ML Injection*
13. *Taurine 50 mg/ml Injection*
14. *Omnitrope 5.8mg Injection*
15. *Glutathione Preserved 200mg/ml Injection*

Response to Observation # 5

The Drug Quality and Security Act, Title I (2013), specifically Section 503B(a)10(B)(ii), states, "B) Container.-- The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include ... the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number)."

As explained during the inspection, due to the limited space on the primary packaging, we included the information to facilitate adverse event reporting on the finished product's secondary packaging and/or an insert included within the finished product's primary packaging.

However, to address this observation, the Company has completed a change control to place the necessary information onto the primary packaging, which now includes the required adverse event reporting contact information.

NOTE: It is important to highlight that in the observation, the product listed as # 14 is **NOT** compounded by our facility. This is an FDA-approved drug product, Omnitrope® (somatropin) injection, that is dispensed directly to a patient based on a patient-specific prescription.

See **Attachment # 12** for a copy of an example of the revised product label for Glutathione Injection Preserved 200 mg/mL.

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Observation # 6

Your outsourcing facility has not submitted adverse event reports in 2019 FDA in accordance with the content and format requirements established through guidance (AE Reporting Guidance) or regulation under section 310.305 of 21 CFR.

Response to Observation # 6

This observation directly corresponds to the industry guidance document titled, "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act."

The guidance specifically states, "The regulation requires reporting of each adverse drug experience received or otherwise obtained that is both serious and unexpected...."

Per the guidance, "Section 310.305(b) defines a ***serious*** *adverse drug experience* to mean:
Any adverse drug experience occurring at any dose that results in any of the following outcomes:

- Death,
- A life-threatening adverse drug experience,
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant disability/incapacity, or
- A congenital anomaly/birth defect."

The Company is not aware of any claim and/or adverse event resulting from use of Empower's compounded formulations that would qualify as **"serious and unexpected"** and thus would *require reporting* to FDA pursuant to the guidance (AE Reporting Guidance) or regulation under 21 C.F.R. § 310.305.

This observation also fails to provide any specific examples or provide any indication that the Agency itself had received, or was aware of, any such complaint or adverse event that meets the definition of a reportable adverse drug event."

The Company is well aware of its reporting obligations, and is fully prepared to report any adverse event (as defined by applicable guidance) to FDA: specifically, "all serious [and] unexpected adverse drug experiences associated with the use of their prescription drug products (which includes any compounded drug products subject to the prescription requirements in section 503(b)(1) of the FD&C Act)."

Should the Company receive notice of or otherwise discover a serious and unexpected adverse event, the Company has a SOP outlining steps to be taken to address the situation. This SOP, titled, "T08.13 Variance Reporting and Investigation," was provided to the investigator for review.

Specifically, the Procedure (Section 5) states, "If a Serious and Unexpected ADE is discovered the below steps must be followed and reported to the FDA within **15 calendar days** of initial report."

For the reasons stated, this observation leaves Empower guessing about exactly what FDA observed concerning Empower's reporting of adverse drug events. Empower has not received any reports whatsoever where it determined the event was in fact "reportable" pursuant to either FDA's guidance or its own SOP. Empower has never received notice of a "serious and unexpected" adverse drug event.

Since FDA's observation cannot and does not address any "event" that the Company in fact failed to report, Empower respectfully requests the Agency withdraw Observation # 6.

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We want to again express our sincere appreciation for the opportunity to engage in a dialogue with the Agency concerning compliance with FDA regulations and guidance at Empower's Section 503B outsourcing facility. The Company will continue to work diligently to maintain compliance with FDA's regulations and other guidance provided by the Agency.

ATTACHMENTS

Attachment # 1:	A copy of the issued FDA 483
Attachment # 2:	A copy of revised SOP T06.04
Attachment # 3:	A copy of the revised batch record that includes the environmental factors to be recorded before, during, and immediately after filling
Attachment # 4:	A copy of a Training Register addressing Observation # 1
Attachment # 5:	A copy of the new procedure establishing in-process time limits (hold times) for the relevant intermediate step during compounding operations
Attachment # 6	A copy of a Training Register addressing Observation # 2
Attachment # 7:	A copy of the CAPA Executive Summary Report addressing Observation # 3, Part A
Attachment # 8	A copy of the revised Deviation Form attached to the Protocols addressing Observation # 3, Part B
Attachment # 9	A copy of a Training Register addressing Observation # 3
Attachment # 10:	A copy of SOP T03.36 regarding essential copy procedure for 503A products
Attachment # 11:	A copy of SOP T08.36 regarding essential copy procedure for 503B products
Attachment # 12:	A copy of an example of the corrected primary packaging for Glutathione Injection Preserved 200 mg/mL

EmpoweR PHARMACY

ATTACHMENT
1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	2/12/2020-3/6/2020* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arta Shaun Noorian, Founder & CEO

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC	5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

Building and Facilities

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm's procedure, T06.04 Lighthouse Environmental Monitoring System, Revision 02, requires that operators document differential pressure, relative humidity, and temperature monitoring before and during sterile drug production. Your procedure fails to require the recording and/or documentation of these results as part of your firm batch record. The Sterile Temperature, Pressure, and Humidity Monitoring Logs dated 2/4/2019 through 2/28/2020 demonstrated that your firm did not always document the differential pressure, relative humidity, and temperature before and during drug production in each ISO classified area. You failed to maintain adequate environmental controls during sterile drug production.

Production and Process Control

OBSERVATION 2

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 03-06-2020 10:30:30	3/6/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	2/12/2020-3/6/2020* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arta Shaun Noorian, Founder & CEO

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC	5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, your firm failed to establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products. For example, the table below shows the date production process steps were performed for selected batch records.

Drug Product Description	Lot #	Formulation Date	Sterile Filter Date 1	Sterile Filter Date 2	Fill Date (s)
Levprolide 10mg/ml	64738	2/11/20	2/12/2020	2/15/2020	2/15/20
Glycine 50mg/ml	64619	2/10/20	2/10/20	2/14/20	2/14/20
Testosterone Cyp.in GSO (5 ml) 200 mg/ml Injectable	64579	2/11/20	2/11/20	2/14/20	2/14/20 & 2/15/20
Testosterone Cyp.in GSO (5 ml) 50 mg/ml Injectable	56796	8/21/19	8/21/19	8/28/19	8/28/19
Pyridoxine HCL (Vit B6) (30 ml) 100 mg/ml Injectable	62303	12/23/19	12/23/19	1/7/20	1/7/20

Your firm's management reported the firm has not established a written hold-time procedure.

Quality

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 03-06-2020 10:30:30	3/6/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	2/12/2020-3/6/2020* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arta Shaun Noorian, Founder & CEO	
FIRM NAME Empower Clinic Services, LLC	STREET ADDRESS 5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, your firm failed to adequately write and fully follow the following procedures applicable to your firm's quality unit:

A. Your firm failed to adequately implement your firm's change control procedure, T01.05 Good Documentation Practices, Revision 03 for changes made to approved protocols. For example;
   1. During a review of your firm's performance qualification report, PennTech Vial Washer, Model RW-250 Performance Qualification Report, Version V 3.0 dated 6/27/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, PennTech Vial Washer, Model RW-250 Performance Qualification Protocol, Version V 3.0 dated 6/27/2019.
   2. During a review of your firm's performance qualification report, PennTech Tunnel Performance Qualification Report, Asset # E1078, Revision V.3 dated November 2019, Approved 11/12/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, PennTech Tunnel Performance Qualification Protocol, Asset # E1078, Revision V.3 dated November 2019, Approved 11/12/2019.

B. Your firm failed to adequately implement your firm's written, procedure T08.19 Investigation of Non-conformance and CAPA Issuance procedure, Revision 03. For example, during a review of your firm's performance qualification report, PennTech Tunnel Performance Qualification Report, Asset # E1078, Revision V.3 dated November 2019, Approved 11/12/2019, I found as a result of investigations into documented deviations, your firm's quality unit made changes to the acceptance criteria documented within the original protocol without obtaining your firm's management approval prior to its implementation and ultimate approval of the performance qualification.

OBSERVATION 4

Your firm compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, a) you compound drug products that are identical or nearly

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	DATE ISSUED 3/6/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	DATE(S) OF INSPECTION 2/12/2020-3/6/2020* FEI NUMBER 3011887629
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Arta Shaun Noorian, Founder & CEO	
FIRM NAME Empower Clinic Services, LLC	STREET ADDRESS 5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

A. Human Chorionic Gonadotropin
B. Menotropins Injection
C. Leuprolide Acetate Injection
D. Pyridoxine HCL Injection

This is a repeat observation.

OBSERVATION 5

The containers of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;

Examples of your container labels that do not contain this information:

3. Testosterone Cypionate 200 mg/ml Injection
4. Testosterone Cypionate 50mg/ml Injection
5. HCG 12000 IU
6. HCG 6000 IU
7. FSH 1500 IU

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	X	DATE ISSUED 3/6/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	2/12/2020-3/6/2020* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arta Shaun Noorian, Founder & CEO

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC	5980 W. Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

8. Menotropins (HMG) 500 IU
9. Ascorbic Acid Preserved 500mg/ml
10. Leuprolide Acetate 40MCG/0.2ml
11. Pyridoxine HCL (Vit B6) 100mg/ml
12. BCAA 30ml 15/10/40 MG/ML Injection
13. Taurine 50 mg/ml Injection
14. Omnitrope 5.8mg Injection
15. Glutathione Preserved 200mg/ml Injection

OBSERVATION 6

Your outsourcing facility has not submitted adverse event reports in 2019 FDA in accordance with the content and format requirements established through guidance (AE Reporting Guidance) or regulation under section 310.305 of 21 CFR.

***DATES OF INSPECTION**

2/12/2020(Wed), 2/13/2020(Thu), 2/14/2020(Fri), 2/19/2020(Wed), 2/20/2020(Thu), 2/21/2020(Fri), 2/24/2020(Mon), 2/26/2020(Wed), 2/27/2020(Thu), 2/28/2020(Fri), 3/02/2020(Mon), 3/03/2020(Tue), 3/06/2020(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 03-06-2020 10:39:20	3/6/2020

EmpoweRx PHARMACY

ATTACHMENT
2

T06.04 Lighthouse Environmental Monitoring System

INTRODUCTION AND SCOPE

The Lighthouse Monitoring system is a real-time recording system that measures temperature, pressure, humidity, and non-viable particulates in real-time in the cleanroom, non-sterile compounding area, and drug storage areas. All the data is saved and it is centrally connected to a designated Lighthouse Server.

PURPOSE

The Lighthouse Monitoring System congregates selected monitors throughout the pharmacy to monitor that operations are running in a state of control. Data is saved to ensure operating conditions are stored in real-time.

RESPONSIBILITY

Pharmacist-in-Charge (PIC) or designee, Facility Manager, and Quality Assurance Manager.

POLICY

1. Environmental monitoring of critical operations is required by cGMP regulations.
2. The following areas shall be monitored for each type of environmental parameters:
   - 2.1. Cleanroom—before compounding daily (during operational hours)
     - 2.1.1. Temperature
     - 2.1.2. Humidity
     - 2.1.3. Pressure differentials
   - 2.2. Sterile production areas—before compounding daily (during operational hours)
     - 2.2.1. Temperature
     - 2.2.2. Humidity
     - 2.2.3. Pressure differentials
     - 2.2.4. Non-viable particulates
   - 2.3. Non-sterile production areas—before compounding daily (during operational hours)
     - 2.3.1. Temperature
     - 2.3.2. Humidity
     - 2.3.3. Pressure differential (Hazardous room only)
   - 2.4. Drug storage areas—at least once a day
     - 2.4.1. Temperature
     - 2.4.2. Humidity
3. Monitoring that occurs during sterile product compounding shall be documented in the specific product batch record.

Author	Approved By	Creation Date	Effective Date	Revision No.
Lauren Keefer	Shaun Noorian	04/01/2016	03/30/2020	03

4. Warning and alarm limits will be set in the system to alert if the levels are higher or lower than specifications.
5. Calibration of the Lighthouse System will be performed per manufacturer's specifications. Calibration documentation shall be retained.
6. Furniture/Equipment Placement
   6.1. PECs and furniture shall not negatively affect the HVAC system and its ability to deliver required Air Changes per Hour (ACPH).
   6.2. PECs and furniture must be placed away from doors or high traffic areas to avoid disruptions in air flow.
   6.3. Personnel must report any deviations in the monitored areas to the PIC and Facility Manager immediately (i.e. doors not closing completely).

PROCEDURE

1. LMS Operation
   1.1. Open LMS Pharma Configuration ViewStation.
   1.2. Click 'File' and select 'Log on…' to log on with personal username and password. NOTE: Username and password are case sensitive.
   1.3. Select the tab 'Map' under 'Main Facility'.
   1.4. Click the appropriate location within the pharmacy to view.
   1.5. Viewing Panel
      1.5.1. Ensure that under "Time Frame to Display," "Rolling" is selected, which indicates real time monitoring.
         1.5.1.1. To view the monitoring data from a specific date, click on "Rolling" and change it to "Fixed Time." Input the historical date and time to view.
      1.5.2. To analyze trend, left click monitor, select the desired monitor, then click trend.
      1.5.3. Filter out certain parameters by clicking the measurement under 'Data to Display' on the bottom left hand corner of the screen
2. Environmental Monitoring
   2.1. Record cleanroom daily environmental data on T09.06 Sterile Temperature, Pressure, and Humidity Monitoring Log.
   2.2. Record cleanroom environmental data taken before, during, and immediately after aseptic filling operations at discrete points, as listed on the batch record in the appropriate section.

2.3. Record non-sterile compounding environmental data for both the hazardous and non-hazardous rooms on T09.78 Non-Sterile Temperature, Pressure, and Humidity Monitoring Log.

REFERENCES

T05.14 Environmental Monitoring of Cleanroom.docx

T09.06 Sterile Temperature, Pressure and Humidity Monitoring Log

T09.78 Non-Sterile Temperature, Pressure, and Humidity Monitoring Log

Author	Approved By	Creation Date	Effective Date	Revision No.
Lauren Keefer	Shaun Noorian	04/01/2016	03/30/2020	03

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ATTACHMENT
3

Compounding Checks	Check by:
Tasks	**Operator(s)**
Ingredient Checks (Name, Lot, and Expiration Date)	
Formula Calculation	
Balance Tare Check	

Mixing				Check by:
Equipment	**Serial Number**	**Check/Calibration Date**		**Operator(s)**
BSC 1	6S-15-BR-16360			
Balance	B611209462			
Balance	B612258000			
Stir Plates	07.271102			
Task(s)	**Location**	**Start Time**	**End Time**	**Operator(s)**
Mixing	BSC 1			
Cleaning and Disinfection				Date
Time	**Cleaning Agents Used**			**Operator(s)**
Before Mixing:				
After Mixing:				
Quality Check(s)				
Visual Inspection				
Initial pH: | Final pH:	pH adjuster(s):	Lot #	Exp Date: _	
Final Batch Volume: mL				

Filtration 1				Check by:
Equipment	**Serial Number**	**Check/Calibration Date**		**Operator(s)**
Repeater pump				
Task(s)	**Location**	**Start Time**	**End Time**	**Operator(s)**
Filtration				
Cleaning and Disinfection				Date:
Time	**Cleaning Agents Used**			**Operator(s)**
Before Filtration:				
After Filtration:				
Environmental Sample(s)	**Time**			**Operator(s)**
Surface Sample	Before Filtration			
Viable Sample	During Filtration			
Viable Sample	After Filtration			
Surface Sample	After Filtration			
Fingertip Samples	After Filtration			
Filter Test				**Operator: __**
Bubble Point Result: Pass/Fail				
Filter Model	Membrane	Lot #	Exp. Date	PSI Rating	Bubble Point PSI

Filtration 2 & Fill			Check by: _
Equipment	**Serial Number**	**Check/Calibration Date**	**Operator(s)**
Repeater pump			
Fill Volume Calibrated: _ mL/Vial		Fill Speed: _	

Task(s)	Location	Start Time	End Time	Operator(s)
Filtration	ISO 5 Rm			
Fill	ISO 5 Rm			
Stopper	ISO 5 Rm			

Cleaning and Disinfection		Date:
Time	**Cleaning Agents Used**	**Operator(s)**
Before Filling:		
During Filling:		
After Filling:		

Environmental Checks					Check by:
Time	**Temperature (°F)**	**RH (%)**	**dP (inH_2O)**	**5.0 µm Particles/ft^3**	**0.5 µm Particles/ft^3**
Before Fill					
During Fill					
Immediately after Fill					

Environmental Sample(s)	Time	Operator(s)
Surface Sample	Before Fill	
Viable Sample	During Fill	
Viable Sample	After Fill	
Surface Sample	After Fill	
Fingertip Samples	After Fill	

Filter Test					Operator: __
Bubble Point Result: Pass/Fail					
Filter Model	Membrane	Lot #	Exp. Date	PSI Rating	Bubble Point PSI

Lyophilization				
	Date	**Cycle Name**	**Operator(s)**	**Check by**
Clean & Disinfect with Sterile 70% IPA		N/A		
Load Vials into LyoMac		N/A		
Lyo Cycle				
Estimated lyo completion		N/A		
Back-fill with nitrogen and stopper		N/A		
Unload product and empty lyo shelves		N/A		

Seal			Check by: _
Equipment	**Serial Number**	**Check/Calibration Date**	**Operator(s)**
Genesis Integra Capper	P1212 \ P1228		

Task(s)	Cap Color	Start Time	End Time	Operator(s)
Seal				
Sealed Quantity:				

Cleaning and Disinfection		Date:
Time	**Cleaning Agents Used**	**Operator(s)**
Before Seal:		
After Seal:		

Quantity Count	Check by	Date

Quantity Released from Cleanroom:		
Quantity Received by QC Department:		

Batch Reconciliation		
	Quantity (vials)	**Check by**
Theoretical Yield		
Adjusted Theoretical Yield (-5%of Theoretic Yield)		
Quantity Released from Cleanroom		
Quantity Received by QC Department (Actual Yield)		
Batch Percent Reconciliation = (Actual Yield) / (Adjusted Theoretical Yield) x 100% = %		

Label Reconciliation				
	Quantity of Labels	**% Yield**	**Personnel**	**Date**
# of Labels Printed		N/A		
# of Labels Used				
# of Labels Scrapped				
# of Labels Remaining & Destroyed				
Labels Percent Reconciliation:				
[(# of Labels Used) + (# of Labels Scrapped) + (# of Labels Remaining)] / (# of Labels Printed) x 100% = %				

Quality Department Check List		
	Date	**Check by**
Send Vials for Testing		
Visual Inspection Completion		
Label Review Completion		
Labeling Completion		\

QC Department Task(s)	**Date**	**Personnel**
Send Vials for Testing		
Print Labels (QTY of Label)	Date: # of label printed:	
Label Information Check		\
Product Visual Inspection		
Label Product and Inspect Labeled Product		\
Shred Remaining Label	Date: # of label remaining:	

Quality Review of Sterile Drug Products:

1. Ingredient Review:

   a. Names of all ingredients verified: YES NO
   b. Balance tared before each ingredient weigh out: YES NO
   c. Lot numbers of all ingredients recorded: YES NO
   d. Expiration dates of all ingredients recorded: YES NO
   e. Calculation check for each ingredient: YES NO
   f. QS or final volume checked: YES NO

2. Final pH checked: YES NO N/A
3. Bubble Point Test completed and filter(s) passed: YES NO
4. Bottle/Cap:
   a. Vial Type:
      i. Color: Clear Amber
      ii. Size : 5 mL 10 mL 30 mL

   b. Cap Color: _____

5. Visual Inspection of Final Compounded Sterile Preparations

a. 100% Inspection Completed: YES NO

b. Quantity of vials rejected: _____

c. Quantity of vials passed inspection: _____

USP <71>: Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch for Sterility Testing:	
Number of Items in the Batch	Minimum # of items to be tested for each medium:
Not more than 100 containers	10% or 4 containers, whichever is the greater
More than 100 but not more than 500 containers	10 containers
More than 500 containers	2% or 20 containers, whichever is less
For large volume parenterals	2% or 10 containers, whichever is less

Testing	# of Vials Test	Vendor/Lab	Result: Pass/Fail	Checked by
Sterility		ARL		
Endotoxin		ARL		
Potency		ARL		

Quantity Retained: _____ Date Released: _____ Total Qty Released to Pharmacy: _____

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ATTACHMENT
4

EmpowerRx PHARMACY

CONFIDENTIAL

TRAINING REGISTER

Training Date: 03/20/2020

TRAINING OBJECTIVE ☒ MANDATORY ☐ VOLUNTARY

Please describe the objective of this training session:

Observation #1 This training addresses the revised SOP, titled, "T06.04 Lighthouse Environmental Monitoring System," as well as the revised batch record that includes documenting environmental factors before and during compounding operations, It is important to document these factors for each batch that is produced. These factors must also be recorded immediately after fill.

TRAINING CATEGORY (Check those which apply) ☐ INDIVIDUAL ☒ GROUP

☐ New Hire Orientation ☒ SOPs ☒ GMP ☐ Forms ☐ Safety ☒ Quality / Regulatory ☐ Complaints
☐ HR Related Material ☐ Other

DESCRIPTION OF TRAINING (Check those which apply)

☐ New Hire Orientation ☒ On-the-Job ☒ Discussion ☐ Worksheet* ☐ Video

TRAINER INFORMATION Start Time 3:00pm End Time 3:30 pm

Print Name Adrian Rodriguez Title Director of Quality Signature [signature] Date 03/20/2020

EMPLOYEE / ATTENDEES

#	Print Name	Signature	Department
1	Sofia GABES	[signature]	Sterile
2	Vic Williams	[signature]	sterile
3	Marra Valdournos	[signature]	sterile
4	Cesar Soto	[signature]	Sterile
5	RACHELLE DE LOS SANTOS	[signature]	sterile
6	Alan Khammivong	[signature]	Sterile
7	Leslie Peterson	[signature]	QA
8	Tiffany Manchan	[signature]	QA
9	Siar Anwar	[signature]	QA
10	Alex Khammivong	[signature]	Quality

*NOTE: Use the Form titled, "Additional Training Attendance Sheet" should more than twenty employees participate in this training course.

Total # of Attendees for this Training 16

SIGNATURES

Reviewed by [signature] Date 3/20/2020
Title CEO

Reviewed by: [signature] Date 03/20/2020
Title Chief Administrative Officer

EmpowerRx PHARMACY

CONFIDENTIAL

ADDITIONAL ATTENDANCE SHEET

Training Date 03/20/2020

EMPLOYEES / ATTENDEES

#	Print Name	Signature	Department
1	Jessica Thornton		Sterile
2	Amber Hickman		Sterile
3	Aaron Moreno	Aaron Moreno	sterile
4	Stephanie Frison		Sterile
5	Jose Martinez		Sterile
6	Ingris Reyes		Sterile
7			
8			
9			
10			
11			
12		N/A 03/20/2020	
13			
14			
15			
16			
17			
18			
19			
20			

*NOTE: This form is to accompany the Form titled, "Training Report" as designated by the Training ID above and should not be used as a stand-alone form.

Page 1 of 1

SIGNATURES

Trainer Name Adrian Rodriguez Title Director of Quality Signature _____ Date 03/20/2020

Reviewed by _____ Date 3/20/2020

Title CEO

Reviewed by: _____ Date 03/20/2020

Title Chief Administrative officer

EmpoweR PHARMACY

ATTACHMENT
5

PROTOCOL APPROVAL PAGE

Date:

PERSPECTIVE	PRINTED NAME	SIGNATURE	DATE
Author			

PERSPECTIVE	PRINTED NAME	SIGNATURE	DATE
Director of Quality, or Designee			
Director of Manufacturing, or Designee			

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DOCUMENT REVISION HISTORY

Version	Date	Details	Author
00	3/11/2020	Protocol created and circulated for initial review	LEK

RESPONSIBILITIES

Department	Responsibility
Manufacturing Operations	Provide materials and necessary operational support needed to complete the protocol.
Quality Assurance	Label and submit samples to Outsourced 3rd Party Laboratory for bioburden testing.
Test Operator	Complete the attached Test Reports in full and verify that information is accurate.

Test Participants Signature Form

Title	Name	Signature	Initials	Date

INTRODUCTION AND SCOPE

During manufacture of sterile injectables, products are formulated, pre-filtered into an IV bag, and then final-filtered into their product packaging. Standard processing involves in-process hold times between the pre- and final-filter operations. As stated by CFR 211.111, "when appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product."

The scope of this validation protocol covers sterile injectable products that are subjected to a hold time more than 8 hours and/or not part of a continuous fill process directly into their final container(s). It has been determined that a continuous fill process is completed within one normal shift (8 hours), so it is appropriate to establish a time limit for the completion of this phase of production outside of this range.

Finished products will be grouped based on concentrations and/or common APIs, with the worst-case product selected for testing.

Objective

To establish a maximum in-process time limit (or hold time) that is acceptable and does not allow for microbial proliferation for products that have been formulated and filtered but have not yet been packaged into their final containers.

Materials

- 250 mL pre-sterilized Nalgene bottles

References and Applicable Documents

- 21 CFR 211.110 (a)(6)
- FDA Guidance for Industry—Sterile Drug Products Produced by Aseptic Processing
- USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
- USP <85> Bacterial Endotoxins Test

Definitions

- Time Limit (or Hold time) — The time a product is held in an intermediate phase of production (such as in a container) following the pre-filtration step, but prior to the final filtration step into its final packaging.

POLICY

1. Testing shall be completed for any injectable product which does not have a continuous fill process or has an intermediate phase of production lasting more than 8 hours.
2. For products available in multiple concentrations or with multiple APIs, the highest concentration and/or most APIs shall represent the product family.
3. Bioburden testing per USP <61> and endotoxin testing per USP <85> shall be performed at the initial start of pre-filtration phase of production (referred to as Day 0) and again at the proposed maximum time limit to be established (referred to as the Max Hold Time).
4. Products with proposed max hold time longer than five (5) days shall be tested for bioburden and endotoxin as an intermediate timepoint check to ensure negative results.
5. Any microbial recoveries from the bioburden testing, regardless of CFU count, shall be identified and documented for trending.
6. Once a time limit (max hold time) has been established, any finished product(s) that exceeds the established time limit shall be subject to a full material review to determine approval (continuation to the final filtration and fill step) or rejection (waste and/or destruction).

Acceptance Criteria

1. Bioburden results for all samples taken must not exceed 10 CFU/100 mL product.
2. Endotoxin results must not exceed the product's endotoxin release specification.

PROCEDURE

1. Product will be sampled from regular production lots. The specific batch number being tested must be identified prior to any sampling and documented on Attachment I.
2. Take a sample immediately following the pre-filtration step into the IV bag. Aseptically sample through one of the outlet ports into the 250-mL Nalgene bottle. A minimum of 200 mL must be collected.
   2.1. Label the Nalgene bottle with product name, strength, lot number, date sampled, and personnel initials.
   2.2. Immediately send the sample to the lab to evaluate bioburden and endotoxin.
3. Close the sampling port and hold the product inside of an ISO 5 space.
   3.1. Hold times will be product-specific and documented on Attachment II. Certain product hold times tested will subsequently be applied to similar products, based on concentration, APIs, etc. Justifications for the groupings will be provided in Attachment II. The default maximum hold time tested will be 5 days.
4. After the appropriate time has elapsed, prepare the product for final filtration. Immediately before filtering, repeat the sampling from Step 2.
   4.1. For products that require holding for longer than 5 days, a third, intermediate sampling must be taken in addition to the samples taken following the pre-filtration and prior to the final filtration.

TEST REPORT APPROVAL PAGE

Date:

Prepared By:

SUMMARY OF RESULTS AND CONCLUSIONS

Approved By:

PERSPECTIVE	PRINTED NAME	SIGNATURE	DATE
Director of Manufacturing or Designee			
Director of Quality or Designee			

ATTACHMENT I—HOLD TIME TESTING RESULTS

Bioburden Results				
Product Name:				
Lot No:				
Date Compounded:				
Date Sampled	**Criteria**	**Results**	**ARL Report No.**	**Pass/Fail**
	<10 CFU/100 mL			☐ Pass ☐ Fail
	<10 CFU/100 mL			☐ Pass ☐ Fail
	<10 CFU/100 mL			☐ Pass ☐ Fail ☐ N/A
Endotoxin Results				
Date Sampled	**Criteria***	**Results**	**ARL Report No.**	**Pass/Fail**
				☐ Pass ☐ Fail ☐ N/A
				☐ Pass ☐ Fail ☐ N/A
				☐ Pass ☐ Fail ☐ N/A
Maximum Hold Time Established:				

*Criteria will be product-specific for endotoxin testing.

Lab reports attached: ☐ Yes ☐ No

Prepared By: _____ Signature: _____ Date: _____

Reviewed By: _____ Signature: _____ Date: _____

ATTACHMENT II—PRODUCT HOLD TIMES

Product Tested	Maximum Holding Time	Additional Products Qualified	Product Grouping Justification

REPORT APPROVAL PAGE

I, _____, authored the In-Process Hold Time Validation Test Report and hereby attest all information on this report to be true.

_____ _____

Tester Signature Date

_____ _____

Director of Quality or designee Date

_____ _____

Director of Manufacturing or designee Date

DEVIATION FORM

Deviation Location:	**Deviation Number:**
Deviation description:	
Deviation cause:	
Proposed corrective action(s):	
Corrective action approved:	☐ Yes ☐ No
Execution Approval (Prior to Implementation)	
Qualifier/Tester Signature | Date:	
Director of Quality or designee | Date:	
Results	
Corrective action outcome(s):	
Corrective action results accepted:	☐ Yes ☐ No
Deviation satisfactorily resolved:	☐ Yes ☐ No
If no, deviation accepted:	☐ Yes ☐ No
Results Approval	
Qualifier/Tester Signature | Date:	
Director of Quality or designee | Date:	

EmpoweR PHARMACY

ATTACHMENT
6

EmpowerRx PHARMACY

CONFIDENTIAL

TRAINING REGISTER

Training Date: 03/20/2020

TRAINING OBJECTIVE ☒ MANDATORY ☐ VOLUNTARY

Please describe the objective of this training session:

Observation # 2 This training will go over the new procedure/protocol established to provide time limits (or hold times) for relevant intermediate steps by R 03/19/20 during compounding operations. These hold times will inform operations how long an in-process product can remain in-process before filling without affecting/promoting microbiological contamination.

TRAINING CATEGORY (Check those which apply) ☐ INDIVIDUAL ☒ GROUP

☐ New Hire Orientation ☐ SOPs ☒ GMP ☐ Forms ☐ Safety ☒ Quality / Regulatory ☐ Complaints
☐ HR Related Material ☐ Other

DESCRIPTION OF TRAINING (Check those which apply)

☐ New Hire Orientation ☒ On-the-Job ☒ Discussion ☐ Worksheet* ☐ Video

TRAINER INFORMATION Start Time 3:00pm End Time 3:30pm

Print Name Adrian Rodriguez Title Director of Quality Signature [signature] Date 03/20/2020

EMPLOYEE / ATTENDEES

#	Print Name	Signature	Department
1	Sofia GABES	[signature]	sterile
2	Vic Williams	[signature]	sterile Maint
3	Marra Valdovinos	[signature]	sterile
4	Cesar Soto	[signature]	"
5	Rachelle De Los Santos	[signature]	sterile
6	Alan Khamnivong	[signature]	sterile
7	Tiffany Manchan	[signature]	QA
8	Siar Anwar	[signature]	QA
9	Leslie Peterson	[signature]	QA
10	Alex Khamnivong	[signature]	Quality

*NOTE: Use the Form titled, "Additional Training Attendance Sheet" should more than twenty employees participate in this training course.

Total # of Attendees for this Training 16

SIGNATURES

Reviewed by [signature] Date 3/20/2020

Title CEO

Reviewed by: [signature] Date 03/20/20

Title Chief Administrative officer

EmpoweRX PHARMACY

CONFIDENTIAL

ADDITIONAL ATTENDANCE SHEET

Training Date 03/20/2020

EMPLOYEES / ATTENDEES

#	Print Name	Signature	Department
1	Jemira Thanlihan	[signature]	Sterile
2	Amber Hickman	[signature]	Sterile
3	SABRINA FATSIN	[signature]	STERILE
4	Aaron Moreno	Aaron Moreno	Sterile
5	Jose Martinez	[signature]	Sterile
6	Ingris Reyes	[signature]	Sterile
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**NOTE: This form is to accompany the Form titled, "Training Report" as designated by the Training ID above and should not be used as a stand-alone form.*

Page 1 of 1

SIGNATURES

Trainer Name Adrian Rodriguez Title Director of Quality Signature [signature] Date 03/20/2020

Reviewed by [signature] Date 3/20/2020 Reviewed by [signature] Date 03/20/2020

Title CEO Title Chief Administrative officer

EmpoweRx PHARMACY

ATTACHMENT
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EmpoweR PHARMACY

CAPA EXECUTIVE SUMMARY REPORT

Date: 03/09/2020

OBJECTIVE

To summarize the findings of the Corrective and Preventive Action initiated on the Performance Qualification documents found during the FDA inspectional audit and described in the Form FDA 483 as Observation # 3.

PURPOSE

The purpose of this executive summary report is to outline the results of the open CAPA initiated in response to Observation # 3 Part A of the Form FDA 483 issued on March 6, 2020 and discuss the impact, if any, the changes made to the PennTech tunnel final reports may have had on the overall performance qualifications that were completed for the respective equipment described in the observation.

OVERVIEW

During the closeout meeting with the FDA Consumer Safety Officer (Inspector), it was stated that the firm did not adequately implement a change control to implement changes made to the company's performance qualification reports for the PennTech Vial Washer and PennTech Tunnel Performance protocols. It was discovered that adjustments were made to the attachments between the approved protocol and the submitted test reports.
This was noted in Observation #3 - Part A, #1 and #2.

Current company practices dictate that such performance qualification protocols are submitted to management for approval with a test report template. However, should the results to be reported need additional space, the report may be adjusted (reformatted) to accommodate the documented results. Therefore, so long as no content is changed or acceptance criteria is changed, the final report submitted may be adjusted (or reformatted) to accommodate the data collected. The current process dictates that any content changes made to the original template must be handled through the T09.02 Policy and Procedure Change Request Form.

In addition, the FDA Inspector stated the firm did not receive our firm's management approval prior to changes made to the acceptance criteria documented within the original protocol. Specifically, he was addressing the protocol's Deviation form (not the Company's Deviation process).

After reviewing the PennTech Vial Washer Performance Qualification Protocol and PennTech Tunnel Performance Qualification Protocol, it was found that deviation forms had been used and executed before receiving approval from the appropriate Quality designee, as is stated in SOP T08.19 Investigation of Non-Conformance and CAPA Issuance Procedure, Rev. 03.

INVESTIGATION

A CAPA investigation was initiated to identify instances where the approved protocol and the submitted final reports differed since the FDA Inspector did not sate, describe, nor clearly identify the "changes" he thought he found in the observed protocols of #1 and #2 of Part A. The differences we gathered from the conversation with the inspector during the audit for each protocol are listed below and outlined in Tables 1 and 2:

PennTech Vial Washer, documented deviations:

1. Deviation description: Initial 10 mL vial inspection for chemical residue was inconclusive. Vials appeared to have a faint residue, but results needed to be confirmed with additional testing. All other vials were found to be acceptable and were dispositioned as pass.
   Deviation cause: May have been due to a handling or processing issue. The black light and fluorescence is a visual qualitative test used to detect gross contamination and results may be inconclusive for minute contaminants.
   Corrective action(s) taken: Additional 62 vials were spiked with same concentration and volume used in the initial test. A 1 mg/mL was placed in each vial and allowed to dry for 24 hours. Sixty vials were washed using the 10 ml vial washing cycle. No changes were made to the vial wash cycle. The vials were inspected for the presence of riboflavin fluorescence under black light. Two positive and negative controls were provided to the inspector for

comparison standards. All vials passed with no visible signs of chemical remains. The qualification was concluded to have met the acceptance criteria.

PennTech Tunnel, documented deviations:

1. Deviation description: One out of the three biological indicators used for testing the 30 mL vials (specifically the middle indicator) appeared to turn positive.
   Deviation cause: it was determined the indicator that appeared to be positive was caused by human error as the pharmacy technician opened each individual ampoule to inoculate the Biological Indicator with BI media. Considering only one biological indicator (BI) turned positive out of the three runs for the 30 mL vial recipe, and given the sensitivity of the indicators and the fact there were no other positive BIs from any of the other recipe runs, human error seems most likely.
   Corrective action(s) taken: Three separate runs of BIs were completed with 30 mL vials to confirm the cross-contamination. The three runs returned sterile and clear of growth, as shown in the results section. All endotoxin results were within acceptable limits as well, further indicating the sterilization occurring for the 30 mL vials.

2. Deviation description: Particle counts for the locations across the three chambers in the tunnel were documented as a deviation in the Protocol's official Deviation Form, where it was specifically stated only particle counts inside the sterilization chamber were performed since a 3rd party vendor was utilized to certify the entire chamber.
   Deviation cause: The entire tunnel was certified through SLSI prior to releasing the tunnel to operations and did not require counts from the infeed and cooling chambers.
   Corrective action(s) taken: The locations across the three chambers have been re-evaluated and the infeed and cooling chambers have been listed as optional so long as a 3rd party certifies the chamber. This has been determined to the fact that the infeed and cooling chambers particle counts were not affected, as differential pressure is maintained between the chambers.

Table 1: PennTech Vial Washer Protocol formatting adjustments

Location in Final Protocol Report	Adjustment Description	Purpose of Adjustment
p. 14, Chemical Challenge Test Vial Preparation	Spike concentration units changed from "mL" to "mg/mL" for 5-, 10-, and 30-mL tables	Adjustment needed to reflect accurate units for concentration
p. 15, Particle Reduction Test Vial Preparation	Spike concentration units changed from "mL" to "mg/mL" for 5-, 10-, and 30-mL tables	Adjustment needed to reflect accurate units for concentration
Pages 18, 19, and 20 Particle Reduction Test Results	Positive control expected outcome corrected from "≤ 600 particles / vial" to "≥ 600 particles / vial"	Simple typo was discovered and corrected.

Table 2: PennTech Tunnel Performance Protocol formatting adjustments

Location in Final Protocol Report	Adjustment Description	Purpose of Adjustment
p. 15, Attachment I (Page 3 of 3)	Formatting made to table headers with 3 additional entries added to the sensors table	Entries to the table adjusted to accommodate sensors inside the tunnel
p. 16, Attachment II	1. Formatting of Attachment II was split over three pages with check boxes for each entry	Necessary adjustment to clearly present relevant calibration data for different sensor types
	2. Formatting of Calibration certificate number and last calibration date	Not necessary but adds clarity to data logger, thermocouple, incubator, and particle counter tables

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	3. Formatting to include Tag Number	Adjustment of tag number clarifies the gauge table
p. 19, Attachment V	1. Biological indicator results table reformatted to allow photos to be included	Not necessary but photos help clarify and present supporting data in a manner that is easy to use
	2. Endotoxin results table formatted	Not necessary but clarifies presented data
	3. Formatting adjusted to allow a table to report values for equivalence destruction	Necessary adjustment since this value was specified as an acceptance criteria
p. 20, Deviation Form	Formatting of approval sign-off	Adjusted for clarity and compliance
p. 21, Report Approval	Formatting of submission report	Adjustment of the front page to provide Sign-off visibility

CONCLUSION

After a full and thorough investigation, no change controls were necessary for Part A examples #1 and #2. The formatting changes and documented deviations within the Protocol Deviation form did not have an impact on the overall results of the performance qualification for the PennTech vial washer, the PennTech tunnel, or the overall functionality of the equipment.

It was determined that only content changes in the Protocol would significantly alter or impact the final results but not adjustments made to accommodate the results in the Protocol's reporting section. Since the purpose of the final report is to document results, format adjustments are expected, allowed, and do not warrant a change control.

With regards to the vial washer positive particle requirements, a typo was discovered and corrected. An evaluation of the results showed they were met according to the corrected criteria specified in the protocol. The critical acceptance criteria did not change, and all were met.

CORRECTIVE ACTIONS

To address Observation # 3 in the Form FDA 483, the adjustments made to the protocols have been identified and documented in a CAPA for both the vial washer and tunnel protocol. The investigation results ensured there was no risk to the validity of either performance qualification.

PREVENTATIVE ACTIONS

The Protocol's attached Deviation form used for the performance qualifications protocol will be re-evaluated and revised to address the need for Change Controls per Observation # 3, Part A, #1 and #2. Additionally, moving forward, a deviation form (with prior approval) will be required for any changes, including those considered to be formatting adjustments to the final report after the protocol has been approved.

Adrian Rodriguez

Adrian Rodriguez
Director of Quality

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ATTACHMENT
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EmpoweRX PHARMACY		Protocol No:

DEVIATION FORM

Deviation Location:	**Deviation Number:**
Deviation description:	
Deviation cause:	
Proposed corrective action(s):	
Corrective action approved:	☐ Yes ☐ No
Execution Approval (Prior to Implementation)	
Qualifier/Tester Signature | Date:	
Director of Quality or designee | Date:	
Results	
Corrective action outcome(s):	
Corrective action results accepted:	☐ Yes ☐ No
Deviation satisfactorily resolved:	☐ Yes ☐ No
If no, deviation accepted:	☐ Yes ☐ No
Results Approval	
Qualifier/Tester Signature | Date:	
Director of Quality or designee | Date:	

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ATTACHMENT
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CONFIDENTIAL

TRAINING REGISTER

Training Date: 03/20/2020

TRAINING OBJECTIVE

☒ MANDATORY ☐ VOLUNTARY

Please describe the objective of this training session:

Observation #3 - This training covers the results found as part of a CAPA initiated into discussions with the FDA inspector regarding prior approval before implementing deviations, as well as determining when change controls should be documented. Training includes discussion over the CAPA Executive Summary Report.

TRAINING CATEGORY (Check those which apply)

☐ INDIVIDUAL ☒ GROUP

☐ New Hire Orientation ☐ SOPs ☒ GMP ☐ Forms ☐ Safety ☒ Quality / Regulatory ☐ Complaints
☐ HR Related Material ☐ Other

DESCRIPTION OF TRAINING (Check those which apply)

☐ New Hire Orientation ☒ On-the-Job ☒ Discussion ☐ Worksheet* ☐ Video

TRAINER INFORMATION

Start Time 03:00 pm End Time 03:30 pm

Print Name Adrian Rodriguez Title Director of Quality Signature [signature] Date 03/20/2020

EMPLOYEE / ATTENDEES

#	Print Name	Signature	Department
1	Rachelle De Los Santos	[signature]	Sterile
2	Alan Khammivong	[signature]	Sterile
3	Siar Anwar	[signature]	QA
4	Alex Khammivong	[signature]	Quality
5	Tiffany Mounchan	[signature]	QA
6	Leslie Peterson	[signature]	QA
7	Jemira Thomlinson	[signature]	Sterile
8	Amber Hickman	[signature]	Sterile
9	Sabrina Faison	[signature]	Sterile
10	Aaron Moreno	[signature]	Sterile

*NOTE: Use the Form titled, "Additional Training Attendance Sheet" should more than twenty employees participate in this training course.

Total # of Attendees for this Training 12

SIGNATURES

Reviewed by [signature] Date 3/20/2020
Title Director of Manufacturing

Reviewed by: [signature] Date 03/20/2020
Title Chief Administrative officer

EmpowerRx PHARMACY

CONFIDENTIAL

ADDITIONAL ATTENDANCE SHEET

Training Date 03/20/2020

EMPLOYEES / ATTENDEES

#	Print Name	Signature	Department
1	Jose Martinez		Sterile
2	Ingris Reyes		Sterile
3			
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*NOTE: This form is to accompany the Form titled, "Training Report" as designated by the Training ID above and should not be used as a stand-alone form.

SIGNATURES

Trainer Name Adrian Rodriguez Title Director of Quality Signature Date 03/20/20

Reviewed by Date 3/20/2020

Title Director of Manufacturing

Reviewed by: Date 03/20/2020

Title Chief Administrative officer

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ATTACHMENT
10

T03.36 Essential Copy Procedure for 503A Products

INTRODUCTION AND SCOPE

This document explains the procedure by which Empower Pharmacy shall collect and/or notate the "statement of significant difference" for an individual patient as determined by the prescribing practitioner, when a compounded product may otherwise be considered "essentially a copy" of an FDA-approved product. This Standard Operating Procedure is pursuant to Guidance for Industry (GFI) "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (Jan. 2018).

PURPOSE

To ensure that proper documentation and oversight are in place for collecting and or notating from the prescriber, a "statement of significant difference" for an individual patient, when the prescribed compounded may otherwise be considered "essentially a copy" of a commercially available drug product.

RESPONSIBILITY

The responsibility for adherence to this policy will fall to the Pharmacist in Charge (PIC) and the Director of Compliance and Operations (DOC).

DEFINITIONS (if applicable)

1. *Essential Copy* (Essentially a copy of an approved drug): A drug product is considered to be essentially a copy of a commercially available drug product if:
   - the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
   - the API(s) have the same, similar, or an easily substitutable dosage strength; and
   - the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,
   - unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

POLICY

1. Upon the receipt of a prescription for any patient-specific compounded product that may otherwise be considered "essentially a copy" of a commercially available drug product, a "statement of significant difference" regarding the need for the compounded medication for an individual patient must be present on the original prescription.
2. If the prescription does not include a "statement of significant difference," one must be collected before the prescription can be processed.
3. When the "statement of significant difference" must be notated after receiving the prescription, the notation shall include the "statement of significant difference," date, the name of the practitioner or practitioner's agent who provided the information, and initials of the individual making the notation.

PROCEDURE

1. Upon receipt of a prescription for any patient-specific compounded product, the pharmacist or technician will fully review the prescription to determine if any of the products may be considered "essentially a copy" of an FDA-approved product. This

review is conducted pursuant to FDA's Final Guidance for Industry titled, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (Jan. 2018)."
2. Should it be determined that one or more of the products appearing on the prescription may be otherwise be considered "essentially a copy" of a commercially available drug product, the pharmacist or technician will determine if a "statement of significant difference" is present on the prescription.
3. If a "statement of significant difference" does not appear on the prescription, the pharmacist shall collect from the practitioner a "statement of significant difference" and notate the significant difference on the prescription. The notation shall include the "statement of significant difference," date, the name of the practitioner or practitioner's agent who provided the information, and initials of the individual making the notation.

TRAINING

1. Personnel involved in the process will be trained on these procedures on a periodic basis.

COMPLIANCE AUDIT (if applicable)

1. On a periodic basis, the DOC shall review prescriptions described herein in order to ensure proper documentation is being maintained.

REFERENCES

FDA's Final Industry Guidance titled, "Compounded Drug Products That Are Essential Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (Jan. 2018).

Author	Approved By	Creation Date	Effective Date	Revision No.
Andy Large	Shaun Noorian	03/13/2020	03/25/2020	01

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ATTACHMENT
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T08.36 Essential Copy Procedure for 503B Products

INTRODUCTION AND SCOPE

This document explains the procedures by which Empower Pharmacy shall collect and/or notate the "statements of clinical difference" for a particular patient as determined by the practitioner, when the compounded product is otherwise "essentially a copy" of a commercially available drug product. This Standard Operating Procedure is pursuant to Guidance for Industry (GFI) titled "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (Jan. 2018).

PURPOSE

To ensure that proper documentation and oversight are in place for collecting and or notating from the practitioner or the practitioner's ordering agent, "statements of clinical difference" for a particular patient, when the compound ordered is otherwise essentially a copy of a commercially available drug product (i.e., contains the same active pharmaceutical ingredient as a commercially available drug product).

RESPONSIBILITY

The responsibility for adherence to this policy will fall to the Pharmacist in Charge (PIC) and the Director of Compliance and Operations (DOC).

DEFINITIONS (if applicable)

1. *Essential Copy* (Essentially a copy of a commercially available drug product):
   - A drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and is not subject to approval in an application submitted under section 505.
     - There must be a change in the compounded formulation that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug (section 503B(d)(2)(B)).

POLICY

1. Upon the receipt of an order for any office use product that contains the same active pharmaceutical ingredient as the commercially available product the ordering entity must provide a statement of clinical difference between the compounded formulation and the commercially available drug product, and that the compounded drug will be administered only to a patient whose prescribing practitioner determines that the formulation will produce this clinical difference, as referenced in FDA's Final Guidance at 8-11.
2. If the order does not include a statement of clinical difference, one must be collected before the order can be processed.
3. When the statement of clinical difference must be notated after receiving the order, the notation shall include the statement, date and the name of individual providing the statement, and the initials of the employee that received the statement.

PROCEDURE

1. Upon receipt of an order for any office use compounded product, the order processor will fully review the order to determine if any of the compounded products contain the same active pharmaceutical ingredients as a commercially available drug product. See FDA

Final GFI "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (Jan. 2018).

2. Should it be determined that one or more of the compounded products appearing on the order contain the same active pharmaceutical ingredients as a commercially available drug product, the employee will determine whether the order contains a sufficient statement of clinical difference.
4. If a statement of clinical difference does not appear on the order, the employee reviewing the order shall obtain from the practitioner or the practitioner's ordering agent a statement of clinical difference.
5. If not originally accompanying the order, the statement of clinical difference shall be notated on the order, which notation shall also include the date, and the name of the practitioner or practitioner's agent that provided the statement, and initials of the employee that received the statement.

TRAINING

1. Personnel involved in the process will be trained on the procedures on a periodic basis.

COMPLIANCE AUDIT (if applicable)

1. On a periodic basis, the DOC will review the orders described herein in order to ensure proper documentation is being maintained.

REFERENCES

FDA's Final Guidance for Industry titled, "Compounded Drug Products That Are Essential Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (Jan. 2018).

Author	Approved By	Creation Date	Effective Date	Revision No.
Andy Large	Shaun Noorian	03/13/2020	03/25/2020	01

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ATTACHMENT
12

NDC 72627-2403-1
30 mL Sterile Multiple Dose Vial

Glutathione (L)

Injection Preserved

200 mg/mL

FOR IM OR IV USE ONLY

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Rx only

Each mL contains: Glutathione (L) 200 mg, Benzyl Alcohol 1% in Sterile Water for Injection, USP. May contain Sodium Hydroxide and/or Hydrochloric Acid to adjust pH.
Osmolarity: 1.4 mOsmol/mL (calc.)
Refrigerate at 2° - 8°C (36° - 46°F).
Not for resale. For office use.
This is a compounded drug.
For adverse event reporting:
www.fda.gov/medwatch and 1-800-FDA-1088

Compounded by: Empower Pharmacy
5980 W Sam Houston Pkwy N Ste 300
Houston, TX 77041 Phone: (877) 562-8577
Compounding Date: XX/XX/XXXX
Beyond Use Date: XX/XX/XXXX **Lot: XXXXX**

2884

Notification of Agreed Order

Empower Pharmacy entered into an Agreed Order with the Oklahoma State Board of Pharmacy regarding allegations involving the compounding of what the Oklahoma State Board of Pharmacy considered essential copies under Oklahoma law. Please note that our home state Board, the Texas State Board of Pharmacy, did not consider these compounds essential copies (see attached). FDA also did not consider these compounds essential copies by their final guidance issued in January 2018 (see attached) and evidenced through FDA's most recent inspection of Empower Pharmacy in January 2018.

In the attached Agreed Order with Oklahoma, Empower did not admit or deny violating any law or the Board's rules. The Agreed Order also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Agreed Order is not considered discipline in Oklahoma. The Oklahoma State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the agreement with the Oklahoma State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Agreed Order.

Please note, this Agreed Order was included and communicated to The Nevada State Board of Pharmacy on 10/25/2019 regarding a new Out-of-State Pharmacy License application. The Board questioned Empower regarding this Agreed Order during the Board's scheduled license approval meeting and had no concerns once explained, and our new Out-of-State Pharmacy License (PH04169) was approved on 12/16/2019.

October 15, 2021

Case #: 613792

WARNING LETTER

VIA ELECTRONIC MAIL

Arta Shaun Noorian
Owner
Empower Clinic Services, LLC dba Empower Pharmacy
5980 West Sam Houston Parkway North
Suite 300
Houston, Texas 77041-5251

Mr. Noorian:

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 July 16, 2016, and most recently on October 26, 2020. From February 12, 2020, to March 6, 2020, an FDA investigator inspected your facility, Empower Clinic Services, LLC dba Empower Pharmacy located at 5980 West Sam Houston Parkway North, Suite 300, Houston, Texas 77041. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA.

FDA issued a Form FDA 483 to your facility on March 6, 2020. FDA acknowledges receipt of your facility's response, dated March 27, 2020. 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

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

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.

In addition, for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must include certain information (section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]).

Further, for a compounded drug product to qualify for the exemptions under section 503B, it must be compounded in an outsourcing facility that is in compliance with the registration and reporting requirements in section 503B(b), including the requirement to submit a report to FDA upon initially registering as an outsourcing facility, once in June of each year and once in December of each year, identifying the drug products compounded during the previous 6-month period (section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]), as well as the requirement to submit adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)" (section 503B(a)(1), (b)(5) of the FDCA [21 U.S.C. § 353b(a)(1), (b)(5)]).

Moreover, subject to certain exceptions, a compounded drug product cannot qualify for the exemptions under section 503B if it will be sold or transferred by an entity other than the outsourcing facility that compounded such drug (section 503B(a)(8) of the FDCA [21 U.S.C. §353b(a)(8)]).

B. Failure to Meet the Conditions of Section 503B

During the inspection, the FDA investigator noted that drug products produced by your facility failed to meet the conditions of section 503B. For example, the investigator noted:

1. Some of your facility's drug products, including HCG (LYO) 12,000 IU Injectable, Testosterone Cypionate in GSO (5ml) 200mg/ml Injectable, FSH (LYO) 1,500 IU Injectable, and Menotropins (HMG)(LYO) 500 IU Injectable, did not include the

[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.

following information on the container to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088. [Section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]].

2. Your facility failed to submit a complete report to FDA in December 2019 and again in June 2020, identifying all the drug products that you compounded during the previous 6-month period, including Leuprolide Acetate 40mcg/0.2ml 10ml Injectable. [Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]].

3. Your facility did not submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations.[3] Specifically, your facility's procedures for reporting adverse events are inadequate. For example, your documented procedures for reporting adverse events do not include a requirement to promptly investigate and submit a follow-up report regarding a serious, unexpected adverse event within 15 calendar days of receipt of new information or as requested by FDA. [Section 503B(b)(5) of the FDCA [21 U.S.C. §353b(b)(5)]; 21 CFR 310.305(c)(2)].

4. Your facility compounded a drug product, BlueChew, that was sold by an entity other than your firm, the outsourcing facility that compounded such drug [Section 503B(a)(8) of the FDCA [21 U.S.C § 353b(a)(8)]].

Because your compounded drug products have not met all of the conditions of section 503B, they are not eligible for the exemptions in that section from the FDA approval requirements of section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements described in section 582 of the FDCA.

Specific violations are described below.

C. Violations of the FDCA

Unapproved New Drug Products

You do not have any FDA-approved applications on file for drug products that you compound.[4] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. §§ 331(d)] a new

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[3] For more information, see FDA's guidance, "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act," which can be found at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf.

[4] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

You compound drug products that are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses causing them to be misbranded under section 502(f)(1) of the FDCA.[5] The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. Further, it is also a prohibited act under section 301(k) of the FDCA 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 misbranded.

Failure to Report Drugs

As noted above, your facility failed to submit a complete report to FDA in December 2019 and again in June 2020, identifying the drug products that you compounded during the previous 6-month period (section 503B(b)(2) of the FDCA). The failure to report drugs by an entity that is registered with FDA in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FDCA [21 U.S.C. § 331(ccc)(3)].

D. Corrective Actions

We have reviewed your facility's response to the Form FDA 483.

Regarding observations related to the conditions of section 503B of the FDCA, some of your corrective actions appear adequate. For example, you state that you have "completed a change control to place the necessary information onto the primary packaging, which now includes the required adverse event reporting contact information."

In addition, regarding observations related to the conditions of section 503B of the FDCA, some of your corrective actions appear deficient. For example, we acknowledge your statement that you "are fully prepared to report any adverse event to FDA." However, we have reviewed the Standard Operating Procedure (SOP) you submitted during the inspection, which "describes the steps Empower Pharmacy follows to fulfill the regulatory requirements for adverse event reporting." Although the SOP addresses adverse event reporting for adverse events "within 15 calendar days of initial report," this SOP does not

[5] Your compounded drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

appear to adequately address adverse event reporting. For example, your SOP does not include information regarding follow-up reports or investigation procedures, and there is no timeline for investigating or providing a follow-up report of an adverse event. When making any corrections, also ensure that your procedures for adverse event reporting comply with the requirements in 21 C.F.R. 211.198.

Furthermore, you did not address certain observations related to the conditions of section 503B of the FDCA. For example, during the inspection, you noted to the FDA investigator that you wholesale drugs that you compound to BlueChew. We remind you of section 503B(a)(8) of the FDCA [21 U.S.C. §353b(a)(8)]), entitled "Prohibition on Wholesaling," which states, in part, that the "drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."

During the inspection, the FDA investigator noted that some of your facility's drug products intended for dispensing to patients pursuant to a prescription included the statement "For office use only." We remind you that for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must comply with the provisions of section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)].

During the inspection, the investigator observed that your facility compounded Pyridoxine HCL 100mg/ml injection using the bulk drug substance Pyridoxine. Pyridoxine is a component of an approved drug product. Please note that for a compounded drug product to qualify for the exemptions under section 503B, it must not be essentially a copy of one or more approved drugs (section 503B(a)(5) of the FDCA [21 U.S.C. § 353b(a)(5)]). The term "essentially a copy of an approved drug" means (A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A) of the FDCA [21 U.S.C. § 353b(d)(2)(A)]); or (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B) of the FDCA [21 U.S.C. § 353b(d)(2)(B)]). For more information on the "essentially a copy" condition, including FDA's recommendations on documenting prescriber determinations of a clinical difference with respect to compounded drugs that would otherwise be copies under section 503B(d)(2)(B), please see FDA's guidance, "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act."[6]

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[6] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-approved-drug-products-under-section-503b-federal.

Furthermore, the FDA investigator noted that your facility produced biological products. Please be advised that federal law does not provide a legal pathway for marketing biological products that have been prepared outside the scope of an approved biologics license application (BLA). Specifically, section 351(a)(1) of the Public Health Service Act (PHS Act) prohibits the introduction into interstate commerce of any biological product unless "a biologics license . . . is in effect for the biological product" (i.e., an approved BLA). Additionally, biological products subject to licensure under section 351 of the PHS Act are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FDCA. We also note that, as required by the Biologics Price Competition and Innovation Act of 2009, on March 23, 2020, an approved application for a biological product under section 505 of the FDCA was deemed to be a license for the biological product (i.e., an approved BLA) under the PHS Act. This transition affects compounding under sections 503A and 503B of the FDCA because, beginning on March 23, 2020, these biological products that previously could have been submitted in a marketing application under the FD&C Act are subject to licensure under section 351 of the PHS Act and thus are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FDCA. *See* Notice to Compounders: Changes that affect compounding as of March 23, 2020[7] and section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 for additional information. Although these biological products are not eligible for the exemptions in sections 503A and 503B, FDA issued guidance explaining conditions under which we do not intend to take action when certain biological products are mixed, diluted, or repackaged in a manner not described in their approved labeling. *See* Guidance for industry, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (January 2018).[8]

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 correct 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 that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of any violations, as well

[7] Available at: https://www.fda.gov/drugs/human-drug-compounding/notice-compounders-changes-affect-compounding-march-23-2020.
[8] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mixing-diluting-or-repackaging-biological-products-outside-scope-approved-biologics-license.

as copies of related documentation. If you believe that 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.

Your written notification should refer to case **# 613792**.

Please electronically submit your reply, on company letterhead, to Jamillah Selby, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to jamillah.selby@fda.hhs.gov and/or john.diehl@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Jamillah Selby via phone at 214-253-5218 or email at jamillah.selby@fda.hhs.gov.

Sincerely,

Tamala P. Bogan -S

Digitally signed by Tamala P. Bogan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300118538, cn=Tamala P. Bogan -S
Date: 2021.10.15 11:34:36 -05'00'

Tamala Bogan
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc: Karen Tannert
Texas Department of State Health Services
karen.tannert@dshs.texas.gov

EMPOWER PHARMACY

Via Email

November 5, 2021

Jamillah Selby
Compliance Officer
Food and Drug Administration, Dallas District
Suite 300
4040 N. Central Expressway
Dallas, TX 75204
Emails: ORAPHARM2_RESPONSES@fda.hhs.gov.
jamillah.selby@fda.hhs.gov
john.diehl@fda.hhs.gov

Re: FDA Warning Letter
Case #: 613792

To Whom It May Concern:

This letter is in response to the Warning Letter dated October 15, 2021, to Empower Clinic Services, LLC (the Company) located at 5980 W. Sam Houston Parkway N., Suite 300, Houston, TX 77041.

We appreciate the opportunity to respond to FDA's issues raised in the Letter and demonstrate the Company's commitment to compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The Company continues to be committed to quality and regulatory compliance, taking its responsibility as an outsourcer of compounded formulations very seriously.

Empower notes, importantly, that it understood and believed FDA's February and March 2020 inspection of its facility intended to cover Empower's Section 503B operations. Notwithstanding, because the Section 503A and Section 503B operations were at that time located in one facility, FDA inspected the Section 503A operations as if Empower were required to comply with the provisions of Section 503B, including but not limited to certain labeling requirements and FDA's current good manufacturing practice regulations (cGMP). In order to obviate such confusion in the future, Empower recently engaged in a multi-million dollar investment to completely separate its Section 503A and 503B operations. Its Section 503A operations are imminently relocating to a new, state-of-the-art, compounding center.

The Company has reviewed the remaining issues set forth in FDA's Letter, specifically, "D. Corrective Actions." Set forth below is the issue noted in FDA's Letter, in bold, followed by Empower's Response. The Response below reflects the Company's business practices and certain changes to the same that either have been initiated in response to FDA's Warning Letter or will imminently be corrected, as noted. Empower will keep FDA informed of its remedial activities, as it considers itself a partner with the Agency in its efforts to ensure access to quality, affordable compounded medications to its customers.

Respectfully,

Shaun Noorian
CEO

Attachments
CC: CDR John Diehl, FDA
{00857004}

FDA Issue:

[Y]our facility failed to submit a complete report to FDA in December 2019 and again in June 2020, identifying all the drug products that you compounded during the previous 6-month period, including Leuprolide Acetate 40mcg/0.2ml 10ml Injectable. [Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]].

Empower's Response:

Empower submitted a complete report of all Leuprolide Acetate 40mcg/.2ml compounded under its 503B license pursuant to 21 U.S.C. § 353b(b)(2), in December 2019 and June 2020. Empower's Leuprolide Acetate 40mcg/.2ml has only been dispensed through our 503A pursuant to patient-specific prescriptions, which is why this compound was not reported as part of our outsourcing facility's biannual report. Notwithstanding, Empower understands FDA's position that 503A operations are subject to the provisions of Section 503B when both take place in the same facility. As such, Empower is relocating its 503A operations to a new facility in an effort to permanently define, distinguish and disjoin both operations.

FDA Issue:

[R]egarding observations related to the conditions of section 503B of the FDCA, some of your corrective actions appear deficient. For example, we acknowledge your statement that you "are fully prepared to report any adverse event to FDA." However, we have reviewed the Standard Operating Procedure (SOP) you submitted during the inspection, which "describes the steps Empower Pharmacy follows to fulfill the regulatory requirements for adverse event reporting." Although the SOP addresses adverse event reporting for adverse events "within 15 calendar days of initial report," this SOP does not appear to adequately address adverse event reporting. For example, your SOP does not include information regarding follow-up reports or investigation procedures, and there is no timeline for investigating or providing a follow-up report of an adverse event. When making any corrections, also ensure that your procedures for adverse event reporting comply with the requirements in 21 C.F.R. 211.198

Empower's Response:

Empower has revised its SOP for adverse event reporting to cover the areas that FDA references above (titled "Adverse Drug Event Reporting"), attached hereto as Exhibit "A", to ensure it fulfills regulatory requirements. Additionally, Empower has updated its SOP for receiving and investigating complaints, including those related to Adverse Drug Event Reporting (titled "Complaint Handling"), and attached hereto as Exhibit "B". In particular, the SOPs state that "product based complaints" shall be forwarded to the clinical pharmacist team to gather the appropriate data outlined in Section 6.3.3 and 6.3.4 of Exhibit "B". The clinical pharmacist team is required to complete Form T09.72, attached as Exhibit "C" and route that document to the Pharmacist-in-Charge. The Pharmacist-in-Charge shall be responsible for reporting all Serious and/or Unexpected Adverse Drug Experiences as defined in Section 4.3 and 4.4 of Exhibit "A" in a manner consistent with Section 6.2 and 6.3, and within the appropriate timeframe outlined in Section 6.4. Simultaneously, the Quality Department shall perform an investigation pursuant to Section 6.4.2 of Exhibit "B". Empower believes these updated SOPs sufficiently outline a robust complaint investigation and reporting structure necessitated by an adverse event, a timeline for completing the same, and complaint handling documentation requirements set forth in 21 C.F.R. § 211.198. Empower's enhanced procedures also add provisions that help determine whether the complaint concerning the compounded formulations represents a "serious and unexpected" adverse drug experience, which Empower understands is required to be reported to FDA in accordance with §§ 310.305 and 514.80. Empower has trained its responsible employees on the revised SOP in advance of submitting this response. That training log has been completed and is attached hereto as Exhibit "D".

{00857004}

FDA Issue:

[Y]ou did not address certain observations related to the conditions of section 503B of the FDCA. For example, during the inspection, you noted to the FDA investigator that you wholesale drugs that you compound to BlueChew. We remind you of section 503B(a)(8) of the FDCA [21 U.S.C. §353b(a)(8)]], entitled "Prohibition on Wholesaling," which states, in part, that the "drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."

Empower's Response:

As of June 21, 2021, Empower no longer compounds or dispenses BlueChew formulations. As such, this observation is no longer at issue. However, prior to that date, Empower only compounded BlueChew pursuant to a lawful, valid prescription and dispensed to individually identified patients accordingly. Empower never engaged in the sale and/or transfer of BlueChew formulations to any third-party entity (including BlueChew itself), as referenced in the observation and outlined in 21 U.S.C. § 353b(a)(8). As such, this code provision is inapplicable to facts at hand. However, assuming arguendo, 21 U.S.C. § 353b(a)(8) was deemed applicable, this code provision "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 353(b)(1)...."

FDA Issue:

During the inspection, the FDA investigator noted that some of your facility's drug products intended for dispensing to patients pursuant to a prescription included the statement "For office use only." We remind you that for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must comply with the provisions of section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)].

Empower's Response:

Empower understands that certain drug products that were intended for dispensing to patients pursuant to a prescription were inadvertently labeled "For office use only." These medications were intended for in-office administration to individually identified patients and pursuant to a prescription. Notwithstanding, Empower understands the requirements of 21 U.S.C. § 353b(a)(10) and has updated its internal labeling checklist, attached as Exhibit "E", to ensure the appropriate labeling is included on drug products which are dispensed pursuant to prescriptions and those which are distributed.

FDA Issue:

During the inspection, the investigator observed that your facility compounded Pyridoxine HCL 100mg/ml injection using the bulk drug substance Pyridoxine. Pyridoxine is a component of an approved drug product. Please note that for a compounded drug product to qualify for the exemptions under section 503B, it must not be essentially a copy of one or more approved drugs (section 503B(a)(5) of the FDCA [21 U.S.C. § 353b(a)(5)]) * unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B) of the FDCA [21 U.S.C. § 353b(d)(2)(B)]).**

Empower's Response:

Empower understands that it may not compound "essentially copies" of commercially available drug products unless there is a change that produces for an individual patient a clinical difference as determined by the

prescribing practitioner, between the compounded drug and the FDA-approved drug product. Empower has diligently undertaken practices to ensure that practitioners and purchasing agents (per FDA's Essentially Copies Final Guidance (2018)) list a clinical difference between the commercially available product and the compounded formulation. For example, Empower's compounded formulation for "Pyridoxine HCL 100mg/ml" cited in the Letter, substitutes Chlorobutanol (used in the commercial formula) for Benzyl Alcohol, to produce a clinical difference for patients with a known sensitivity. Empower recognizes the need for robust clinical statements and has revised its SOP as a result of FDA's Form 483 Observations and this Letter, attached hereto as Exhibit "F". As such, compounded products like Pyridoxine will only be dispensed or distributed for patients who present an individual clinical need for the compounded formulation, appropriately documented by a physician or the purchasing agent (as set forth in FDA's Essentially Copies Guidance). As part of its commitment to the same, Empower's employees have received updated "essential copy" training, attached as Exhibit "G".

FDA Issue:

[T]he FDA investigator noted that your facility produced biological products.

Empower's Response:

Empower is in the process of pursuing a biologics license application (BLA) so that it may continue to provide biologics to its patients that require them. However, given FDA's position on the compounding of biologics, Empower has ceased compounding and dispensing biologics.

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We want to again express our sincere appreciation for the opportunity to engage in a dialogue with the Agency concerning compliance with FDA regulations and guidance at Empower's facilities. The Company will continue to work diligently to maintain compliance with FDA's regulations and other guidance provided by the Agency.

ATTACHMENTS

Exhibit A:	A copy of revised SOP "Adverse Drug Event Reporting"
Exhibit B:	A copy of revised SOP "Complaint Handling"
Exhibit C:	A copy of Form "Product Complaint / Adverse Drug Event / Therapy Form"
Exhibit D:	A copy of the Training Register addressing revised SOP "Adverse Drug Event Reporting"
Exhibit E:	A copy of Form "Label Check And Line Clearance"
Exhibit F:	A copy of revised SOP "Essential Copy Procedure for 503B Products"
Exhibit G:	A copy of the Training Register addressing revised SOP "Essential Copy Procedure for 503B Products"

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Exhibit A: A copy of revised SOP "Adverse Drug Event Reporting"

1.0 Purpose

1.1 The purpose of this procedure is to outline the requirements and process for reporting adverse drug experiences to the Food and Drug Administration (FDA).

2.0 Scope

2.1 This procedure applies to all serious and unexpected adverse drug experiences reported to the outsourcing facility.

3.0 Roles and Responsibilities

3.1 Clinical pharmacists are responsible for taking calls and other notifications of adverse drug experiences and performing an investigation to obtain all necessary information related to the adverse event. The clinical pharmacist shall document the information using the **T09.72 Product Complaint / Adverse Drug Event / Therapy Form**.

3.2 The Pharmacist in Charge, or designee, is responsible for reporting all serious unexpected adverse drug experiences to the FDA according to this procedure.

3.3 The Quality Unit is responsible for assisting with any investigations and coordinating corrective action when necessary. For more information see the **Complaint Handling SOP**.

4.0 Terms and Abbreviations

4.1 Individual Case Safety Report (or "ICSR") – A description of an adverse drug experience related to an individual patient or subject.

4.2 ICSR Attachments – Supporting information for ICSRs, such as relevant hospital discharge summaries, copies of the current labeling of the suspect drug product(s), and autopsy or death certificates.

4.3 Serious Adverse Drug Experience – Any adverse drug experience occurring at any dose that results in any of the following outcomes:

- 4.3.1 Death,
- 4.3.2 A life-threatening adverse drug experience,
- 4.3.3 Inpatient hospitalization or prolongation of existing hospitalization,
- 4.3.4 A persistent or significant disability/incapacity, or
- 4.3.5 A congenital anomaly/birth defect.

4.4 Unexpected Adverse Drug Experience – Any adverse drug experience that is not listed in the current labeling for the drug product. For example, if current labeling for a compounded drug product does not list any adverse drug experiences, all adverse drug experiences associated with the compounded drug product would be considered "unexpected."

5.0 Policy

5.1 All serious unexpected adverse events associated with the use of a compounded prescription drug product shall be reported to the FDA in accordance with section 503B(b)(5) of the Food Drug and Cosmetic Act.

- 5.1.1 The adverse event reporting requirements apply to prescription drug products regardless of whether the outsourcing facility distributes them pursuant to prescriptions.

5.2 Adverse event reporting for drug products compounded by outsourcing facilities is a critical mechanism by which FDA identifies signals of potential quality problems that may be associated with a particular drug or drug component.

6.0 Procedure

6.1 Reporting

6.1.1 Reporting of each adverse drug experience received or otherwise obtained that is both serious and unexpected shall be completed no later than 15 calendar days from the date of initial receipt.

6.1.2 Reports should not include the names and/or addresses of individual patients. A unique code should be assigned for each individual patient.

6.1.3 All records relating to adverse drug experiences required to be reported under 21 CFR section 310.305 shall be kept for 10 years.

6.1.4 The report or information submitted does not necessarily reflect a conclusion that the report or information constitutes an admission that the drug caused or contributed to an adverse effect.

6.2 What to Report

6.2.1 The four following data elements are required when reporting adverse drug experiences to the FDA:

6.2.1.1 An identifiable patient

6.2.1.1.1 There should be enough information to indicate the existence of a specific patient (i.e., age or category, gender, initials, date of birth, name, patient identification number).

6.2.1.1.2 Each identifiable patient should be distinguished to prevent duplicate reports of a single adverse event.

6.2.1.2 An identifiable reporter

6.2.1.2.1 The person who initially notifies the outsourcing facility about an adverse event, can be a patient, consumer, doctor, or other individual.

6.2.1.2.2 Sufficient information to indicate the reporter as an identifiable person should be obtained [i.e., a personal identifier (name), a professional identifier (title), contact information (email, phone number)].

6.2.1.2.3 When possible, the reporter's contact information should be obtained so that the facility and/or the FDA can conduct follow-up investigations.

6.2.1.2.4 If the reporter requests that their information not be submitted to the FDA, submit the report with the *reporter field* as "Requested Anonymity."

6.2.1.3 A suspect drug

6.2.1.3.1 The drug product that the initial reporter suspected was associated with the adverse event.

6.2.1.3.2 Describe the known product attributes (e.g., active ingredient(s), dosage form, strength, color, lot number, etc.).

6.2.1.3.3 If multiple drugs are involved submit only one report that notes the drug product considered most suspect by the reporter. If the reporter views each drug product as equally suspect submit only one report that lists all of the drug products as suspect.

6.2.1.3.4 If the compounded drug contains multiple components (e.g., excipients, drugs substances, finished dosage forms), list each component and its manufacturer if known.

6.2.1.3.5 List any other known medial product(s) the patient was taking at the time he or she experienced the adverse event and the manufacturer of that product(s).

6.2.1.4 A serious adverse event

6.2.1.4.1 Report the unexpected adverse event that results in one or more of the following patient outcomes:

6.2.1.4.1.1 Death,

6.2.1.4.1.2 A life-threatening adverse drug experience,

6.2.1.4.1.3 Inpatient hospitalization or prolongation of existing hospitalization,

6.2.1.4.1.4 A persistent or significant disability or incapacity, or

6.2.1.4.1.5 A congenital anomaly or birth defect.

6.2.1.4.2 Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious adverse drug experiences if, when based on appropriate medical judgement, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

6.2.1.4.3 For reporting purposes, an adverse event should be described in terms of signs (including abnormal laboratory findings, if appropriate), symptoms, or disease diagnosis (including any colloquial descriptions obtained), if available.

6.3 Report Attachments

6.3.1 A copy of the current labeling for the compounded drug product that is the subject of the report must be submitted as an attachment.

6.3.2 The following may also be appropriate to provide, if available:

6.3.2.1 Hospital discharge summaries,

6.3.2.2 Autopsy reports/death certificates,

6.3.2.3 Relevant laboratory data, and

6.3.2.4 Other critical clinical data.

6.3.3 In the case of a death any available information on the event(s) that led to the death should be provided.

6.4 When to Report

6.4.1 The facility must submit the report as a 15-day "alert report" to the FDA as soon as possible, but not later than 15 calendar days after first receiving information about the adverse event.

6.4.1.1 Reports should be submitted so long as information on at least the suspect drug and the adverse event are known.

6.5 Investigations

6.5.1 All serious and unexpected adverse drug experiences must be promptly investigated, and a follow-up report submitted within 15 calendar days of receipt of new information or as requested by the FDA.

6.5.1.1 Initial investigations must be completed within 15 calendar days.

6.5.2 If all four data points listed in section 6.2.1 were not included in the initial report, every effort shall be made to obtain the missing information.

6.5.2.1 Records of the efforts to obtain this and other relevant information shall be retained (e.g., dates of discussions with the reporter to determine how many patients experienced a particular adverse event or dates of discussion with a health care facility to obtain contact information for an identifiable person who purports to have knowledge about the patient, adverse event, or drug involved).

6.5.3 New information obtained about the initial report should be reported when it could assist the FDA in investigating an adverse event. If additional information is not obtainable, records shall be maintained documenting the steps that were taken to attempt to seek the additional information.

6.6 How to Report Adverse Events

6.6.1 Reports shall be submitted electronically to the FDA using the Safety Reporting Portal (SRP). http://www.safetyreporting.hhs.gov

6.6.2 Initial Report

6.6.2.1 When submitting an adverse event report for the first time notify the FDA Adverse Event Reporting System (FAERS) Electronic Submission Coordinator at faersesub@fda.hhs.gov. The coordinator will assist the organization and ensure that all steps have been completed for successful submission of adverse event reports.

6.6.3 Adverse event reporting is considered postmarketing safety reporting and involves submitting a series of reports consisting of the initial individual case safety report (ICSR) and follow-up ICSRs, along with any associated attachments, over the life cycle of an individual case.

6.6.3.1 An ICSR is a description of an adverse drug experience related to an individual patient or subject. ICSR attachments include supporting information for ICSRs, such as relevant hospital discharge summaries and autopsy reports or death certificates.

6.6.3.2 To avoid duplicate adverse event reports in the FAERS database, each report should have a unique case identification number, regardless of how it is transmitted to the FDA.

6.6.4 Safety Reporting Portal Use

6.6.4.1 The ICSR information is entered manually into a web-based form and then submitted to the FDA to be uploaded into the FAERS database.

6.6.4.2 When the initial ICSR is submitted through the SRP, users will be able to return to the initial ICSR and submit follow-up reports as more information about the reported adverse experience becomes available.

6.6.4.3 Users may log in to their SRP accounts, locate the ICSR record, and modify or add to the initial ICSR to create a follow-up submission. Users may submit as many follow-up reports as necessary.

6.6.4.3.1 All staff who submit reports shall create an SRP account which can be done from the SRP homepage.

6.6.4.4 After a submission is made an acknowledgement message will be sent to the user. The SRP acknowledgement provides the user the status of the submission and indicates whether it was accepted into the FAERS database. This acknowledgement should be retained as part of the facility's internal documentation.

6.6.4.4.1 Any issue should be corrected by the user and resubmitted within the reporting timeframe. The receipt date of the corrected resubmission serves as the official FDA receipt date of the report.

6.6.4.5 If SRP is not functional contact the FAERS Electronic Submission Coordinator at faersesub@fda.hhs.gov for assistance.

6.7 Inspection of Adverse Event Reporting

6.7.1 As part of its inspections of outsourcing facilities the FDA may review adverse event information received by the outsourcing facility.

6.7.2 Records shall be retained for 10 years and shall be readily retrievable.

7.0 Forms

Form Number	Description/Title
T09.72	Product Complaint / Adverse Drug Event / Therapy Form

8.0 Notes and Comments

8.1 N/A

9.0 References

Reference Source	Reference Code	Section Code	Section Description
FDCA	503B	§503B(b)(5)	Adverse Event Reporting
CFR	Title 21	§211.198	Complaint Files
FDA	GFI	-	Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, October 2015
FDA	GFI	-	Providing Submissions in Electronic Format – Postmarketing Safety Reports (Draft Guidance), June 2014

EMPOWER PHARMACY

Exhibit B: A copy of revised SOP "Complaint Handling"

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for the handling of complaints related to compounded preparations.

2.0 Scope

2.1 This procedure applies to Empower Pharmacy's 503B Outsourcing Facility operations.

3.0 Roles and Responsibilities

3.1 The Clinical Pharmacist team is responsible for creating and maintaining Incident Reports in Salesforce as complaints related to products are received either via phone or in writing and completing Form T09.72 when required.

3.2 The Quality Unit is responsible for reviewing product related Incident Reports and assisting in investigations as needed.

3.3 The Incident Team is responsible for ensuring complaint resolutions are coordinated and documentation is complete.

3.4 The Pharmacist in Charge, or their designee, is responsible for reporting all serious and unexpected adverse drug experiences to the FDA.

4.0 Terms and Abbreviations

4.1 N/A

5.0 Policy

5.1 Written procedures describing the handling of all written and oral complaints regarding drug product shall be established and followed.

5.2 Such procedures shall include a provision for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation.

5.3 Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration. See the **Adverse Drug Event Reporting SOP** for more information.

6.0 Procedure

6.1 Complaints are generally reported via the call center, clinic support, or the sales team. All complaints shall be recorded in Salesforce as an Incident Report.

6.1.1 See **Attachment 1 – Incident Types**, for some examples of different types of complaints.

6.2 If a complaint regarding delivery or customer experience is reported, technicians, managers, pharmacists, and directors have been granted authority to give credits to help resolve some incidents that would not need further review.

6.2.1 Any refunds of credits shall require management approval prior to being processed.

6.3 All complaints that are related to the product (such as adverse reactions or product issues) go to the clinical pharmacist team for a pharmacist consultation, initial information gathering and

documentation. This would include pharmacist consultation for a patient that has had an adverse reaction to the medication.

6.3.1 The complaint shall be documented as an Incident in the Salesforce platform.

6.3.2 The clinical pharmacist shall initiate the incident record which can be collaborated on by other staff involved in the complaint handling process.

6.3.3 The Incident contains the following information:

6.3.3.1 Basic Incident Information

6.3.3.1.1 Incident Number (generated by Salesforce)

6.3.3.1.2 Site

6.3.3.1.3 Owner

6.3.3.1.4 Status

6.3.3.1.5 Priority

6.3.3.1.6 Record Type

6.3.3.1.7 Root Cause

6.3.3.1.8 Record Subtype

6.3.3.1.9 Department

6.3.3.2 Incident Overview

6.3.3.2.1 How the incident was reported.

6.3.3.2.2 Overview of the incident – a description according to the initial report.

6.3.3.3 Clinical and Patient Information

6.3.3.3.1 Prescriber and/or Clinic name

6.3.3.3.2 Patient information (if known)

6.3.3.3.3 Provider information

6.3.3.4 Medication and Incident Cost Information

6.3.3.4.1 Invoice number

6.3.3.4.2 Medication name and strength

6.3.3.4.3 Prescription number

6.3.3.4.4 Lot number

6.3.3.4.5 Case / RX / Tracking Number

6.3.3.4.6 Case number

6.3.3.4.7 Cost

6.3.3.5 Full Details and Resolution

6.3.3.5.1 A full description of information gathered during the incident handling and resolution.

6.3.3.6 Activity History

6.3.3.6.1 Lists each inbound or outbound call related to the incident, includes comments so information about the call can be documented, time, date, and the person it was assigned to.

6.3.3.7 Notes and Attachments

6.3.3.7.1 All supporting documentation shall be attached to the record.

6.3.4 The clinical pharmacists shall make at least three attempts to contact the patients and/or the prescriber (if they were not the incident reporter) for further information.

6.3.4.1 Each attempt is documented in the Activity History section of the Incident Report.

6.4 Investigation

6.4.1 Product related complaints are submitted to the clinical quality group after the incident has been created so that members of the Quality Unit can review the incident and assist in the investigation.

6.4.1.1 When the Quality Unit performs an independent investigation a copy of that documentation shall be attached to the Incident Report in Salesforce.

6.4.2 Investigations can include, but are not limited to, the following:

6.4.2.1 Batch record review

6.4.2.2 Test results review

6.4.2.3 Retention sample review

6.4.2.4 Raw materials and components review

6.4.2.5 Related incidents review/incident trending

6.4.2.6 Review of the returned medication (if applicable)

6.4.3 The Incident Team shall help ensure documentation is complete, assist in replacing medication or retrieving medication, processing refunds, etc. as appropriate.

6.4.4 Results of the investigation shall be documented in the Incident Report and should be reported back to the initial incident reporter and/or prescriber by a clinical pharmacist.

6.4.4.1 All replies to the complainant shall be documented in the Incident Report.

6.4.5 If an investigation is found to be unnecessary the reason that the investigation was found not to be necessary and the name of the person responsible for making that determination shall be included in the Incident Report.

6.5 Documentation

6.5.1 In addition to the Incident Report the **Product Complaint / Adverse Drug Event / Therapy Form T09.72** is completed if the incident is related to a product issue, adverse drug event or clinical therapy issue.

6.5.1.1 The original shall go to the PIC or designee and a copy of the form will go to the Customer Service Quality and Compliance Coordinator for retention.

6.5.1.2 A completed copy of this form shall be attached to the Salesforce Incident Report in the Notes and Attachments section.

6.5.1.3 The form shall document the determination of whether the incident is a serious and unexpected adverse drug experience.

6.5.2 If the incident is determined to be a serious and unexpected adverse drug experience the form will be escalated to the Pharmacist in Charge (PIC) and/or the Compliance Department for review.

6.5.2.1 The PIC, or designee, shall report the ADE to the FDA per the **Adverse Drug Event Reporting SOP** within 15 days of the incident notification.

6.6 Timeframes

6.6.1 Documentation for adverse drug experiences shall be initiated within 72 hours of becoming aware of the incident unless the incident resulted in hospitalization or death in which case documentation must occur within 24 hours.

6.6.1.1 The Product Complaints / Adverse Drug Event / Therapy Form must be completed within 5 days of the incident.

6.6.1.2 Documentation shall be submitted to the FDA within 15 calendar days.

6.6.1.3 Follow-up reports shall be submitted to the FDA within 15 calendar days of when new information is obtained.

6.6.2 Upon completion of the investigation the PIC or designee is responsible for ensuring appropriate corrective action is implemented within 14 days.

6.6.3 All complaint records involving drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer.

6.6.4 All complaint records for serious and unexpected adverse drug experiences shall be retained for 10 years.

7.0 Forms

Form Number	Description/Title
T09.72	Product Complaint / Adverse Drug Event / Therapy Form

8.0 Notes and Comments

8.1 N/A

9.0 References

Reference Source	Reference Code	Section Code	Section Description
CFR	Title 21	§211.198	Complaint Files

Attachment 1 – Incident Types

Product	
The call reporting these types of incidents should be forwarded to a pharmacist.	
	Mixed medication incorrectly
	Received wrong medication
	Medication doesn't work
	Adverse reaction
	Quality concern
Accounting / Financial	
	Charged the wrong card on file
	Charge the wrong account
	Double charged
	No charge on account
	Entered card on file incorrectly
Other Inaccuracy	
	Missing supplies
	Missing package that was delivered
	Wrong shipping method selected
	Shipped to the wrong address
Process and Procedure	
	Delay in order
	Complaint on policies and procedures
	Complaint on the price of medication or shipping
Shipping (FedEx, USPS, UPS)	
	The package shows delivered but the customer claim that it was not delivered
	The package was damaged upon delivery
	The package was lost in transit
Other	
	Any other complaints from the patient or clinic

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Exhibit C: A copy of Form "Product Complaint / Adverse Drug Event / Therapy Form"

T09.72 Product Complaint / Adverse Drug Event / Therapy Form

EMPOWER PHARMACY PRODUCT COMPLAINT / ADVERSE DRUG EVENT/ THERAPY FORM

SECTION A: CUSTOMER INFORMATION

Customer Name				Reference/Case #		Date of Birth (mm/dd/yy)	
Gender	M	F	Unknown	Weight (kg)		Race	
Allergies				Pregnant?	[ ] Yes [ ] No	Est. Delivery Date	

BRIEF DESCRIPTION OF THE COMPLAINT:

CHECK TYPE OF COMPLAINT OR ISSUE: [ ] PRODUCT/QUALITY (C) [ ] THERAPY/EFFICACY OR ADVERSE DRUG EVENT

PERSON WHO CONTACTED THE PHARMACY REGARDING THE COMPLAINT IF NOT THE PATIENT:
If reporter is not the patient, fill out information below: [ ] Relative [ ] Caregiver [ ] Nurse [ ] Physician [ ] Other: _____
Name: _____ Phone: _____ Fax: _____
Address: _____ Email: _____
Note: contact patient to complete report and if patient cannot be contacted, please state reason(s): _____

SECTION B: DRUG INFORMATION

Drug Name	Dose & frequency	Route (& site if injection)	Date Started	Date Stopped	Indication or reason for use	Lot / Batch #	Expire date or BUD

First date drug therapy started: | Date filled on drug prescription label:

If suspected drug is a compounded drug, list all active and inactive ingredients:

Direction on prescription label of suspected drug:

Actual direction reported use by patient / caregiver / medical provider:

If drug requires reconstitution:

What diluent was used to reconstitute the drug, amount of diluents, and lot?	
Date drug reconstituted?	
Who reconstituted the drug if not the patient?	

What is the storage temperature for the reconstituted drug?

SECTION C: PRODUCT QUALITY COMPLAINT:

Provide full details regarding product quality complaint: may be associated with label, vial, cap seal, stopper, drug integrity/quality/color, etc)

When did the patient noticed the issue?

Did the patient use any of the product? [ ] Yes [ ] No
If so, how many? _____

Did the patient experience any adverse drug event as a result of using the product? [ ] Yes [ ] No
If yes, describe the adverse drug event:

Did the patient contact the doctor? [ ] Yes [ ] No
If yes, what did the doctor tell the patient?

SECTION D: THERAPY/EFFICACY COMPLAINT(S) OR ADVERSE DRUG EVENT

Description of adverse event or therapy/efficacy:

If complaint involves therapy/efficacy issues:

When did the drug stop working or become less effective?

How many dose(s) were taken when customer started to notice the drug being less effective or not working?

T09.72 Product Complaint / Adverse Drug Event / Therapy Form

OTHER DRUG(S) PATIENT WAS TAKING AT TIME OF ADE OR THERAPY COMPLAINT (INCLUDING OVER THE COUNTER AND HERBAL PRODUCTS)

Drug Name	Dose & frequency	Route (& site if injection)	Date Started	Date Stopped	Indication or reason for use	Lot / Batch #	Expire date or BUD

MEDICAL HISTORY / OTHER MEDICAL CONDITIONS OR CO-MORBIDITIES:

Date and time of onset of ADE		Date ADE resolved or stopped or duration of event?	

INTERVENTION OF ADVERSE EVENT OR THERAPY/EFFICACY(check all that apply):

[ ] No intervention
[ ] Intervention unknown
[ ] Patient Counseled / non-medical treatment
[ ] Discontinued Suspected Drug: Date if known: _____
  [ ] Temporarily stopped medication
  [ ] Permanently Discontinued
[ ] Decreased Suspected Drug Dosage; New Dose: _____
[ ] Treated Adverse Drug Event- with:
_____
[ ] Other intervention (e.g. dialysis): _____

OUTCOME OF ADVERSE EVENT (check all that apply)

[ ] Adverse event resolved / Recovered
[ ] Symptom(s) continuing
[ ] Adverse Drug Event reappeared after restarting drug (rechallenge?:
  [ ]Yes [ ]No [ ]Not Done [ ]UNKNOWN

[ ] Impairment / Disability
[ ] Congenital Anomaly
[ ] Patient Hospitalized or Hospitalization prolonged
Indicate the name and date in and date out or duration of Hospital, name of Doctor and Phone #:
_____

[ ] Life Threatening
[ ] Other: _____
[ ] Patient Deceased (Date of death): _____
[ ] Cause(s) of death (attach any report, death certificate, or any relevant clinical laboratory assessments to confirm event). _____

Note: If the reported adverse drug event is an unexpected and serious adverse event that results in one or more of above outcomes, notify PIC immediately.

Has the patient discussed the adverse drug event or therapy issue with a medical provider? [ ] Yes [ ] No [ ] Unknown

Has the patient sought medical treatment for the adverse drug event from a medical provider? [ ] Yes [ ] No [ ] Unknown
If yes, describe the medical treatment and provide the medical provider's information:
Description of medical treatment:
_____

Medical Provider's Name: _____ Address: _____ Phone: _____

Did a pharmacy staff notify the patient's medical provider of the ADE or therapy complaint? [ ] Yes [ ] No

If yes, name of pharmacy staff: _____ Name of doctor or representative _____
Date notified: _____

Is suspected product being returned for assessment? [ ] Yes [ ] No
If not, state reason(s) below:

Pharmacist comment(s):

SECTION E: QUALITY REVIEW

Has batch record associated with the suspected drug been reviewed? [ ] Yes [ ] No

Any previous complaint(s) associated with the suspected drug lot? [ ] Yes [ ] No

T09.72 Product Complaint / Adverse Drug Event / Therapy Form

Is reporting to FDA required? [ ] Yes [ ] No
If yes, indicate the date of report submitted to FDA: _____
Note: If the reported adverse drug event is an unexpected and serious adverse event that results in one or more of the following patient outcomes:

1. Death, a life-threatening adverse drug experience,
2. Inpatient hospitalization or prolongation of existing hospitalization,
3. A persistent or significant disability or incapacity,
4. A congenital anomaly or birth defect

FDA must be notified within 15 days via MEDWATCH OR via the current FAERS. Please notify and send report to PIC immediately.

ADDITIONAL COMMENTS:

PHARMACY INFORMATION

Name		Title	
Signature		Date	

REVIEWED BY:

Name		Title	
Signature		Date	

THIS REPORT IS NOT A CONFIRMATION THAT THE SUSPECTED DRUG CAUSED THE ADE OR THERAPY ISSUE.

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Exhibit D: A copy of the Training Register addressing revised SOP "Adverse Drug Event Reporting"

Pharmacists	Email	Adverse Drug Events and Handling Complaints	Completion Date
Anu Patel	apatel@empowerpharmacy.com	Completed	2021-10-29 00:23:06
Colleen Nguyen	cnguyen1@empowerpharmacy.com	Completed	2021-10-29 04:37:17
Courtney Yeung	cyeung@empowerpharmacy.com	Completed	2021-10-28 23:43:18
Diana Nemry	dnemry@empowerpharmacy.com	Completed	2021-10-29 11:45:26
Gwenn Iyer	giyer@empowerpharmacy.com	Completed	2021-10-28 20:13:59
Ha Wong	hwong@empowerpharmacy.com	Completed	2021-10-29 14:50:49
Kathryn Lenz	klenz@empowerpharmacy.com	Completed	2021-10-28 19:17:47
Kavya Kolavasi	kkolavasi@empowerpharmacy.com	Completed	2021-10-29 07:49:07
Linda Mai	lmai@empowerpharmacy.com	Completed	2021-10-29 14:44:17
Marwa Elsiad	melsiad@empowerpharmacy.com	Completed	2021-10-28 20:42:17
Mary Katherine Weeks	mweeks@empowerpharmacy.com	Completed	2021-10-29 15:40:28
Nicolle Fritschle	nfritschle@empowerpharmacy.com	Completed	2021-10-28 19:43:07
Robert Valadez	rvaladez@empowerpharmacy.com	Completed	2021-10-29 17:28:11
Tailynn Dinh	tdinh@empowerpharmacy.com	Completed	2021-10-29 16:06:52
Whitney Louis	wlouis@empowerpharmacy.com	Completed	2021-10-29 17:28:17
Clinic Support		**Adverse Drug Events and Handling Complaints**	
Crystal Marinucci	cmarinucci@empowerpharmacy.com	Completed	2021-10-28 20:35:35
Amy Carrington	acarrington@empowerpharmacy.com	Completed	2021-10-29 18:24:13
Angelic Rivera	arivera@empowerpharmacy.com	Completed	2021-10-29 18:51:42
Brittany Butler	bbutler@empowerpharmacy.com	Completed	2021-10-29 18:34:02
Debbi Ilegbusi	dilegbusi@empowerpharmacy.com	Completed	2021-10-28 20:50:28
Juan Catalan	jcatalan@empowerpharmacy.com	Completed	2021-10-28 22:52:44
Kailyn Estrada	kestrada@empowerpharmacy.com	Completed	2021-10-29 19:10:09
Kiera Martin	kmartin@empowerpharmacy.com	Completed	2021-10-29 18:53:52
Latisha Schwartz	lschwartz@empowerpharmacy.com	Completed	2021-10-28 21:31:49
Michala Hayman	mhayman@empowerpharmacy.com	Completed	2021-10-29 18:44:22
Michelle Anthony	manthony@empowerpharmacy.com	Completed	2021-10-29 18:22:57
Monica Cavazos	mcavazos@empowerpharmacy.com	Completed	2021-10-29 13:56:03
Nida Naqvi	nnaqvi@empowerpharmacy.com	Completed	2021-10-28 23:17:04
Rogelio Menchaca	rmenchaca@empowerpharmacy.com	Completed	2021-10-29 18:44:27
Ruth Fuller	rfuller@empowerpharmacy.com	Completed	2021-10-29 19:06:28
Sabrine Barrett	sbarrett@empowerpharmacy.com	Completed	2021-10-29 18:56:52
Samreen Naqvi	snaqvi@empowerpharmacy.com	Completed	2021-10-29 18:37:04
Taylor Rhodes	trhodes@empowerpharmacy.com	Completed	2021-10-29 13:33:53
Tiffany Stewart	tstewart@empowerpharmacy.com	Completed	2021-10-28 22:19:56
Toni Williams	twilliams1@empowerpharmacy.com	Completed	2021-10-29 19:07:51
Vanessa Jansen	vjansen@empowerpharmacy.com	Completed	2021-10-28 20:34:54
Incident Team		**Adverse Drug Events and Handling Complaints**	
Brooke Allison	ballison@empowerpharmacy.com	Completed	2021-10-28 21:34:37
Jannah Perry	jperry@empowerpharmacy.com	Completed	2021-10-28 20:17:06
Kirsten Roland	kroland@empowerpharmacy.com	Completed	2021-10-28 21:05:54
Laura Allamaa	lallamaa@empowerpharmacy.com	Completed	2021-10-28 20:27:51
Marcus Walker	mwalker@empowerpharmacy.com	Completed	2021-10-28 21:38:25
Rickhard Huggup	rhuggup@empowerpharmacy.com	Completed	2021-10-28 20:10:42
Tatona Lewis	tlewis@empowerpharmacy.com	Completed	2021-10-28 20:10:56
Zachary Andrews	zandrews@empowerpharmacy.com	Completed	2021-10-28 20:22:48

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Exhibit E: A copy of Form "Label Check And Line Clearance"

T09.77 Label Check And Line Clearance

Product Description: _____ **Lot #:** _____

Date compounded: _____ **BUD:** _____

Label Information checklist **Date:** _____

NDC (If any)	☐	☐	Osmolarity (If any)	☐	☐
Unit vial size	☐	☐	Storage conditions	☐	☐
Name	☐	☐	Auxiliary label (If any)	☐	☐
Strength	☐	☐	Pharmacy address	☐	☐
Route of Administration	☐	☐	Compounding date	☐	☐
Logo	☐	☐	Beyond Use Date	☐	☐
Rx Only	☐	☐	Lot #	☐	☐
Label claim	☐	☐	Barcode	☐	☐

Office use statement has been verified (if any) ☐ ☐

Checked by (PIC/Designee): _____ Reviewed by (QA): _____

Date Labeled: _____

Line Clearance Checklist-

Sr. No	Check points	Remarks
1	Identify correct batch to be labeled	Lot # -
2	Ensure the batch to be labeled is fully inspected.	☐ Yes ☐ No
3	Labeling machine and surrounding area is clean.	☐ Yes ☐ No
4	Ensure absence of any previous product and labels. If Yes, record Product name, lot # and BUD listed on the previous product label. Quantity of previous product label remaining from previous run.	☐ Yes ☐ No
5	Ensure label check by the PIC or Designee and QA.	☐ Yes ☐ No
6	Put the product label on the batch log.	☐ Yes ☐ No

Checked By: _____ Verified By: _____

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Exhibit F: A copy of revised SOP "Essential Copy Procedure for 503B Products"

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements that ensure drug products compounded by Empower Pharmacy are not essentially a copy of one or more approved drug product.

2.0 Scope

2.1 This procedure applies to Empower Pharmacy's 503B Outsourcing Facility operations.

3.0 Roles and Responsibilities

3.1 The Pharmacist in Charge (PIC) is primarily responsible for this procedure.

3.2 The Clinical Pharmacist receiving the prescription or order shall use this procedure to determine if the requested compounded preparation is essentially a copy of an approved drug and obtain a determination of clinical difference when necessary.

3.2.1 If they cannot make the determination the prescription or order shall be provided to the PIC for further guidance.

4.0 Terms and Abbreviations

4.1 Approved Drug – A drug product that (1) is approved under section 505 of the FD&C Act, (2) does not appear on the list described in subsection 503B(a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

4.2 Bulk Drug Substance – Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

4.3 Drug that appears on the drug shortage list in effect under section 503E – if the drug is in "currently in shortage" status, and not in "resolved" status, as indicated in the FDA's drug shortage database.

4.4 Marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505 – any nonprescription drug product marketed without an approved application. FDA also refers to these products as 'covered OTC drug products.'

5.0 Policy

5.1 To qualify for the exceptions under section 503B of the FD&C Act compounded drug products must not be essentially a copy of one or more approved drugs.

5.2 Section 503B(d)(2) defines essentially a copy of an approved drug as –

5.2.1 A drug that is identical or nearly identical to an approved drug, or marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505 (New Drugs), unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A))); or

5.2.2 A drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and is not subject to approval in an application submitted under section 505 (New Drugs), unless

there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B)).

5.3 Drug products compounded by outsourcing facilities in accordance with the conditions of section 503B are exempt from FDA drug approval requirements and the requirement to be labeled with adequate directions for use.

5.4 Under section 503B(a)(5) of the FD&C Act, a compounded drug must not be essentially a copy of one or more approved drugs.

6.0 Procedure

6.1 A compounded drug is essentially a copy of an approved drug if the compounded drug is identical or nearly identical to an approved drug unless the approved drug appears on the drug shortage list in the FDA's Drug Shortage Database at the time of compounding, distribution, and dispensing.

6.2 Identical or Nearly Identical Drugs

6.2.1 A compounded drug product is considered to be identical or nearly identical to an approved drug if the compounded drug product and the FDA-approved drug product have the same:

6.2.1.1 Active ingredient(s),

6.2.1.1.1 The substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.

6.2.1.2 Route of administration,

6.2.1.2.1 Describes the way a drug is administered to the body.

6.2.1.3 Dosage form,

6.2.1.3.1 The way of identifying the drug in its physical form.

6.2.1.4 Dosage strength, and

6.2.1.5 Excipients.

6.2.1.5.1 Inactive ingredients which may include preservatives, dyes, and flavorings.

6.2.2 A compounded drug product that has all of these characteristics in common with an FDA-approved drug product is essentially a copy of an approved drug, unless the approved drug appears on the FDA Drug Shortage list at the time of compounding, distribution, and dispensing.

6.2.2.1 If the compounded drug product is identical or nearly identical to an approved drug that is not on FDA's drug shortage list at the time of compounding, distribution, and dispensing, the compounded product is essentially a copy, and an outsourcing facility may not produce it under section 503B.

6.2.3 The identical or nearly identical compounded product cannot be exempted from the copying restriction by a prescriber determination that there is a change to the compounded product that produces a clinical difference for an individual patient. Compounded products meeting the criteria outlined above are not expected to contain changes from an approved drug that would product such difference.

6.2.4 If the compounded product differs on *one or more* of these characteristics, the FDA will generally not consider the product to be identical or nearly identical to the approved drug. If the compounded drug product is not considered identical or nearly identical it would then be evaluated under section 503B(d)(2)(B). See Attachment 2, **Essential Copy Determination Guide**.

6.3 Drug Shortage

6.3.1 A compounded drug that is identical, or nearly identical, to an approved drug is not considered essentially a copy if the approved drug is in shortage at the time of compounding, distribution and dispensing.

6.3.1.1 It is important to patient and prescribers that compounded drugs prepared to address a shortage closely resemble the drug in shortage, and for that reason, the statute seeks to allow compounders to compound drugs that are as close as possible to the drug in shortage.

6.3.2 There may be circumstances where the drug product is in shortage when the outsourcing facility compounds the drug, but the shortage is resolved before the outsourcing facility distributes it. The FDA does not intend to take action for filling orders that are received for identical or nearly identical compounded drug products that were on the FDA drug shortage list at the time the facility received the order, provided the drug also appears on the FDA drug shortage list within 60 days of the outsourcing facility distributing or dispensing the drug.

6.4 Essential Copy

6.4.1 If a component of the compounded drug is a bulk drug substance that is also a component of an approved drug, the compounded product is essentially a copy of an approved drug, and cannot be compounded under section 503B, unless there is a prescriber determination of clinical difference as described below. This applies to a compounded drug whether it was compounded from bulk drug substances or from drugs in finished form.

6.4.2 If the facility compounds a drug, the component of which is a bulk drug substance that is a component of an approved drug, there must be a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner.

6.5 Prescriber Determination of Clinical Difference

6.5.1 To establish that a compounded drug is not essentially a copy of an approved drug the determination shall be noted on the prescription order (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug.

6.5.1.1 In the case when a prescriber orders office stock and will not know the identity of the individual patients who will receive the compounded drug at the time of the order the facility shall obtain a statement from the practitioner that specifies the change between the compounded drug and the comparable approved drug and indicates that the compounded drug will be administered or dispensed only to a patient for whom the change produces a clinical difference, as determined by the prescribing practitioner for that patient.

6.5.1.2 Such assurances should be provided by the health care practitioner or a person able to make the representation for the health care practitioner.

6.5.2 For example, a physician who regularly treats patients with an allergy to an inactive ingredient in a particular approved injectable drug product could order a compounded version of the drug for office use provided he or she includes a statement on the order that removing the particular inactive ingredient produces a clinical difference for his or her individual patients and that he or she will provide the drug only to patients with that particular clinical need.

6.5.3 There is no specific form that is needed for the determination of clinical need statement, only that it is included on the prescription or medication order. See Attachment 1, **Clinical Difference Statement Examples**.

6.5.3.1 The clinical difference must be produced by the change between the compounded product and the approved drug.

6.5.4 If a prescription or order does not make clear that the determination required has been made, the facility shall contact the prescriber or health care facility, and if the prescriber or health care facility contact confirms it, make a notation on the prescription or order that the prescriber has determined that the compounded product contains a change that produces a clinical difference for patient(s).

6.5.4.1 The notations should be as specific as those described in attachment 1, and shall indicate the date of the conversation, the contact or prescriber and the name of the individual who provided the determination.

6.6 Essential Copy of One or More Approved Drug Products

6.6.1 Compounded drug product that has bulk drug substances that are components of one or more approved drugs will be considered essentially a copy unless the prescribing practitioner determines that there is a change that produces a clinical difference for an individual patient.

6.6.1.1 For example, if there are two approved drug products that are tablets, one containing 5 mg of active ingredient A and the other containing 10 mg of active ingredient B and the facility compounded a tablet that offered both active ingredients in the same dosage strengths, the compounded drug would be essentially a copy absent a prescriber determination of clinical difference.

6.7 OTC Drugs

6.7.1 A compounded drug product is essentially a copy and cannot be compounded under section 503B if a component of the compounded drug product is a bulk drug substance that is also a component of a covered OTC drug, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

6.8 Recordkeeping

6.8.1 Records shall be maintained that demonstrate compliance with the essentially a copy provision on section 503B(a)(5).

6.8.1.1 Prescription and/or order records of a prescriber's determination of clinical difference shall be retained.

6.8.2 If a compounded drug considered to be identical or nearly identical to an approved product that appeared on FDA's drug shortage list is made the facility shall maintain documentation (e.g., a notation on the order for the compounded drug) regarding the

status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

6.8.3 Record shall be retained for at least three (3) years.

7.0 Forms

Form Number	Description/Title
N/A	

8.0 Notes and Comments

8.1 N/A

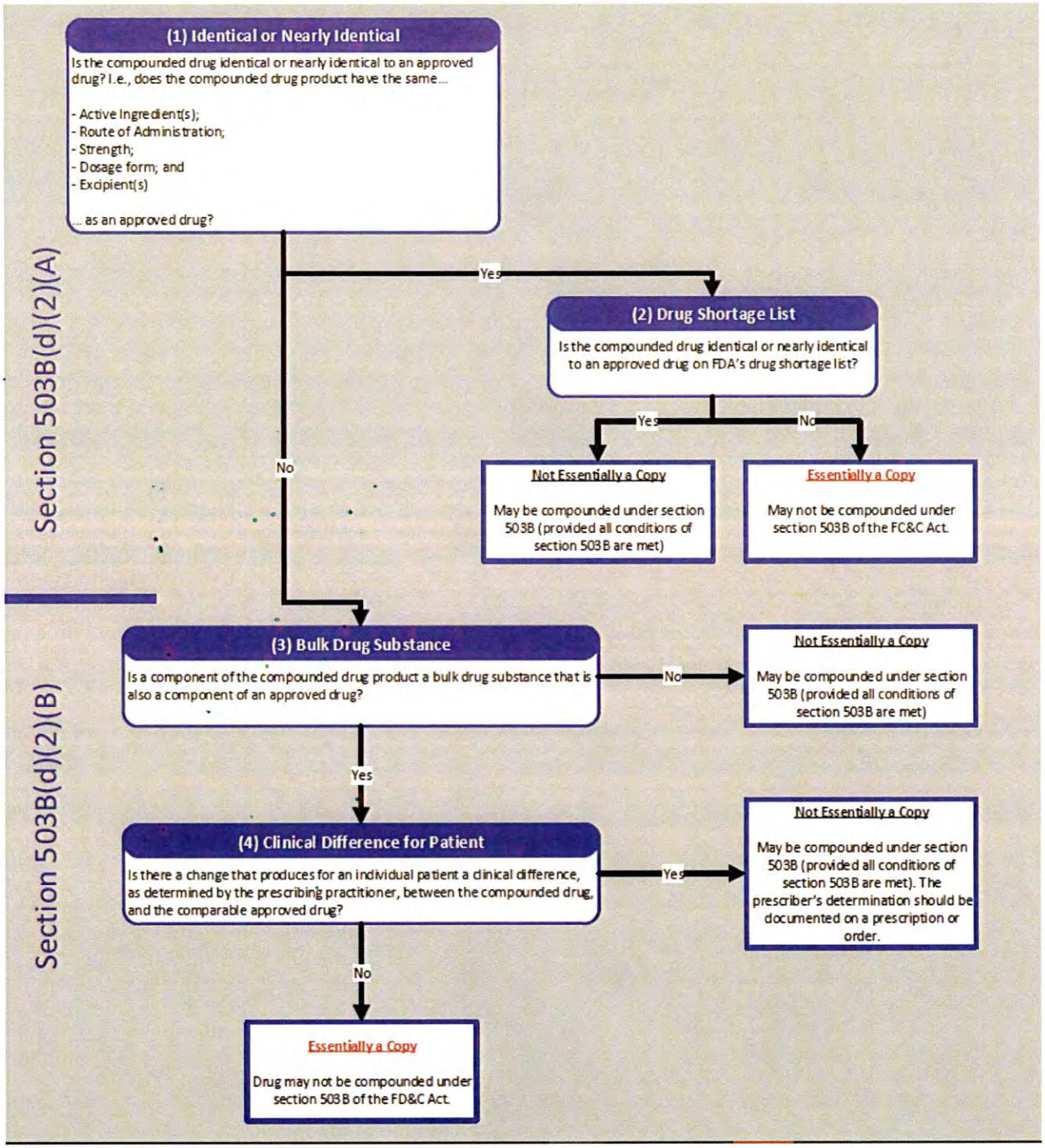
9.0 References

Reference Source	Reference Code	Section Code	Section Description
FD&C Act	Ch 5	§503B	Outsourcing Facilities
FDA	GFI	-	Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 2018

Attachment 1 – Clinical Difference Statement Examples

- "Liquid form, compounded drug will be prescribed to patients who can't swallow tablets" (if the comparable drug is a tablet)
- "Dilution for infusion solution to be administered to patients who need this formulation during surgery" (if the comparable drug is not available at that concentration, pre-mixed with the particular dilutant in an infusion bag)
- "1 mg, pediatric patients need lower dose" (if the comparable drug is only available in 25 mg dose)
- "No dye X, patient allergy" (if the comparable drug contains the dye)
- "150 mg drug X in 120 mL cherry-flavored syrup USP, patient needs alcohol-free preparation (if the comparable drug is only available in formulations that contain alcohol)

Attachment 2 – Essential Copy Determination Guide



EMPOWER PHARMACY

Exhibit G: A copy of the Training Register addressing revised SOP "Essential Copy Procedure for 503B Products"

Pharmacists	Email	Essential Copy Procedure for 503B Products	Completion Date
Anu Patel	apatel@empowerpharmacy.com	Completed	2021-10-29 20:39:01
Courtney Yeung	cyeung@empowerpharmacy.com	Completed	10/29/2021 20:39
Diana Nemry	dnemry@empowerpharmacy.com	Completed	11/1/2021 15:44
Gwenn Iyer	giyer@empowerpharmacy.com	Completed	11/1/2021 19:45
Ha Wong	hwong@empowerpharmacy.com	Completed	2021-10-29 20:28:27
Kathryn Lenz	klenz@empowerpharmacy.com	Completed	2021-10-29 20:28:03
Linda Mai	lmai@empowerpharmacy.com	Completed	2021-10-29 20:34:33
Marwa Elsiad	melsiad@empowerpharmacy.com	Completed	2021-10-29 20:38:39
Mary Katherine Weeks	mweeks@empowerpharmacy.com	Completed	2021-10-29 21:18:34
Nicolle Fritschle	nfritschle@empowerpharmacy.com	Completed	2021-10-29 20:25:03
Robert Valadez	rvaladez@empowerpharmacy.com	Completed	2021-10-29 20:42:12
Tailynn Dinh	tdinh@empowerpharmacy.com	Completed	2021-10-29 20:30:31
Whitney Louis	wlouis@empowerpharmacy.com	Completed	2021-10-29 20:33:36
Clinic Support	Email	Essential Copy Procedure for 503B Products	Completion Date
Crystal Marinucci	cmarinucci@empowerpharmacy.com	Completed	2021-10-29 20:33:25
Amy Carrington	acarrington@empowerpharmacy.com	Completed	2021-10-29 21:01:46
Angelic Rivera	arivera@empowerpharmacy.com	Completed	2021-10-29 20:26:39
Brittany Butler	bbutler@empowerpharmacy.com	Completed	2021-10-29 20:51:01
Debbi Ilegbusi	dilegbusi@empowerpharmacy.com	Completed	2021-10-29 20:28:50
Juan Catalan	jcatalan@empowerpharmacy.com	Completed	2021-10-29 20:49:49
Kiera Martin	kmartin@empowerpharmacy.com	Completed	2021-10-29 20:32:01
Latisha Schwartz	lschwartz@empowerpharmacy.com	Completed	2021-10-29 20:23:38
Michala Hayman	mhayman@empowerpharmacy.com	Completed	2021-10-29 20:48:06
Michelle Anthony	manthony@empowerpharmacy.com	Completed	2021-10-29 20:28:45
Monica Cavazos	mcavazos@empowerpharmacy.com	Completed	2021-10-29 20:27:53
Nida Naqvi	nnaqvi@empowerpharmacy.com	Completed	2021-10-29 20:28:26
Rogelio Menchaca	rmenchaca@empowerpharmacy.com	Completed	2021-10-29 21:05:42
Ruth Fuller	rfuller@empowerpharmacy.com	Completed	2021-10-29 20:29:49
Sabrine Barrett	sbarrett@empowerpharmacy.com	Completed	2021-10-29 20:27:45
Taylor Rhodes	trhodes@empowerpharmacy.com	Completed	2021-10-29 20:24:43
Tiffany Stewart	tstewart@empowerpharmacy.com	Completed	2021-10-29 20:26:09
Toni Williams	twilliams1@empowerpharmacy.com	Completed	2021-10-29 20:24:52
Vanessa Jansen	vjansen@empowerpharmacy.com	Completed	2021-10-29 20:28:30
Bulk	Email	Essential Copy Procedure for 503B Products	Completion Date
Jessica Romero	jromero@empowerpharmacy.com	Completed	2021-10-29 20:33:06
Michael Grant	mgrant@empowerpharmacy.com	Completed	2021-10-29 21:18:03
Shanteria Cleveland	scleveland@empowerpharmacy.com	Completed	2021-10-29 21:25:46
Ana Contreras	acontreras@empowerpharmacy.com	Completed	2021-10-29 21:26:13
Freddy Castillo	fcastillo@empowerpharmacy.com	Completed	11/1/2021 17:46
Monica Borja	mborja@empowerpharmacy.com	Completed	2021-10-29 20:51:09
Chaniya Nunn	cnunn@empowerpharmacy.com	Completed	11/1/2021 14:34

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RE0519085	08-31-2022	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N	MANUFACTURER	08-30-2021

EMPOWER PHARMACY
5980 W SAM HOUSTON PKWY N
STE 300
HOUSTON, TX 77041

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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EMPOWER PHARMACY
5980 W SAM HOUSTON PKWY N
STE 300
HOUSTON, TX 77041

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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)

17

17A

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: ASC03981 expired 10/31/2020	☐ 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 *		☐ 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: ~~Centennial Specialty Surgery Center~~ Centennial Specialty Surgery Center

Physical Address: 5550 Painted Mirage Rd #100

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Email: Michelle.Saady@SkinandCancerInstitute.com Website N/A

Nevada Business License # G65-09129 Centennial Specialty Surgery Center

Employed/Contracted Pharmacist Name: Mary Grear NV Pharmacist License #: ~~16827~~ 10687

Medical Director Name: Daniel Taheri, MD

Days of Operation

☐ Monday	■ Tuesday	☐ Wednesday	☐ Thursday	☐ Friday	☐ Saturday	☐ Sunday

* every other Tuesday 10:00am – 12:00 pm

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: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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: Daniel P. Taheri

Business Name: Centennial Specialty Surgery Center

Business Address: 5550 Painted Mirage Rd #100

City: Las Vegas State: NV Zip: 89149

Telephone: 310-922-1412 Email: dantaheri@gmail.com

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Mary Grear, RPh NV Pharmacist License #: 10687

As the employed/contracted pharmacist, for (ASC/RC Name): Centennial Specialty Surgery Center :

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 policie 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?		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?	X	
4. Has your license 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 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
Board Hearing 4/24/02	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 records 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 to PRN, Inc. Board sent notice of request for hearing to the wrong address even though the correct address was on file at the Board. 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 Board auditors who found no discrepancies in the funds granted by the Board of Pharmacy to PRN and the 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)

10/14/2021
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.

section 8, question 2

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
3/8/17	6/2/17	NV	Reno	Washoe

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
17-31390-1	Nevada State Board of Medical Examiners.

Reason/Charge: California State Medical Board, Carried over from regarding completion of medical records.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Daniel Taheri, MD	

Name of Business/Industry/Entity:

Provide explanation below:

See attached explanation sent to the Board.

Original Signature (electronic, copies or stamps not accepted)

10/14/2021
Date

Applicant's initials DT

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 TAHERI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/14/2021

Date

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

State of California, ss. County of Los Angeles

I, Daniel Taheri, 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

10/14/21

Date

Subscribed and Sworn to before me this 14 day of oct, 2021

Notary Public Signature

FARAMARZ BOLANDPOUR
Notary Public - California
Los Angeles County
Commission # 2291124
My Comm. Expires Jun 2, 2023

(Seal)

LA. CA

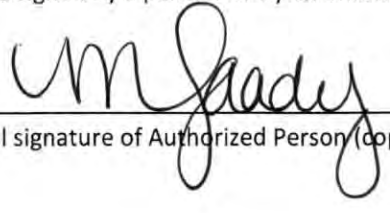
Applicant's initials DT

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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **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.

Michelle Anne Saady, Cheif Operating Officer

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)

10/14/2021

Date

Board Use Only	Date Received: _____	Amount: _____

Effective Date : 01/01/2022
Expiration Date : 12/31/2022

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
9001-ASC-3

This Is To Certify That

CENTENNIAL SPECIALTY SURGERY CENTER, INC.

5550 PAINTED MIRAGE ROAD, STE 115
LAS VEGAS, NV 89149

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

Endorsement : CLASS - C

Bed Information : Operating Room - C - 2

MICHELLE SAADY / Administrator

CENTENNIAL SPECIALTY SURGERY CENTER, INC.,DANIEL TAHERI

Lisa Sherych / Administrator

Please display this license conspicuous

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to https://nvdpbh.aithent.com/login.aspx.

If your license is not completely accurate Please contact us at (775) 684-1030 so that we may resolve any problems.

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: Centennial Specialty Surgery Center

Physical Address: 5550 Painted Mirage Rd #100

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 702-432-3800 Website: N/A

Licensing Company Email: MICHELLE.SAADY@SKINANDCANCERINSTITUTE.COM

Section 2: Personal Information

First: Daniel Middle: Parviz Last: Taheri

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

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

Mailing Address: PO BOX [redacted]

City: Beverly Hills State: CA Zip: 90209

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: DT

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)	
UCSD		06/01/1990 graduated	
Address	**City**	**State**	**Zip**
531 Pereira Dr	Irvine	CA	92697
Diploma/Degree obtained, if any			
Bachelors			

School Name		From - To (MM/YY – MM/YY)	
UCLA - Medical School		06/01/1994 graduated	
Address	**City**	**State**	**Zip**
405 Hilgard Ave	Los Angeles	CA	90024
Diploma/Degree obtained, if any			
Medical Doctor			

School Name		From - To (MM/YY – MM/YY)	
University High School		08/1981	06/1985
Address	**City**	**State**	**Zip**
4771 Campus Dr.	Irvine	CA	92612
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
9/2019 - current	[redacted]WALKER DR.	BEVERLY HILLS	CA	90210
01/2011 - 08/2019	628 HILLCREST RD	BEVERLY HILLS	CA	90210

Applicant's initials DT

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: CENTENNIAL SPECILATY SURGERY CENTER			From - To (MM/YY – MM/YY): 5/2016 - CURRENT
Business Address: 5550 PAINTED MIRAGE RD	City: LAS VEGAS	State: NV	Zip: 89149
Phone: 702-432-3800	Title: OWNER / MEDICAL DIRECTOR		
Description of Duties:			

Business Name: DANIEL TAHERI MD PC			From - To (MM/YY – MM/YY): 07/2007 - current
Business Address: PO Box 16297	City: Los Angeles	State: CA	Zip: 90209
Phone: 702-346-7200	Title: OWNER / MEDICAL DIRECTOR		
Description of Duties:			

Business Name: LA LASER CENTER PC			From - To (MM/YY – MM/YY): 07/1997 - current
Business Address: PO BOX 16297	City: Los Angeles	State: CA	Zip: 90209
Phone: 310-446-4600	Title: OWNER / MEDICAL DIRECTOR		
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.

Applicant's initials DT

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?		✓

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)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **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.

Daniel P. Taheri, 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)

10/14/2021

Date

Board Use Only	Date Received: _____	Amount: 500 CHECK # 1023

10003144.2/002544-1/1-0

1:5
554/656

CENTENNIAL SPECIALTY SURGERY CENTER INC.
PO BOX 16297
BEVERLY HILLS, CA 90209-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC8997201	08-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	HOSPITAL/CLINIC	01-09-2020

CENTENNIAL SPECIALTY SURGERY CENTER INC.
5550 PAINTED MIRAGE RD STE 115
LAS VEGAS, NV 89149-4581

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
FC8997201	08-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	HOSPITAL/CLINIC	01-09-2020

CENTENNIAL SPECIALTY SURGERY CENTER INC.
5550 PAINTED MIRAGE RD STE 115
LAS VEGAS, NV 89149-4581

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
FC8997201	08-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	HOSPITAL/CLINIC	01-09-2020

CENTENNIAL SPECIALTY SURGERY CENTER INC.
5550 PAINTED MIRAGE RD STE 115
LAS VEGAS, NV 89149-4581

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:

BUSINESS LICENSE

City of Las Vegas | Las Vegas, Nevada

IN ACCORDANCE WITH THE PROVISIONS OF THE LAS VEGAS MUNICIPAL CODE, AS AMENDED, LICENSE IS HEREBY GRANTED TO OPERATE THE BUSINESS REFERENCED BELOW.

LICENSE #: G65-09129

RENEWAL DATE: 07/01/2021

EXPIRATION DATE: 01/01/2022

TYPE OF LICENSE: C55 - CLINIC OR LABORATORY SURGERY CENTER

BUSINESS LOCATION: 5550 PAINTED MIRAGE RD 115

ISSUED TO:

CENTENNIAL SPECIALTY SURGERY CENTER
2409 ARTESIA BLVD, SUITE C
REDONDO BEACH, CA 90278

Director of Community Development, Department of Planning

Failure to maintain an active state license or SNHD health permit, if required, renders this business license invalid.

Post in a conspicuous place.

Nevada State Board of Pharmacy

For current information on disciplinary actions taken against licensees please contact Board Staff at shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov) or (775) 850-1440.

VERIFY LICENSE

Facility Name	License Number#	City	State	Country	Discipline	Action
CENTENNIAL SPECIALTY SURGERY CENTER INC.	ASC03981	LAS VEGAS	NV	United States	None	

License Number : ASC03981

Name : CENTENNIAL SPECIALTY SURGERY CENTER INC.

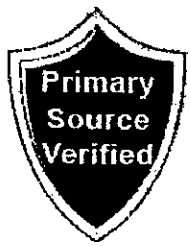
License Type : Pharmacy

License Status : Closed

License Date : 09/18/2018

Discipline :

Expiration Date : 10/31/2020



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The center closed March 2020.
We are now ready to open.

Education

Yale University School of Medicine/
Norwalk Hospital Surgical Residency
September 2002- August 2003
PA Surgical Resident, Norwalk Hospital
Norwalk, CT

Howard University
December 2001 Bachelor of Science
Adult and Pediatric Primary Care Physician Assistant Program
Washington, DC

The George School
Graduated June 1982
High School Diploma
Newtown, PA

Certifications, Licenses, Memberships

NCCPA Certified
AAPA Fellow
SDPA Fellow, Diplomate

Federal DEA License: Active
Georgia PA License: Active

MISCELLANEOUS

Camino de Santiago 2017, 2018, 2019
Volunteer at Mercy Healthcare Free Clinic Athens, GA 2011-2021
Athens Regional Medical Center: Skin Cancer Screenings Athens, GA 2010-2014
Trustees Award, Yale University 2003 New Haven, CT
House of Delegates Representative, AAPA Conference 2000
AIDS Ride, Raleigh, NC to Washington, DC 2001
Washington Home and Hospice Volunteer 1998-2001
NIH Internship, Radiology

The University of California, Irvine School of Medicine certifies that

Dan Taheri, MD

has participated in the live activity titled

Medical Record Keeping Course

at

Irvine, CA

on

March 12-13 2016

The activity was designated for 17 AMA PRA Category 1 Credits ™
The University of California, Irvine School of Medicine has verified that this participant attended **17 hours** of the activity.

"The University of California, Irvine School of Medicine (Provider No. 853) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians."

Samuel Eric Wilson, MD, FACS
Professor of Surgery
Vice Chair, CME Committee

Daniel Taheri MD PC
Medical & Cosmetic Dermatology

October 10, 2018

Date of Action: 06/02/2017

Explanation regarding the public reprimand issued by the Nevada State Board of Medical Examiners:

The public reprimand from the Nevada State Board of Examiners was issued in response to violating NRS 630.301(3), *receiving a disciplinary action from another jurisdiction.* In this case, a public reprimand from the Medical Board of California, Department of Consumer Affairs.

The public reprimand was for a deficiency in recordkeeping. The records for four patients were reviewed and a few items were found to be incomplete. These deficiencies were primarily a result of the practice's transition to a new EMR. Our practice successfully transitioned to the new EMR and a medical recordkeeping course was taken and all recordkeeping issues have been resolved.

I write this letter not because I need to justify myself, rather I do so because I sincerely believe that both me and my practice are an asset to each of the communities we serve and provide exceptional dermatologic care and wish to continue to provide it to your members.

Sincerely,

Daniel Taheri, MD

Board Certified in Dermatology

Daniel Taheri MD PC
Medical & Cosmetic Dermatology

October 10, 2018

Date of Action: 03/08/2016

Explanation regarding the public reprimand issued by the Medical Board of California:

I have been practicing dermatology for over 20 years without any issues. I was a Regents Scholar and given the Valentine Award, the highest honor bestowed upon a UCLA medical school graduate.

A few years back, we had a couple of complaints to the medical board that in my opinion, were meritless. To my shock and surprise, the medical board, despite my attorney and my vehement objections, picked Bernard Raskin as the expert in the case. Raskin has been our main competitor in Valencia and we have had a number of run-ins since we began our practice in town. When we started our practice in Valencia in 2002, he responded by writing derogatory articles in the local paper about us and we were forced to hire an attorney to write letters to cease his behavior. We continued to have significant issues with him in the ensuing years.

Despite our objections, the board for some reason refused to replace him, mostly because Raskin persisted that he was unbiased. Raskin proceeded to formulate a number of complaints against my level of care in the treatment of these patients that were completely unfounded. We had no choice but to hire an expert who systematically refuted all his allegations. The charges were all dismissed but there were deficiencies in our medical notes, some including the charts not being finalized contemporaneously with the date of service. Most of these issues were due to the rudimentary versions of EMR and the difficult in adjusting to the EMR. Nonetheless, I accepted the public reprimand and took a notekeeping course.

Regards,

Daniel Taheri, MD

On March 05, 2021, the Texas Medical Board offered an "Agreed Order" based on the action taken by the California Medical Board in 2016. The public reprimand from Texas Medical Board was issued, per Section 164.051 of the Act authorizes the Board to impose disciplinary action against Applicant for disciplinary action taken against his license to practice medicine by another state.

In April 2016, the California Medical Board issued a public reprimanded for recordkeeping violation. This deficiency accord during the time the practice was in transition to new EMR. The reprimand was accepted and note keeping course was completed.

Thank you,

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

CENTENNIAL SPECIALTY SURGERY CENTER INC.

Nevada Business Identification # NV20121069765
Expiration Date: 02/28/2022

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 02/10/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202102101422250
You may verify this certificate online at http://www.nvsos.gov

17B

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)

y

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 *		☐ 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: Mountain West Surgical Center

Physical Address: 500 Damonte Ranch Pkwy #958

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Email: amanda@mountainwestsurgical.com Website _____

Nevada Business License # NV20201684730

Employed/Contracted Pharmacist Name: Mary Grear NV Pharmacist License #: 10687

Medical Director Name: Timothy Janiga, MD

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: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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: Timothy Janiga

Business Name: Mountain West Surgical Center

Business Address: 500 Damonte Ranch Pkwy #958

City: Reno State: NV Zip: 89521

Telephone: 775-398-4600 Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Mary Grear, RPh NV Pharmacist License #: 10687

As the employed/contracted pharmacist, for (ASC/RC Name): Mountain West Surgical Center :

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 639.48S 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 records 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. to Mary Grear, Executive Director. The Board of Pharmacy sent notice of a request for hearing to the wrong mailing address even though the correct 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 the expense record under my administration. A rehearing was held and the case was closed finding all monies wre accounted for the PRN, Inc. grants.

Mary Grear, RPh

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

12/2/21

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) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ 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.

Timothy A. Janiga

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)

12/8/21

Date

Board Use Only	Date Received: _____	Amount: $500 CC

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 Mountain West Surgical Center

Physical Address 500 Damonte Ranch Pkwy #958

City Reno State NV Zip 89521

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website mountainwestsurgery.com

Licensing Company Email _____

Section 2: Personal Information

First Timothy Middle Andrew Last Janiga

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

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

Mailing Address 500 Damonte Ranch Pkwy. #958

City Reno State NV Zip 89521

Telephone 775-722-2771 Email drtimothy@janigamds.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 TJ

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 Nevada School of Medicine		08/97-05/01	
Address	**City**	**State**	**Zip**
1664 N Virgina St.	Reno	NV	89557
Diploma/Degree obtained, if any			
Medical Doctor			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Reno		08/92-5/97	
Address	**City**	**State**	**Zip**
1664 N Virgina St.	Reno	NV	89557
Diploma/Degree obtained, if any			
BS Major: Cell Biology			

School Name		From - To (MM/YY – MM/YY)	
Blaine High School		08/89-06/93	
Address	**City**	**State**	**Zip**
12555 University Ave. NE	Blaine	MI	55434
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
11/11-12/21	[redacted] Pronghorn Ct.	Reno	NV	89521
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	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

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)	
Timothy A Janiga, MD, PLLC			01/09-12/21	
Business Address	**City**		**State**	**Zip**
500 Damonte Ranch Pkwy. #703	Reno		NV	89521
Phone	**Title**			
(775) 398-4600	Medical Doctor/Owner			
Description of Duties				
Plastic Surgeon and oversee business operations.				

Business Name			From - To (MM/YY – MM/YY)	
Violettree Property Management			03/21-12/21	
Business Address	**City**		**State**	**Zip**
500 Damonte Ranch Pkwy. #703	Reno		NV	89521
Phone	**Title**			
(775) 398-4600	Managing Member			
Description of Duties				
Oversee business operations.				

Business Name			From - To (MM/YY – MM/YY)	
Mountain West Surgical Center LLC			01/20-12/21	
Business Address	**City**		**State**	**Zip**
500 Damonte Ranch Pkwy. #958	Reno		NV	89521
Phone	**Title**			
(775) 398-4600	Managing Member			
Description of Duties				
Oversee business operations.				

Business Name			From - To (MM/YY – MM/YY)	
Janiga MDs Plastic Surgery & Cosmetic Center			11/10-12/21	
Business Address	**City**		**State**	**Zip**
500 Damonte Ranch Pkwy. #703	Reno		NV	89521
Phone	**Title**			
(775) 398-4600	Managing Member			
Description of Duties				
Oversee business operations.				

Business Name			From - To (MM/YY – MM/YY)	
TAJ Management			01/09-12/21	
Business Address	**City**		**State**	**Zip**
500 Damonte Ranch Pkwy. #703	Reno		NV	89521
Phone	**Title**			
(775) 398-4600	Managing Member			
Description of Duties				
Oversee business operations.				

Continue on next page if additional space is needed.

Applicant's initials

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

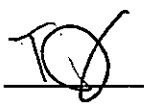
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

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 

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 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 Janiga

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-6-21

Date

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

State of Nevada, ss. County of Washoe

I, Timothy Janiga, 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

12-6-21

Date

Subscribed and Sworn to before me this 6 day of December

Notary Public Signature

SHANNON GUNTER
Notary Public - State of Nevada
Appointment Recorded in Washoe County
No: 16-3057-2 - Expires July 20, 2024

(Seal)

Applicant's initials

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Mountain West Surgical Center, LLC

Nevada Business Identification # NV20201684730
Expiration Date: 01/31/2021

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 01/07/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200107494972
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

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

CHRISTINE SCHOLL
353 MARY ANNE CT
PASO ROBLES, CA 93446

Work Order #: W2020010702197
January 7, 2020
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 146219

Charges

Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Organization	20200403884	1/7/2020 5:15:49 PM	InternalReview	1	$75.00	$75.00
Initial List	20200403886	1/7/2020 5:15:49 PM	InternalReview	1	$350.00	$350.00
Total						$425.00

Payments

Type	Description	Payment Status	Amount
Credit Card	5784461373536760303074	Success	$425.00
Total			$425.00

Credit Balance: $0.00

CHRISTINE SCHOLL
353 MARY ANNE CT
PASO ROBLES, CA 93446

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

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Fax (702) 486-2888

CHRISTINE SCHOLL
353 MARY ANNE CT
PASO ROBLES, CA 93446

Work Order #: W2020010702197
January 7, 2020
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 146219

Charges

Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Organization	20200403884	1/7/2020 5:15:49 PM	InternalReview	1	$75.00	$75.00
Initial List	20200403886	1/7/2020 5:15:49 PM	InternalReview	1	$350.00	$350.00
Total						$425.00

Payments

Type	Description	Payment Status	Amount
Credit Card	5784461373536760303074	Success	$425.00
Total			$425.00

Credit Balance: $0.00

CHRISTINE SCHOLL
353 MARY ANNE CT
PASO ROBLES, CA 93446

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
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2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

01/07/2020

Work Order Item Number:	W2020010702197 - 335568
Filing Number:	20200403884
Filing Type:	Articles of Organization
Filing Date/Time:	01/07/2020 17:15:49 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E4038852020-2

Entity Name: Mountain West Surgical Center, LLC

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
JENNIFER JANIGA
500 DAMONTE RANCH PKWY STE 703, RENO, NV 89519, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
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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

Business Entity - Filing Acknowledgement

01/07/2020

Work Order Item Number:	W2020010702197 - 335569
Filing Number:	20200403886
Filing Type:	Initial List
Filing Date/Time:	01/07/2020 17:15:49 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E4038852020-2

Entity Name: Mountain West Surgical Center, LLC

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
JENNIFER JANIGA
500 DAMONTE RANCH PKWY STE 703, RENO, NV 89519, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Mountain West Surgical Center, LLC** did, on 01/07/2020, 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 01/07/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200107494971
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
Barbara K. Cegavske	E4038852020-2
Secretary of State	Filing Number
State Of Nevada	20200403884
	Filed On
	01/07/2020 17:15:49 PM
	Number of Pages
	2

Formation - Limited-Liability Company

- [x] NRS 86 - Articles of Organization Limited-Liability Company
- [ ] NRS 86.544 - Registration of Foreign Limited-Liability Company
- [ ] NRS 89 - Articles of Organization Professional Limited-Liability Company
- [ ] NRS 86.555 - Registration of Professional Foreign Limited-Liability Company

1. Name Being Registered in Nevada: (See instructions)
Mountain West Surgical Center, LLC

2. Foreign Entity Name: (Name in home jurisdiction)

3. Jurisdiction of Formation: (Foreign Limited-Liability Companies)
3a) Jurisdiction of formation: **3b)** Date formed:
3c) I declare this entity is in good standing in the jurisdiction of its formation. ☐

4. Registered Agent for Service of Process*: (check only one box)
☐ Commercial Registered Agent (name only below) ☑ Noncommercial Registered Agent (name and address below) ☐ Office or position with Entity (title and address below)

JENNIFER JANIGA
Name of Registered Agent **OR** Title of Office or Position with Entity

500 DAMONTE RANCH PKWY STE 703 Street Address — **RENO** City — Nevada **89519** Zip Code

Mailing Address (If different from street address) City — Nevada Zip Code

4a. Certificate of Acceptance of Appointment of Registered Agent:
I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.

X **Christine Scholl** — **01/07/2020**
Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity — Date

5. Management: (Domestic Limited-Liability Companies only)
Company shall be managed by: (check one box) ☐ Manager(s) **OR** ☑ Member(s)

6. Name and Address of each Manager(s) or Managing Member(s): (NRS 86 and NRS 86.544, see instructions)
Name and Address of the Original Manager(s) and Member(s): (NRS 89, see instructions)
IMPORTANT:
A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing.

1) **TIMOTHY Janiga Janiga**
Name
25 PRONGHORN CT Address — **RENO** City — **NV** State — **89519** Zip Code

7. Dissolution Date: (Domestic only)
Latest date upon which the company is to dissolve (if existence is not perpetual):

This form must be accompanied by appropriate fees.

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Formation - Limited-Liability Company

Continued, Page 2

8. Profession to be Practiced: (NRS 89 only)	
9. Series and/or Restricted Limited-Liability Company: (Optional)	Check box if a Series Limited-Liability Company ☐ Domestic Limited-Liability Company's only: The Limited-Liability Company is a Restricted Limited-Liability Company ☐
10. Records Office: (Foreign Limited-Liability Companies)	Address City State Zip code Country
11. Street Address of Principal Office: (Foreign Limited-Liability Companies)	Address City State Zip code Country
12. Name, Address and Signature of the Organizer: (NRS 86. NRS 89 -Each Organizer must be a licensed professional.) **Name and Signature of Manager or Member:** (NRS 86.544 only) See instructions	*Foreign Limited-Liability Company - In the event the designated Agent for Service of Process resigns and is not replaced or the agent's authority has been revoked or the agent cannot be found or served with exercise of reasonable diligence, then the Secretary of State is hereby appointed as the Agent for Service of Process. 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. Christine Scholl Name Country Address City State Zip/Postal Code X Christine Scholl (attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees.

BARBARA K. CEGAVSKE
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

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Mountain West Surgical Center, LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

- ☐ Corporation
  - ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☑ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of	Business Number
Barbara K. Cegavske	**E4038852020-2**
	Filing Number
	20200403886
Secretary of State	Filed On
State Of Nevada	**01/07/2020 17:15:49 PM**
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

- ☐ Unit-owners' Association
- ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

BARBARA K. CEGAVSKE
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
TIMOTHY A Janiga	USA

Address	City	State	Zip/Postal Code
25 PRONGHORN CT	RENO	NV	89519

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 Christine Scholl
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*

Organizer
Title

01/07/2020
Date

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EXECUTIVE SECRETARY REPORT
March 2-3, 2022

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **CHANGE OF ADDRESS BUSINESS LIST**
- **STAFF ACTIVITIES**
  - Meetings with Other Health Care Boards
  - COVID-19
  - Citations & Fines issued pursuant to NRS 632.2895
- **REPORT TO BOARD**
  - Legislative Update
- **BOARD RELATED NEWS**
- **ACTIVITIES REPORT**
  - Covid Vaccine update
  - Covid Therapeutics Update

March 2022 Temporary Licenses since the last Board Meeting

Name	License Type	Name	License Type	Name	License Type	Name	License Type
Agnes Shin	Pharmacist	Favin Tran	Pharmacist	Mary Kliewer	Pharmacist	Thanh Le	Pharmacist
Aileen Belitz	Pharmacist	Grace Kim	Pharmacist	Mary Urban	Pharmacist	Therese Buszta	Pharmacist
Alexandrina Kostova	Pharmacist	Greg Gibson	Pharmacist	Melinda Chau	Pharmacist	Thuy Nguyen	Pharmacist
Alexis Dott	Pharmacist	Gregg Smith	Pharmacist	Michael Broome	Pharmacist	Thuy Vuong	Pharmacist
Alicia Berry	Pharmacist	Hannah Jones	Pharmacist	Mikayla Pennington	Pharmacist	Tiffany Hanson	Pharmacist
Allison Norrington	Pharmacist	Hutson Sargent	Pharmacist	Monica Childers	Pharmacist	Tiffany Le	Pharmacist
Alton Kwong	Pharmacist	Jack Hermann	Pharmacist	Monisha Kelly	Pharmacist	Timothy Brian	Pharmacist
Alycee Law	Pharmacist	Jacob Hoferer	Pharmacist	Mruga Patel	Pharmacist	Timothy Sanders	Pharmacist
Alysia Laycock	Pharmacist	James Cooksley	Pharmacist	Narges Shansab	Pharmacist	Tracee Coleman	Pharmacist
Alyssa Farbak	Pharmacist	Jane Kalichak	Pharmacist	Nga Nguyen	Pharmacist	Tracy Manning	Pharmacist
Amber Pfister	Pharmacist	Jay Barnhart	Pharmacist	Nhu Nguyen	Pharmacist	Treyvon Jones	Pharmacist
Amira Kojan	Pharmacist	Jeanhie Kim	Pharmacist	Nicholas Pham	Pharmacist	Tyler Foster	Pharmacist
Andrea DeWitt	Pharmacist	Jennifer Bach	Pharmacist	Nicholas Scheurer	Pharmacist	Tyler Tran	Pharmacist
Andrew Wee	Pharmacist	Jennifer Harris	Pharmacist	Nikita Patton	Pharmacist	Venus Hensley	Pharmacist
Angela Onkst	Pharmacist	Jennifer Runfolo	Pharmacist	Norma Garza-Gallegos	Pharmacist	Vickey Situ	Pharmacist
Arvind Rangani	Pharmacist	Jennifer Stegman	Pharmacist	Omar Melik	Pharmacist	Vickie Jones	Pharmacist
Benito Gomez	Pharmacist	Jeremy Edmonds	Pharmacist	Patricia Shakarian	Pharmacist	Vimitha Simon	Pharmacist
Binhyen Tran	Pharmacist	Jeswin Jacob	Pharmacist	Paul Koenig	Pharmacist	Vy Tran	Pharmacist
Bo Jeon	Pharmacist	Jiten Patel	Pharmacist	Paul Stoneburg	Pharmacist	William Pfister	Pharmacist
Brittany Jew	Pharmacist	John Noe	Pharmacist	Pegah Abdollahi	Pharmacist	William Woods	Pharmacist
Brooke Floreacre	Pharmacist	Jon Staples	Pharmacist	Perisha Adapa	Pharmacist	Xuan Pham	Pharmacist
Bryan Satter	Pharmacist	Jordan Abel	Pharmacist	Pritesh Patel	Pharmacist	Yogesh Salvi	Pharmacist
Bucky Galloway	Pharmacist	Joseph Tran	Pharmacist	Rama Ramachandran	Pharmacist	Zachary Martin	Pharmacist
Caleb Oh	Pharmacist	Juan De La Cruz	Pharmacist	Raymond Farr	Pharmacist		
Camille Tackett	Pharmacist	Julia Kang	Pharmacist	Raymond Umbarger	Pharmacist		
Casey Greene	Pharmacist	Julia Wolf	Pharmacist	Rebecca Emch	Pharmacist		
Chae Owe	Pharmacist	Julie Cooper	Pharmacist	Rebecca Kitowski	Pharmacist		
Charles Porter	Pharmacist	Julie Jackson	Pharmacist	Rebecca Storck	Pharmacist		
Christina Parks	Pharmacist	Julie Munson	Pharmacist	Rebecca Wilson	Pharmacist		
Cletis Koukoulakis	Pharmacist	Karen Thompson	Pharmacist	Redi Dema	Pharmacist		
Collin Browning	Pharmacist	Katherine Kaarle	Pharmacist	Renee Willett	Pharmacist		
Courtney Johnson	Pharmacist	Katrina Johnson	Pharmacist	Richard Zimmerman	Pharmacist		
Daniel Deem	Pharmacist	Katrina Nguyen	Pharmacist	Rikki Trussel	Pharmacist		
Danielle Bufalino	Pharmacist	Kendall Schwentker	Pharmacist	Robert Schwartz	Pharmacist		
Debra Baldacci	Pharmacist	Kimberly Mattingly	Pharmacist	Safi Khan	Pharmacist		
Debra Gangemi	Pharmacist	Kip Ferguson	Pharmacist	Samantha Alexander	Pharmacist		
Deepali Chachare	Pharmacist	Kristi Zimmerman	Pharmacist	Samara Johnsen	Pharmacist		
Denise Bowker	Pharmacist	Kristopher Waller	Pharmacist	Sarita Kaushik	Pharmacist		
Dhilona Valand	Pharmacist	Larry Wirtley II	Pharmacist	Savannath Wealing	Pharmacist		
Dung Le	Pharmacist	Laura Mistalski	Pharmacist	Sharon Faust	Pharmacist		
Dung Tathiah	Pharmacist	Laura Petters	Pharmacist	Shatera Peace	Pharmacist		
Edward Wahl	Pharmacist	Lauren Bode	Pharmacist	Shawn Hodges	Pharmacist		
Elaina Baaklini	Pharmacist	Le Mai Cwikla	Pharmacist	Shelley Kustes	Pharmacist		
Elizabeth Johanson	Pharmacist	Leena Mathew	Pharmacist	Stacey Oliva	Pharmacist		
Emily Austin	Pharmacist	Lisa Cook	Pharmacist	Stacy Rosenberger	Pharmacist		
Emily King	Pharmacist	Lisa Walker	Pharmacist	Stuart Pursley	Pharmacist		
Emma Callahan	Pharmacist	Loc Tran	Pharmacist	Sujin Kim	Pharmacist		
Eric Galey	Pharmacist	Madison Neville	Pharmacist	Surbhikumari Vishanagra	Pharmacist		
Eric Hsieh	Pharmacist	Mark Scovotti	Pharmacist	Susan Brackhahn	Pharmacist		
Erum Naqvi	Pharmacist	Marlene Shaposky	Pharmacist	Susan Sun	Pharmacist		
Evan Qualey	Pharmacist	Martin Farrell	Pharmacist	Tabatha Phillips	Pharmacist		

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			
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

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
453.510 – Schedule II - Kratom	07/16/20	07/21/20	R144-20	12/14/20	Hold per Dave			
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					
NAC 639.501 – Workplace Assessment Tool	10/15/20	10/21/20	R165-20	11/17/21	12/09/21	01/13/22		
NAC 639 Pharmacist Practice Location	10/15/20	10/21/20	R164-20					
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			
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		
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		
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					

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
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	
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 euthanasia technician. (Senate Bill 408)	07/15/21	07/20/21	R025-21	09/30/21 (under review) by Dave/Yenh	01/19/22	03/03/22		
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 09/02/21	09/08/21	R039-21	11/04/21	11/05/21 Under review by Yenh 12/12/21 Under review by Dave	03/03/22		
NAC 639: Prescription information in English and another language (AB 177).	09/02/21 Continued 12/02/21	12/08/21	R119-21					

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
NAC 639.010, 639.240, 639.242, 639.256: PT/PTT registration requirements.	09/02/21	09/08/21	R041-21					
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		
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.				
NAC 453.510: Schedule I - Isotonitazene	01/13/22	01/14/22	R006-22					
(NAC) 453B: Prescription Drug Donation Program	01/13/22	01/14/22	R007-22					

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21A

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R040-21

December 29, 2021

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted

AUTHORITY: §§ 1 and 2, NRS 639.070, 639.120 and 639.134.

A REGULATION relating to the practice of pharmacy; revising the requirement that an applicant for a certificate as a registered pharmacist complete a certain number of hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist; revising the requirements for the issuance of a certificate as a registered pharmacist by reciprocity; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations governing the practice of pharmacy. (NRS 639.070, 639.120) Existing law requires an applicant for a certificate as a registered pharmacist to complete not less than 1,500 hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist. (NRS 639.120) Existing regulations establish that 1,740 hours of such practical pharmaceutical experience as an intern pharmacist are required to satisfy the requirement of not less than 1,500 hours of such practical pharmaceutical experience. (NAC 639.208) **Section 1** of this regulation removes the requirement that an applicant complete 1,740 hours of such practical pharmaceutical experience, thereby requiring an applicant to complete not less than 1,500 hours of such practical pharmaceutical experience pursuant to existing law.

Existing law authorizes the Board to grant an application for a certificate as a registered pharmacist, without requiring an examination, if the person (1) is registered as a pharmacist in another jurisdiction which requires the person to pass an examination in order to be registered in that jurisdiction; (2) produces evidence satisfactory to the Board that the person has the required secondary and professional education and training; and (3) is of good moral character. (NRS 639.120, 639.134) **Section 1** authorizes such an applicant to satisfy the requirement to provide evidence of having the required secondary and professional education and training by providing evidence that the applicant has satisfied the requirements of reciprocation of the Electronic Licensure Transfer Program of the National Association of Boards of Pharmacy.

Section 2 of this regulation establishes that the provisions of this regulation apply to any applicant who has submitted an application for a certificate as a registered pharmacist before the effective date of this regulation if the Board has not been approved or denied the application before the effective date of this regulation.

Section 1. NAC 639.208 is hereby amended to read as follows:

639.208 ~~[For the purposes of paragraph (d) of subsection 1 of NRS 639.120, an]~~ *An* applicant for a certificate as a registered pharmacist in this State ~~[must complete 1,740 hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist.]~~ *by reciprocity pursuant to NRS 639.134 may provide evidence that the applicant has satisfied the requirements of paragraphs (b) and (d) of subsection 1 of NRS 639.120 by completing the requirements of reciprocation of the Electronic Licensure Transfer Program of the National Association of Boards of Pharmacy.*

Sec. 2. The amendatory provisions of this regulation apply to any applicant for a certificate as a registered pharmacist who has submitted an application for such a certificate to the State Board of Pharmacy before the effective date of this regulation if the Board has not approved or denied the application before the effective date of this regulation.

21B

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R025-21

September 30, 2021

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted

AUTHORITY: §§ 1 and 4, NRS 639.070; § 2, NRS 453.226 and 639.070; § 3, NRS 639.070 and 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; § 5, NRS 639.070 and 639.170, as amended by section 7 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019; § 6, NRS 639.070 and 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; §§ 7 and 9, NRS 639.070, 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018 and 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; § 8, NRS 639.070 and 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017.

A REGULATION relating to pharmacy; requiring certain euthanasia technicians to register with the State Board of Pharmacy; revising requirements for certain applications with the Board; increasing certain fees; clarifying that an applicant for registration as a pharmacist or pharmaceutical technician is required to undergo a criminal background check in certain circumstances; revising requirements for an outsourcing facility that is engaged in the compounding of sterile drugs; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires every practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State to obtain a registration issued by the State Board of Pharmacy in accordance with its regulations. (NRS 453.226) Existing regulations prescribe the prerequisites for a euthanasia technician to possess and administer sodium pentobarbital, including registering with the Board. (NAC 638.510) **Section 2** of this regulation requires a euthanasia technician who possesses or administers or who proposes to possess or administer sodium pentobarbital within this State to obtain a registration issued by the Board.

Existing law provides that an application for registration as a pharmacist is only valid for 1 year after the date it is received by the Board. (NRS 639.127) Existing regulations require an applicant for a certificate as a registered pharmacist to provide all information and make all appearances required by the Board within 1 year after passing the North American Pharmacist

Licensure Examination. (NAC 639.205) **Section 3** of this regulation provides that an application for any certificate, license or permit issued by the Board is only valid for 1 year after the application is received by the Board.

Senate Bill No. 408 of the 2021 Legislative Session increased the maximum fees that the Board is authorized to impose for the investigation or issuance or the renewal of a license as a manufacturer or wholesaler from $500 to $1,000. (section 7 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019) **Section 5** of this regulation amends existing regulations to increase those fees from $500 to $1,000.

Existing law requires an applicant for registration as a pharmacist or a pharmaceutical technician to submit his or her fingerprints to the Board for the purpose of conducting criminal background check. (NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019)

Section 6 of this regulation makes a conforming change to clarify in the Nevada Administrative Code that an applicant for registration as a pharmaceutical technician is required to comply with this requirement. **Section 4** of this regulation makes a conforming change to account for changes in numbering made by **section 6**. **Section 7** of this regulation authorizes an applicant for registration as a pharmacist or a pharmaceutical technician to submit his or her fingerprints electronically to the Board. **Section 9** of this regulation requires an applicant for registration as a pharmacist or pharmaceutical technician to submit a second set of fingerprints if his or her first set of fingerprints is rejected by the Central Repository for Nevada Records of Criminal History.

Existing regulations prescribe certain duties for an outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State. (NAC 639.6915) **Section 8** of this regulation requires such a facility to submit an application for a license as a manufacturer in accordance with existing law on a form prescribed by the Board.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. *1. A euthanasia technician who possesses or administers or proposes to possess or administer sodium pentobarbital pursuant to NAC 638.510 must apply to the Board on a form prescribed by the Board for a certificate of registration pursuant to NRS 453.226.*

2. Any certificate of registration issued pursuant to subsection 1 is a revocable privilege and no holder of such a certificate acquires any vested right therein or thereunder.

3. As used in this section, "euthanasia technician" has the meaning ascribed to it in NRS 638.005.

Sec. 3. *Except as otherwise provided in NAC 639.205, an application for any certificate, license or permit issued by the Board is valid for 1 year after the date on which the application is received by the Board unless the Board extends the period of validity for the application. An applicant who fails to provide all required information or make all required appearances within 1 year after that date must submit a new application for the applicable certificate, license or permit.*

Sec. 4. NAC 639.010 is hereby amended to read as follows:

639.010 As used in this chapter, unless the context otherwise requires:

1. "Board" means the State Board of Pharmacy.

2. "Controlled substances" has the meaning ascribed to it in NRS 0.031.

3. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.

4. "Direct supervision" means the direction given by a supervising pharmacist 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.

5. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

6. "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.

7. "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 ~~[(c)]~~ *(f)* 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.

8. "Practitioner" has the meaning ascribed to it in NRS 639.0125.

9. "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.

10. "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.

11. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

Sec. 5. 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..... Actual cost pharmacist..... of the examination

..... For the investigation or registration of an applicant as a registered pharmacist.....$180

.. For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....180

..... 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 issuance of an original or duplicate certificate of registration as a registered pharmacist.....50

..... For the biennial renewal of registration as a registered pharmacist.....180

.... 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 or pharmaceutical technician in training 40

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training 40

.....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, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 80

.....For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....80

..... For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

..... For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....500

..... For the investigation or issuance of an original license to a manufacturer or wholesaler .....~~[500]~~

1,000 ..... For the biennial renewal of a license for a manufacturer or wholesaler.....~~[500]~~

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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both 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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....300

.....For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....150

..For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....150

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 health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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 the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.

6. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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.

7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

Sec. 6. NAC 639.240 is hereby amended to read as follows:

639.240 1. No person may perform the duties of a pharmaceutical technician until the person has been issued a certificate of registration.

2. An applicant for registration as a pharmaceutical technician must:

(a) Be 18 years of age or older;

(b) Be a high school graduate or the equivalent;

(c) Not have been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs;

(d) Have no history of drug abuse; ~~[and]~~

(e) ***Have complied with the requirements of subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; and***

(f) Have complied with one of the following requirements:

(1) The successful completion of a program of training for pharmaceutical technicians, including, but not limited to, a program of training offered by a postsecondary school, that is approved by the Board pursuant to NAC 639.256.

(2) Registration in another state as a pharmaceutical technician, 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 pharmaceutical technician in a pharmacy in that state, which must be verified by the managing pharmacist of the pharmacy.

(3) If the state in which the applicant has been employed does not offer registration, licensure or certification as a pharmaceutical technician:

(I) 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 was submitted;

(II) The successful completion of at least 350 hours of employment in a pharmacy in this State; and

(III) The acquisition of a written statement to the Board from the managing pharmacist of the pharmacy referred to in sub-subparagraph (II) stating that the applicant, during his or her employment, demonstrated competence to perform the tasks assigned to him or her.

➥ Such an applicant must register as a pharmaceutical technician in training before he or she completes the requirements of sub-subparagraph (II).

(4) The successful completion of at least 1,500 hours of training and experience as a pharmaceutical technician in training. A pharmaceutical technician in training may accumulate certified hours of training from each place of employment.

(5) The successful completion of a program of training for pharmaceutical technicians conducted by a branch of the Armed Forces of the United States, the Indian Health Service of the United States Department of Health and Human Services or the United States Department of Veterans Affairs.

(6) Certification by the Pharmacy Technician Certification Board or the National Healthcareer Association as a pharmacy technician if:

(I) The applicant successfully completes a program of training for pharmaceutical technicians conducted by a postsecondary school in another state;

(II) The program is accredited or otherwise approved by the appropriate regulatory authority in that state; and

(III) The applicant successfully completes at least 240 hours of employment as a pharmaceutical technician in training in a pharmacy in another state, which must be verified by the managing pharmacist of the pharmacy.

3. An applicant who attended a school outside the United States must submit to an organization which evaluates educational credentials a copy of the transcript of his or her academic record from that school for a determination of whether the grades the applicant received are substantially equivalent to the grades required for an applicant who attended a school, or a program of training for pharmaceutical technicians that is accredited by the American Society of Health-System Pharmacists, in the United States. The applicant must ensure that a copy of the organization's evaluation of the transcript is submitted to the Board.

4. Upon receipt of an application and the required fee, the Executive Secretary shall, unless he or she has good cause to deny the registration, issue a certificate of registration to the pharmaceutical technician.

Sec. 7. NAC 639.5931 is hereby amended to read as follows:

639.5931 A person who is required to submit a complete set of his or her fingerprints to the Board pursuant to ***subsection 2 of NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018,*** NRS 639.500 or 639.505 or NAC 639.593 or section 3 of LCB File No. R040-20 may submit the fingerprints electronically in a format prescribed by the Board.

Sec. 8. NAC 639.6915 is hereby amended to read as follows:

639.6915 An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:

1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100, ***as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017,*** and ***NRS*** 639.233 ~~[:]~~ ***by submitting an application on a form prescribed by the Board;***

2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and

3. Comply with all the requirements of 21 U.S.C. § 353b.

Sec. 9. Section 4 of LCB File No. R040-20 is hereby amended to read as follows:

1. If a complete set of fingerprints from any person required to submit fingerprints pursuant to ***subsection 2 of NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018,*** NRS 639.500 ***or 639.505*** or NAC 639.593 or section 3 of LCB File No. R040-20 is rejected by the Central Repository for Nevada Records of Criminal History, the person shall submit a second complete set of fingerprints and written permission authorizing the Board to forward the second complete

set of fingerprints to the Central Repository for submission to the Federal Bureau of Investigation for its report.

2. If the second complete set of fingerprints of any person pursuant to subsection 1 is rejected by the Central Repository for Nevada Records of Criminal History, the Executive Secretary shall request a name-based background check of the person.

21C

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R013-21

October 28, 2021

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: § 1, NRS 639.070; § 2, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacy; establishing certain fees relating to the use of an automated drug dispensing system or a mechanical device at certain locations; authorizing a pharmacy to dispense prescription drugs to a patient using an automated drug dispensing system under certain circumstances; 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 practice of pharmacy as necessary for the protection of the public. Existing law authorizes the Board to adopt regulations governing the dispensing, recordkeeping, storage and handling of drugs. Additionally, existing law authorizes the Board to charge and collect fees for any incidental service the Board provides. (NRS 639.070) Existing law further allows a pharmacist to use computerized mechanical equipment to perform work that a pharmacist is authorized to perform by law in accordance with the regulations adopted by the Board. (NRS 639.2655)

Under existing regulations, the Board has adopted a schedule of fees for certain applications, licenses and registrations. (NAC 639.220) **Section 1** of this regulation adds fees for the licensing of an automated drug dispensing system and the certification of certain mechanical devices to the schedule of fees. **Section 1** also makes a conforming change by removing a reference to a previously deleted fee.

Existing regulations authorize pharmacies and medical facilities to use mechanical devices to dispense drugs to a patient. (NAC 639.718, 639.720) **Section 2** of this regulation establishes certain requirements that a pharmacy must follow to use an automated drug dispensing system. **Section 2** requires an automated drug dispensing system to track who uses the system, what drugs are in the system, the temperature of the system and other information to ensure that the drugs in the system are safely stored and only dispensed to a person authorized to receive the dispensed drug. **Section 2** of this regulation further requires the Board to issue a license to a pharmacy for an automated drug dispensing system upon approval of an application for a license by the Board and payment of the requisite fee.

Section 1. 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 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 or pharmaceutical technician in training 50

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical 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, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 200

For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

For the investigation or issuance of an original license to a manufacturer or wholesaler 500

For the biennial renewal of a license for a manufacturer or wholesaler 500

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 certificate to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy..... 250

For the biennial renewal of a certificate to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy..... 250

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 health center:~~

~~(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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 the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.~~

~~6.]~~ A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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.

~~[7.]~~ *6.* A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

~~[8.]~~ *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. 2. NAC 639.718 is hereby amended to read as follows:

639.718 1. Except as otherwise provided in this section, a pharmacy may use ~~[a mechanical device to furnish]~~ *an automated drug dispensing system to dispense* a prescription drug to a patient *if the pharmacy obtained a license from the Board for the automated drug dispensing system.*

2. The Board will provide to a pharmacy an application for a license for an automated drug dispensing system upon request. The Board will issue a license for an automated drug dispensing system if the application for a license is approved and the requisite fee is paid. A license must be:

(a) Issued for each automated drug dispensing system at a designated location; and

(b) Posted on the system so that the license is visible to the public.

3. The ~~[device]~~ *automated drug dispensing system* must conform to all of the following provisions:

(a) The ~~[device]~~ *system* must contain only prescription drugs:

(1) Approved for use in the system by a registered pharmacist employed by the pharmacy;

~~[(1)]~~ *(2)* For which counseling is not required pursuant to NAC 639.707~~[;]~~*, unless the system uses user-based access technology that includes, without limitation, an audio-visual*

function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708; and

~~[(2)]~~ ***(3)*** For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The ~~[device]~~ ***system*** must not contain ***:***

(1) ~~[controlled]~~ ***Controlled*** substances included in schedule II ~~[.]~~ ***; or***

(2) Controlled substances included in schedules III, IV and V unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The ~~[device]~~ ***system*** must***:*** ~~[be designed to ensure that the device:]~~

(1) ~~[Is located such that access to the device:~~

~~(I) For]~~***Control and track access to the system for*** stocking, cleaning, maintenance or any other purpose ***so that access to the system*** can be obtained only by a pharmacist or a member of the staff of the pharmacy from within a secured area of the pharmacy ***using user-based access technology.***~~[; and~~

~~(II) Is]~~

(2) Be secure from unauthorized access to and removal of prescription drugs***.*** ~~[from the device.~~

~~(2) Records the name of each person at the pharmacy who authorizes access to the device.~~

~~(3) Cannot be used by a patient:~~

~~(I) Outside the physical location of the pharmacy.~~

~~(II) Unless the]~~

(3) Be owned or leased by the pharmacy who obtained the license for the automated drug dispensing system and operated under the supervision and control of that pharmacy.

(4) Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system, including, without limitation, an alarm that records when the temperature of the system reaches a level outside the range compatible with the proper storage of a prescription drug and a method to notify the pharmacy of the temperature change.

(5) Create and maintain a complete, accurate and readily retrievable record of all transactions. The record must include, without limitation:

(I) The name, strength, quantity and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;

(II) Each day and time the system is accessed;

(III) An inventory of the prescription drugs stored in the system; and

(IV) The identity of each person who accesses the system.

(6) Restrict access to a patient ***who*** previously has indicated to the pharmacy that the patient desires that his or her prescription drugs be ~~[furnished]~~ ***dispensed*** by the ~~[mechanical device.]~~ ***system.***

~~[(4) Provides]~~ ***(7) Provide*** a method to identify the patient and ~~[furnishes]~~ ***dispense*** a prescription drug only to the patient or to an authorized agent of the patient.

~~[(5) Can furnish]~~ ***(8) Dispense*** one, any combination or all of the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the ~~[device.]~~ ***system.***

~~[(6) Records]~~ ***(9) Record*** the date and time that the patient removes the prescription drugs from the ~~[device.]~~ ***system.***

~~[(7) Informs]~~ ***(10) Inform*** a patient:

(I) That a prescription drug is not available to be ~~[furnished]~~ ***dispensed*** by the ~~[device]~~ ***system*** if the pharmacist wishes to counsel the patient regarding the prescription drug.

(II) If the patient is using the ~~[device]~~ ***system*** at the time that the pharmacy is open, that the patient may discuss questions and concerns regarding the prescription drug with a pharmacist at the pharmacy ~~[.]~~ ***or through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.***

(III) If the patient is using the ~~[device]~~ ***system*** at the time that the pharmacy is closed, that the patient may discuss questions and concerns regarding the prescription drug ~~[using a toll-free telephone number at which a pharmacist at a pharmacy licensed by the Board will respond at all hours when the pharmacy at which the device is located is closed. A pharmacist who responds to questions or concerns pursuant to this sub-subparagraph must have access by computer to the same information regarding the patient that a pharmacist would have using the computer system of the pharmacy at which the device is located.]~~ ***through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate,***

in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

(IV) That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.

(11) Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.

(12) Be installed in such a place and manner that a person is unable to remove the system from its location and any attempts to obtain access to the device without authorization are visible to the pharmacist of the pharmacy either through the system being in view of the pharmacist or by real-time audio-visual communication technology or audio-visual recording technology.

(13) Be located in a:

(I) Pharmacy;

(II) Medical facility, as defined in subsections 1 to 14, inclusive, or 16 of NRS 449.0151; or

(III) Practice site of one or more practitioners of medicine.

(14) Be approved for use by the Board upon determination that the system:

(I) Dispenses prescription drugs accurately; and

(II) Otherwise satisfies the provisions of this section.

~~[2. A pharmacy shall not use a mechanical device to furnish a prescription drug to a patient until the pharmacy has notified the Board in writing of:~~

~~(a) The type of device that will be used; and~~

~~(b) The anticipated date that the device will first be used.]~~

4. A pharmacy that dispenses prescription drugs by an automated drug dispensing system pursuant to this section shall maintain a written policy that sets forth:

(a) The duties of all persons who are authorized to access the system; and

(b) The procedures for:

(1) Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;

(2) The preparation of an inventory of the prescription drugs stored in the system; and

(3) Stocking the system with prescription drugs.

5. A pharmacy that dispenses prescription drugs through an automated drug dispensing system pursuant to this section shall comply with all applicable federal and state recordkeeping requirements and shall maintain those records in a readily retrievable manner separate from other pharmacy records.

6. Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory and the responsibility of the pharmacy that was issued the license for the system. Prescription drugs dispensed from the system shall be considered to have been dispensed by that pharmacy.

~~[3.]~~ *7.* The Board may prohibit a pharmacy from using a ~~[mechanical device]~~ ***system*** to furnish a prescription drug to a patient if the Board determines that the ~~[device]~~ ***system*** or the pharmacy's use of the ~~[device]~~ ***system*** does not comply with this section.

~~[4.]~~ *8.* The provisions of this section do not prohibit the use of a ~~[mechanical device]~~ ***system*** to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the pharmacy using the ~~[mechanical device]~~ ***system*** is otherwise authorized to use the ~~[mechanical device]~~ ***system*** pursuant to this section.

9. As used in this section:

(a) "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

(b) "User-based access technology" means software or hardware that restricts access to the system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708; and

~~[(2)]~~ *(3)* For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The ~~[device]~~ *system* must not contain *:*

(1) ~~[controlled]~~ *Controlled* substances included in schedule II ~~[.]~~ *; or*

(2) Controlled substances included in schedules III, IV and V unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The ~~[device]~~ *system* must*:* ~~[be designed to ensure that the device:]~~

(1) ~~[Is located such that access to the device:~~

~~(I) For~~]*Control and track access to the system for* stocking, cleaning, maintenance or any other purpose *so that access to the system* can be obtained only by a *registered* pharmacist ~~[or a member of the staff of the pharmacy from within a secured area of]~~ *, pharmaceutical technician, or intern pharmacist employed by* the pharmacy *using user-based access technology.* ~~[; and~~

~~(II) Is]~~

(2) Be secure from unauthorized access to and removal of prescription drugs *.* ~~[from the device.~~

~~(2) Records the name of each person at the pharmacy who authorizes access to the device.~~

~~(3) Cannot be used by a patient:~~

Conforming Amendment to Page 5:

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 ~~[certificate]~~ license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

For the biennial renewal of a ~~[certificate]~~ license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

Conforming Amendment to Page 7:

~~[7.]~~ *6.* A practitioner who is exempt from the payment of a fee pursuant to subsection ~~[6]~~ *5* shall notify the Board in writing of each change of address or additional address, or both.

~~[8.]~~ *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. 2. NAC 639.718 is hereby amended to read as follows:

639.718 1. Except as otherwise provided in this section, a pharmacy may use ~~[a mechanical device to furnish]~~ *an automated drug dispensing system to dispense* a prescription drug to a patient *if the pharmacy obtained a license from the Board for the automated drug dispensing system.*

2. The Board will provide to a pharmacy an application for a license for an automated drug dispensing system upon request. The Board will issue a license for an automated drug dispensing system if the application for a license is approved and the requisite fee is paid. A license must be:

(a) Issued for each automated drug dispensing system at a designated location; and

(b) Posted on the system so that the license is visible to the public.

3. The ~~[device]~~ *automated drug dispensing system* must conform to all of the following provisions:

(a) The ~~[device]~~ *system* must contain only prescription drugs:

(1) Approved for use in the system by a registered pharmacist employed by the pharmacy;

~~[(1)]~~ *(2)* For which counseling is not required pursuant to NAC 639.707~~[;]~~*, unless the system uses user-based access technology that includes, without limitation, an audio-visual*

Conforming Amendments to NAC 639.720:

1. Except as otherwise provided in ~~[subsections 4 and 6]~~ ***this section***, a mechanical device may be used to furnish drugs and medicines for administration to registered patients in a medical facility ***by obtaining a license from the Board for the mechanical device in conformance with subsection 4. A license shall not be required for a mechanical device in a hospital that meets the requirements of this section***.

2. The ***mechanical*** device must conform to all the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by the:

(1) Medical facility in which the drug or medicine is administered; or

(2) Pharmacy that supplies the medical facility in which the drug or medicine is administered.

(b) Access to the device must be:

(1) Limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists, registered pharmacists, licensed practical nurses, registered nurses or other practitioners who are:

(I) Authorized by law to prescribe or administer controlled substances, poisons, or dangerous drugs and devices; and

(II) Employed by the medical facility or pharmacy that supplies the medical facility.

(2) Monitored and controlled by the pharmacy which supplies the medical facility or the registered pharmacist who is employed by the medical facility.

(c) Each container of a drug or medicine stored in the device must be labeled in a manner which includes the information required pursuant to subsection 2 of NAC 639.476.

(d) The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, the device automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for administration to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a code which identifies that person.

3. ~~[2.]~~ A pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection 1 shall maintain a written policy which sets forth:

(a) The duties of all persons who are authorized to obtain access to the device; and

(b) The procedure for:

(1) Maintaining the security of the drugs and medicines stored in the device during the maintenance and repair of the device;

(2) The preparation of an inventory of the drugs and medicines stored in the device; and

(3) Stocking the device with drugs and medicines.

~~[3. A pharmacy which supplies drugs or medicines to a medical facility which uses a mechanical device to furnish drugs or medicines for administration to patients pursuant to subsection 1 shall provide written notice to the Board. The notice must include:~~

~~(a) A description of each mechanical device used by the medical facility to furnish drugs or medicines for administration to patients, including, without limitation, the name of the manufacturer of the device; and~~

~~(b) The address of the medical facility at which the mechanical device is located.]~~

4. ***The Board will issue a license for mechanical device if the application for a license is approved and the requisite fee is paid.*** A ***license*** ~~[pharmacy shall not stock a mechanical device with drugs or medicines and a mechanical device must not be used to furnish drugs or medicines for administration to patients until:~~

~~(a) The pharmacy has notified the Board as required by subsection 3; and~~

~~(b) The Board has issued a certificate to the pharmacy that]~~ authorizes the use of the mechanical device at the medical facility at which the mechanical device is located.

5. Each medical facility that uses a mechanical device pursuant to subsection 1 must make and maintain a record of any waste of a controlled substance in the manner provided in NAC 639.486. The record of any waste of a controlled substance may be prepared:

(a) By the mechanical device if the mechanical device is capable of making and maintaining such a record and documenting the record of the waste being witnessed by another person as provided in paragraph (g) of subsection 1 of NAC 639.486; or

(b) As a written record.

6. A mechanical device may be used to furnish drugs and medicines for ***administration to*** a patient receiving treatment in the emergency room of a hospital. The device must conform to all the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by or contracted with the:

(1) Hospital in which the drug or medicine is furnished; or

(2) Pharmacy that supplies the hospital in which the drug or medicine is furnished.

(b) Access to the device for the purposes of stocking, inventory and monitoring must be limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists or registered pharmacists employed by the hospital or the pharmacy that supplies the hospital.

(c) ~~[Use of the device to furnish a drug or medicine to a patient must be:~~

~~(1) By a practitioner who:~~

~~(I) Is authorized by law to prescribe controlled substances or dangerous drugs;~~

~~(II) Is employed by or who has privileges at the hospital;~~

~~(III) Prescribed the drug or medicine that is furnished to the patient;~~

~~(IV) Personally verifies the correctness of the prescription for the drug or medicine before he or she furnishes it to the patient; and~~

~~(V) Has offered to the patient the choice of being provided a prescription that may be filled at a pharmacy, which offer first must be declined by the patient before the prescription is transmitted to the mechanical device to fill and furnish the prescription [; or~~

~~(2) By the patient where:~~

~~(I) The device requires from the patient a unique code known only to the patient to allow the patient to access the device; and~~

~~(II) The patient is notified by the device that he or she may choose not to purchase the drug or medicine from the device at any time before the device furnishes the drug or medicine.~~

~~(d) Each container of a drug or medicine dispensed by the device is labeled pursuant to NRS 639.2801.]~~

(d) ~~[(c)]~~ The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, the device automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for ~~[dispensing]~~ ***administration*** to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for ~~[dispensing]~~ ***administration*** to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a unique code which identifies that person.

(e) ~~[(f)]~~ The device must be located in such a place and manner that a person is unable to remove it from the hospital, and that attempts to obtain access to the device without authorization are visible to employees of the hospital.

~~[(g) Before the device is used to furnish a drug or medicine directly to a patient pursuant to paragraph (c), the manufacturer of the device must appear before the Board for its approval of that use of the device and submit evidence satisfactory to the Board that the device:~~

~~(1) Furnishes drugs and medicines accurately; and~~

~~(2) Otherwise satisfies the provisions of this subsection.]~~

7. As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

21D

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R039-21

November 4, 2021

EXPLANATION – Matter in *italics* is new, matter in brackets [~~omitted material~~] is material to be omitted

AUTHORITY: §§ 1-5, NRS 639.070 and section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201.

A REGULATION relating to pharmacy; prescribing training that is required for a pharmacist to be authorized to prescribe, dispense and administer certain drugs for preventing the acquisition of human immunodeficiency virus; prescribing certain requirements concerning the prescribing, dispensing and administering of those drugs by a pharmacist; adopting certain publications by reference; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Pharmacy to adopt regulations that establish a protocol to authorize a pharmacist to: (1) order and perform laboratory tests that are necessary for therapy that uses a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus; and (2) prescribe, dispense and administer any of those drugs to a patient. (Section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201)

Section 2 of this regulation requires a pharmacist to complete certain training concerning the prescribing, dispensing and administering of drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus before prescribing, dispensing or administering such drugs. **Section 2** also requires a pharmacist who prescribes, dispenses or administers such drugs to maintain and make readily available proof of completion of that course of training. **Section 2** additionally requires such a pharmacist to maintain professional liability insurance coverage of at least $1,000,000.

Section 3 of this regulation requires a pharmacist to complete an assessment of the patient prior to prescribing, dispensing or administering a preexposure prophylaxis drug. **Section 3** authorizes a pharmacist to prescribe, dispense or administer a postexposure prophylaxis drug immediately to a patient exposed to the human immunodeficiency virus and requires the pharmacist to complete an assessment to continue the treatment after the initial dispensing or administering of such a drug. **Section 3** also requires a pharmacist who prescribes, dispenses or administers a preexposure prophylaxis drug or postexposure prophylaxis drug to provide counsel and certain information to the patient.

Section 4 of this regulation adopts by reference certain guidelines from the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. **Section 5** of this regulation requires a pharmacist to comply with those guidelines when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 5** authorizes a pharmacist to prescribe, dispense and administer not more than a 30-day supply of such a drug without completing the laboratory testing required by those guidelines and **section 3** under certain circumstances. **Section 5** additionally requires a pharmacist who prescribes, dispenses or administers such a drug to establish and adhere to a plan of care for treatment using the drug.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.

Sec. 2. *1. A pharmacist may prescribe, dispense and administer drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, if the pharmacist has completed a course of training concerning treatment using such drugs. The course must be:*

(a) Approved by the Accreditation Council for Pharmacy Education, or its successor organization; or

(b) Offered by a college of pharmacy or department of pharmacy at a university accredited by the Accreditation Council for Pharmacy Education, or its successor organization.

2. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, shall maintain and make readily available proof of completion of a course completed pursuant to subsection 1 while the pharmacist prescribes, dispenses or administers such drugs, as applicable, and for at least 2 years following that prescribing, dispensing or administering.

3. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, shall maintain professional liability insurance coverage of at least $1,000,000.

Sec. 3. *1. Except as otherwise provided in subsection 2 of section 5 of this regulation, a pharmacist shall, before prescribing, dispensing or administering a preexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, complete an assessment of the patient that includes, without limitation:*

(a) A test for human immunodeficiency virus;

(b) A test for renal function;

(c) A test for hepatitis B; and

(d) An evaluation for any signs and symptoms of acute human immunodeficiency virus infection.

2. A pharmacist may prescribe, dispense or administer a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, immediately upon the request of a patient who has recently been exposed to human immunodeficiency virus. Except as otherwise provided in subsection 2 of section 5 of this regulation, the pharmacist shall, before continuation of treatment using such drugs beyond the initial prescribing, dispensing or administering, complete an assessment of the patient that includes, without limitation:

(a) A test for human immunodeficiency virus;

(b) A pregnancy test if the patient is a woman of child-bearing age;

(c) A test for liver function;

(d) A test for renal function;

(e) A test and screening for sexually transmitted infections;

(f) A test for hepatitis B; and

(g) A test for hepatitis C.

3. Upon prescribing, dispensing or administering a preexposure prophylaxis drug or a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, a pharmacist shall counsel the patient and provide information on the drug dispensed or administered, including, without limitation:

(a) The proper administration and storage of the medication;

(b) The proper dosage of the medication;

(c) The effectiveness of the medication;

(d) The potential side effects of the medication;

(e) The need to be regularly tested for human immunodeficiency virus;

(f) The need to adhere to the treatment; and

(g) The inability of the drug to prevent sexually transmitted infections other that the human immunodeficiency virus.

4. As used in this section:

(a) "Preexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered before exposure to the virus.

(b) "Postexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered after exposure to the virus.

Sec. 4. *1. Except as otherwise provided in subsection 2, the following publications are hereby adopted by reference:*

(a) "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update - A Clinical Practice Guideline," published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf or, if that Internet website ceases to exist, from the Board.

(b) "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV" published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf or, if that Internet website ceases to exist, from the Board.

2. Except as otherwise provided in this subsection, the most current version of a publication adopted by reference in subsection 1 which is published will be deemed to be adopted by reference. The Board will periodically review and determine, within 30 days after the review, whether any change made to a publication listed in subsection 1 is appropriate for application in this State. If the Board does not disapprove a change to an adopted publication within 30 days after the review, the change is deemed to be approved by the Board.

Sec. 5. *1. Except as otherwise provided in subsection 2, a pharmacist shall comply with the publications adopted by reference in section 4 of this regulation when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201.*

2. A pharmacist may prescribe, dispense and administer up to a 30-day supply of a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus to continue treatment without completing the requirements for laboratory testing prescribed in section 3 of this regulation or the publications adopted by reference in section 4 of this regulation if the pharmacist:

(a) Makes a good faith effort to obtain and review the laboratory history of the patient;

(b) Completes an assessment of the patient;

(c) Reviews potential adverse side effects with the patient; and

(d) Determines that the benefit of continuing the treatment outweighs the risk of not continuing the treatment.

3. A pharmacist who dispenses or administers a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, must establish and adhere to a plan of care for treatment using the drug. The plan must include, without limitation, support and ongoing assessment as required by the publications adopted by reference in section 4 of this regulation.

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R039-21

February 7, 2022

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§ 1-6, NRS 639.070 and section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085); § 7, NRS 639.070 and 639.210.

A REGULATION relating to pharmacy; prescribing the training that is required for a pharmacist to be authorized to prescribe, dispense and administer certain drugs for preventing the acquisition of human immunodeficiency virus; prescribing certain requirements concerning the prescribing, dispensing and administering of such drugs by a pharmacist; adopting certain publications by reference; providing that failure by a pharmacist to make certain reports is unprofessional conduct; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Pharmacy to adopt regulations that establish a protocol to authorize a pharmacist to: (1) order and perform laboratory tests that are necessary for therapy that uses a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus; and (2) prescribe, dispense and administer any of those drugs to a patient. (Section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085)) Existing law defines "drug" to include devices intended for use in the prevention of disease. (NRS 639.007)

Section 2 of this regulation provides that a latex or polyurethane prophylactic device is a drug and, therefore, that a pharmacist may prescribe such devices where approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 3** of this regulation requires a pharmacist to complete certain courses of training concerning the prescribing, dispensing and administering of drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus before prescribing, dispensing or administering such drugs. **Section 3** also requires a pharmacist who prescribes, dispenses or administers such drugs to maintain and make readily available proof of completion of each course of training. **Section 3** additionally requires such a pharmacist to maintain professional liability insurance coverage of at least $1,000,000.

Section 4 of this regulation requires a pharmacist to complete an assessment of the patient before prescribing, dispensing or administering a preexposure prophylaxis drug. **Section 4** authorizes a pharmacist to prescribe, dispense or administer a postexposure prophylaxis drug immediately upon the request of a patient who has been exposed to the human

immunodeficiency virus and requires the pharmacist to complete an assessment to continue the treatment after the initial prescribing, dispensing or administering of such a drug. **Section 4** also requires a pharmacist who prescribes, dispenses or administers a preexposure prophylaxis drug or postexposure prophylaxis drug to provide counsel and certain information to the patient.

Section 5 of this regulation adopts by reference certain guidelines from the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. **Section 6** of this regulation requires a pharmacist to comply with those guidelines and all applicable federal and state laws when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 6** authorizes a pharmacist to prescribe, dispense and administer not more than a 30-day supply of such a drug without completing the laboratory testing required by those guidelines and **section 4** under certain circumstances. **Section 6** additionally requires a pharmacist who prescribes, dispenses or administers such a drug to establish and adhere to a plan of care for treatment using the drug.

Existing law: (1) requires providers of health care to make certain reports concerning cases of communicable diseases, drug overdoses and attempted suicides; and (2) deems a pharmacist to be a provider of health care for that purpose. (NRS 441A.110, as amended by section 5 of Senate Bill No. 229, chapter 290, Statutes of Nevada 2021, at page 1663, NRS 441A.150, as amended by section 6.4 of Assembly Bill No. 181, chapter 185, Statutes of Nevada 2021, at page 864) **Section 7** of this regulation provides that the failure by a pharmacist to comply with those reporting requirements is unprofessional conduct, thereby subjecting the pharmacist to disciplinary action. (NRS 639.210)

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 6, inclusive, of this regulation.

Sec. 2. ***For the purposes of section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), and sections 2 to 6, inclusive, of this regulation, "drug" includes a latex or polyurethane prophylactic device, including, without limitation, a latex or polyurethane condom.***

Sec. 3. ***1. A pharmacist may prescribe, dispense and administer drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), if the pharmacist has completed a course of training concerning the prescribing, dispensing and administering of such drugs. The course must be:***

(a) Approved by the Accreditation Council for Pharmacy Education, or its successor organization; or

(b) Offered by a college of pharmacy or department of pharmacy at a university accredited by the Accreditation Council for Pharmacy Education, or its successor organization.

2. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), shall maintain and make readily available proof of completion of a course completed pursuant to subsection 1 while the pharmacist prescribes, dispenses or administers such drugs, as applicable, and for at least 2 years following that prescribing, dispensing or administering.

3. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), shall maintain professional liability insurance coverage of at least $1,000,000.

Sec. 4. *1. Except as otherwise provided in subsection 2 of section 6 of this regulation, a pharmacist shall, before prescribing, dispensing or administering a preexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), complete an assessment of the patient that includes, without limitation:*

(a) A test for human immunodeficiency virus;

(b) A test for renal function;

(c) A test for hepatitis B; and

(d) An evaluation for any signs and symptoms of acute human immunodeficiency virus infection.

2. A pharmacist may prescribe, dispense or administer a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), immediately upon the request of a patient who has recently been exposed to human immunodeficiency virus. Except as otherwise provided in subsection 2 of section 6 of this regulation, the pharmacist shall, before continuation of treatment using such drugs beyond the initial prescribing, dispensing or administering, complete an assessment of the patient that includes, without limitation:

(a) A test for human immunodeficiency virus;

(b) A pregnancy test if the patient is a woman of child-bearing age;

(c) A test for liver function;

(d) A test for renal function;

(e) A test and screening for sexually transmitted infections;

(f) A test for hepatitis B; and

(g) A test for hepatitis C.

3. Upon prescribing, dispensing or administering a preexposure prophylaxis drug or a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), a pharmacist shall counsel the patient and provide information on the drug dispensed or administered, including, without limitation:

(a) The proper administration and storage of the drug;

(b) The proper dosage of the drug;

(c) The effectiveness of the drug;

(d) The potential side effects of the drug;

(e) The need to be regularly tested for human immunodeficiency virus;

(f) The need to adhere to the treatment; and

(g) If applicable, the inability of the drug to prevent sexually transmitted infections other than the human immunodeficiency virus.

4. As used in this section:

(a) "Postexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered after exposure to the virus.

(b) "Preexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered before exposure to the virus.

Sec. 5. *1. Except as otherwise provided in subsection 2, the following publications are hereby adopted by reference:*

(a) Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update - A Clinical Practice Guideline, published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf, or, if that Internet website ceases to exist, from the Board.

(b) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016, published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf, or, if that Internet website ceases to exist, from the Board.

2. Except as otherwise provided in this subsection, the most current version of a publication adopted by reference in subsection 1 which is published will be deemed to be adopted by reference. The Board will periodically review and determine, within 30 days after the review, whether any change made to a publication listed in subsection 1 is appropriate for application in this State. If the Board does not disapprove a change to an adopted publication within 30 days after the review, the change is deemed to be approved by the Board.

Sec. 6. *1. Except as otherwise provided in subsection 2, a pharmacist shall comply with the publications adopted by reference in section 5 of this regulation and all applicable federal and state laws and regulations, including, without limitation, laws and regulations relating to labeling of prescriptions and keeping records, when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085).*

2. A pharmacist may prescribe, dispense and administer up to a 30-day supply of a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus to continue treatment without completing the requirements

for laboratory testing prescribed in section 4 of this regulation or the publications adopted by reference in section 5 of this regulation if the pharmacist:

(a) Makes a good faith effort to obtain and review the laboratory history of the patient;

(b) Completes an assessment of the patient;

(c) Reviews potential adverse side effects with the patient; and

(d) Determines that the benefit of continuing the treatment outweighs the risk of not continuing the treatment.

3. A pharmacist who prescribes, dispenses or administers a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), must establish and adhere to a plan of care for treatment using the drug. The plan must include, without limitation, support and ongoing assessment as required by the publications adopted by reference in section 5 of this regulation.

Sec. 7. NAC 639.945 is hereby amended to read as follows:

639.945 1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

(a) Manufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations.

(b) Except as otherwise provided in NRS 639.2583 to 639.2808, inclusive, for substitutions of generic drugs, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed, unless the express permission of the orderer

or prescriber is obtained and, in the case of a written prescription, unless the following information is recorded on the prescription by the person obtaining permission:

(1) The date on which the permission was granted;

(2) The name of the practitioner granting the permission;

(3) The name of the person obtaining the permission;

(4) The name of the drug dispensed; and

(5) The name of the manufacturer or distributor of the drug.

(c) Using secret formulas.

(d) Except as otherwise provided by subsection 2 of NRS 639.2396, failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling, the content of the label of the prescription or giving a copy of the prescription or chart order to any person except as permitted by law.

(e) Failing to confer with the person writing, making or ordering a prescription or chart order if there is an error or omission in it which should be questioned.

(f) Operating a pharmacy at a location other than the location at which the pharmacy is licensed to operate.

(g) 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.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

(j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.

(k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

(l) Violating any term or condition of a subpoena or order issued by the Board or the staff of the Board.

(m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 585 and 639 of NRS and chapters 453, 454, 585 and 639 of NAC to a member of the Board or a member of the staff of the Board upon his or her request.

(n) Except as otherwise provided in subsection 2:

(1) Dispensing a drug as a dispensing practitioner to a patient or animal or owner of an animal with whom the dispensing practitioner does not have a bona fide therapeutic relationship; or

(2) Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship.

(o) Failure by a pharmacist to comply with the provisions of chapter 441A of NRS and chapter 441A of NAC concerning the reporting of cases of communicable diseases, drug overdoses and attempted suicides.

2. It is not unprofessional conduct or conduct contrary to the public interest for a practitioner to prescribe or dispense a drug under the circumstances described in paragraph (n) of

subsection 1 if the drug is prescribed or dispensed in accordance with either publication adopted by reference in section 1 of this regulation.

3. 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.

4. For the purposes of this section, a bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the practitioner dispenses or prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.

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