NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: Cantrell Drug Company

Physical Address: 7321 Cantrell Road

City: Little Rock State: Arkansas Zip Code: 72207

Telephone: 501-663-3642 Fax: 501-296-9936

Toll Free Number: 877-666-5222 (Required per NAC 639.708)

E-mail: kallen@cantrelldrug.com Website: www.cantrelldrug.com

Supervising Pharmacist: Ashley D. Wagner Nevada License #: 19708

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

FEI Number (From FDA application): 71-0555575

Please provide the name of the facility as registered with the FDA and the registration number:
Cantrell Drug Company - 3004483441

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Ashley DeAnn Wagner Nevada License Number: 19708

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☒ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☒ No ☐

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is **"yes"**, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

James L. McCarley, JR CEO

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

JAMES L. McCARLEY, JR CEO — 10/05/2017

Print Name of Authorized Person — Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Arkansas

Parent Company if any: Cantrell Drug Company

Address: 7321 Cantrell Road

City: Little Rock State: AR Zip: 72207

Telephone: 501-663-3642 Fax: 501-296-9936

Contact Person: Kayla Allen

For any corporation non publicly traded, disclose the following:

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

a) James L. McCarley, Jr. (Name) Calle Nairn, Condo , San Juan, PR 00907 (Address)

b) Lynn H. McCarley (Name) Calle Nairn, Condo , San Juan, PR 00907 (Address)

c) N/A (Name) (Address)

d) N/A (Name) (Address)

2) Provide the number of shares issued by the corporation. 200

3) What was the price paid per share? $1

4) What date did the corporation actually receive the cash assets? 01-31-1992

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

* see attached

CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, Nevada 89509

Ladies and Gentlemen:

In reference to question #2, Georgia Board of Pharmacy denied our application for a Manufacturer license. We will provide additional documentation to Georgia Board of Pharmacy. We are currently licensed in Georgia as a Wholesaler Pharmacy. See attached letter from Georgia Board of Pharmacy.

In reference to question #3, after an FDA Inspection of our Outsourcing Facility and our remediation of all the observations of the FDA, the Boards of Pharmacy in South Carolina, Alabama, and Illinois asked for additional information and suspended our right to ship into those Sates until they are satisfied. Upon receiving our newly acquired Verified-Accredited Wholesale Distributors certification, Illinois has reinstated our right to ship. The South Carolina and Alabama Boards of Pharmacy have now held hearings. Following the hearing in South Carolina, its Board concluded that Cantrell Drug Company will be placed on a two year probationary period. Following the hearing in Alabama, its Board concluded that there had been a deficiency in sterile compounding and imposed a fine. See attached final orders from Alabama Board of Pharmacy and South Carolina Board of Pharmacy.

The Boards of Pharmacy in Colorado, Florida, Indiana, Missouri, and Minnesota have investigated the same facts surrounding this FDA Inspection and allowed us to continue shipping. In Florida, we have voluntarily agreed to restrict our practice in the state until we have a new Florida-approved inspection of our facility.

Also in reference to question #3, James L. McCarley was disciplined by the Kentucky Board of Pharmacy due to a miscalculation in completing continuing education credits which has now been rectified.

In reference to question #4, in 2003, the Drug Enforcement Administration investigated Cantrell Drug Company for an alleged violation of Title 21 USC in regard to compounded intrathecal pump refills sent to the ordering physician for administration by the physician. This practice is standard in most compounding pharmacies dispensing intrathecal medication refills in the United States. A settlement was reached in 2004 upon the terms set forth in a written agreement, a copy of which is attached. Furthermore, Cantrell Drug Company complied with DEA request to register the pharmacy as a "manufacturer" with the agency.

Let me know if you need further information.

Dell McCarley, Pharm D
CEO

7321 Cantrell Road • Little Rock, AR 72207 • Toll Free 877-666-5222 • www.cantrelldrug.com

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Frank Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-651-8000 | www.dch.georgia.gov

September 26, 2017

Cantrell Drug Company
7321 Cantrell Road
Little Rock AR 72207

Application # 1885579
Email: kallen@cantrelldrug.com

Re: Manufacturing Pharmacy Application

Dear Cantrell Drug Company:

The Georgia Board of Pharmacy reviewed your application for licensure at its recent meeting. After careful consideration of your application and supporting documents, the Board respectfully disapproved your application for licensure for the following reason(s):

- Series of disciplinary action(s) and recall of sterile drug products; have not shown you meet the inspection standard of a 503B outsourcing facility.

Please be advised that you do have the right to an appearance before the Board to discuss your application. A written request for such must be put in writing within 30 days of the date of this letter. The request may be faxed to 770-344-5727 or emailed to bhowell@dch.ga.gov.

If our office can be of further assistance, please do not hesitate to contact us.

Sincerely,

Georgia Board of Pharmacy

SUSAN ALVERSON R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

ALABAMA
BOARD OF PHARMACY

May 4, 2017

CANTRELL DRUG COMPANY
7321 CANTRELL RD
LITTLE ROCK AR 72207

RE: Final order

Dear Cantrell Drug Company:

Enclosed you will find a FINAL ORDER resulting from your hearing before the Board. While the entire order is important, I particularly direct your attention to the portion of the Order setting forth discipline and specifically the mandatory obligation of your payment of a fine and costs. As you will see, those amounts are due within a specified period of time from the date of the Final Order and not the date of this letter.

If the referenced fine and costs are not received by the Board within the prescribed period of time, or special arrangements have not been made with the Secretary of the Board, the Board will file a lawsuit to enforce the Final Order which can result in the entry of a judgment against you and subsequent collection procedures.

Sincerely,

Wendy Passmore

Legal / Executive Assistant
Alabama State Board of Pharmacy
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
CANTRELL DRUG COMPANY	)	BOARD OF PHARMACY
	)	
Manufacturer/Wholesaler/ Distributor Permit Number 194828	)	Case Number 16-0168

FINAL ORDER

On April 18, 2017, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Cantrell Drug Company (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Stipulation and Agreement, Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Stipulation and Agreement

Pursuant to Code of Alabama 1975, § 41-22-12 (f), the Respondent denies the allegations of the Statement of Charges, as Amended but stipulated that the Board could introduce sufficient evidence to establish a prima facie case necessary to meet the legal burden of proof as required by the Board for this proceeding. Therefore the Board finds the Respondent is guilty of committing the acts and violating the provisions of law set forth in the Statement of Charges, as Amended. The parties further agreed to the terms listed below in this Final Order.

Findings of Fact

1. The Respondent is a manufacturer/wholesaler/distributor to which the Board issued permit number 194828.

2. The Respondent was notified of the charges; the Respondent was represented at the administrative hearing by counsel, Mr. Michael W. Whisonant, Jr., Esq. and Mr. H. Hube Dodd, Esq. Mr. Dell McCarley, the Respondent's representative, also attended the hearing.

3. The Respondent made no objection to the timeliness of the Notice of Hearing.

4. The Respondent committed and is guilty of the acts specified as violations in the Statement of Charges and Notice of Hearing dated December 28, 2016 as Amended on March 23, 2017.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction in this cause pursuant to Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92 (11) and (12) and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges; the Respondent was represented at the administrative hearing by counsel.

3. The Respondent made no objection to the timeliness of the Notice of Hearing.

4. The Respondent's permit as a manufacturer/wholesaler/distributor in the State of Alabama is due to be have disciplinary sanctions imposed in that it is guilty of the acts specified in Count One of the Statement of Charges and Notice of Hearing dated December 28, 2016 and as Amended on March 23, 2017.

ORDER

In accordance with the foregoing Stipulation and Agreement, Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

1. The Respondent is ORDERED to pay to the Board an administrative fine of Thirty Thousand ($30,000.00) Dollars; said fine shall be paid in sixty (60) days from the date of this Final Order; and

2. Upon submission by the Respondent of a letter to the Board describing the circumstances, reasons and factors by which the products listed on the "Tier One Product List" provided to the Board by the Respondent on April 18, 2017, are not commercially available, the Board shall not take the position that the products listed on the "Tier One Product are commercially available; and

3. Upon agreement by the Respondent and the Board, the Respondent shall notify the Board of any other products to be added to the above mentioned "Tier One Product List" and in the event the Respondent fails to so notify the Board of such products, the Board shall have the authority and jurisdiction to take disciplinary action it deems appropriate; and

4. Any future violations of this Order, the Alabama Pharmacy Practice Act, the laws that regulate the sale and or dispensing of prescription or legend drugs and or narcotics or any Rule of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state may, upon hearing and proof thereof, result in further disciplinary sanctions.

DONE and ORDERED, this 4th day of April 2017

Buddy Bunch

Mr. Buddy Bunch, R. Ph., President
Alabama State Board of Pharmacy

c: Mr. Michael W. Whisonant, Jr., Esq.
Mr. H. Hube Dodd, Esq.
Mr. James S. Ward, Esq.
Dr. Susan Alverson, Executive Secretary
Mr. Vance L. Alexander, Esq.

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE BEFORE THE STATE BOARD OF PHARMACY

IN THE MATTER OF: **CANTRELL DRUG COMPANY** **CANTRELL DRUG COMPANY INC** 7321 Cantrell Rd. Little Rock, AR 72207 PY.10776 & PY.16647 OIE # 2016-149 Respondent.	**FINAL ORDER** **(PUBLIC)**

On March 15, 2017, the above licensing board ("Board"), with a quorum present, held a hearing on the Memorandum of Agreement and Stipulations ("MOA") in the above referenced matter entered into between the State and Respondent. The Board also heard Respondent's Petition to Resume Shipping Compounded Products. Patrick Hanks, Esquire, Chief Disciplinary Counsel, represented the State. Respondent was represented by Jon Wallace, Esquire. Dell McClary, CEO of Respondent; Dr. Eric Goode, Interim Chief of Compliance and Regulatory Affairs; and Ashley Wagener, Pharmacist in Charge, appeared on behalf of Respondent.

FINDINGS OF FACT

1. Respondent was properly served with a Notice of Hearing.

2. In the MOA, Respondent admitted to the following, which the Board adopts:

   a. Respondent is an FDA Registered Outsourcing Facility under Section 503B of the Federal Food, Drug, and Cosmetic Act and is permitted in this state as a Nonresident Outsourcing facility, duly permitted by the State Board of Pharmacy (the "Board") in this State, and was so permitted at all times relevant to the matters asserted herein; thus, the Board has jurisdiction over this matter.

   b. As a registered Outsourcing Facility under Section 503B of the Federal Food, Drug, and Cosmetic Act, Respondent must comply with cGMP requirements, be routinely inspected by FDA, and must meet certain other conditions, such as adverse event reporting, among other requirements.

   c. FDA conducted an Outsourcing Facility Inspection of Respondent ending on October 14, 2016. As a result of the inspection, FDA issued Form 483 observations.

   d. Respondent fully responded with a corrective action plan to the FDA Dallas District Office on November 4, 2016.

e. In order to implement response items submitted to FDA, Respondent voluntarily ceased operations on November 2, 2016 and began to remediate issues raised by Form 483 observations. Respondent resumed operations on December 15, 2016, and currently, Respondent's facility is fully operational and is not restricted by the FDA.

f. As an additional response to the Form 483 observations, on November 18, 2016, Respondent issued a voluntary recall of certain sterile drug products due to a potential lack of sterility assurance occurring over an isolated period of time. The recalled lots were only associated with any hood, gowning, or room out of specification. None of the recalled product revealed any contamination.

g. Respondent entered into an engagement with ProPharma Group, which is a regulatory consulting company focused on cGMP compliance in the pharmaceutical industry.

h. On November 22, 2016, the Board issued an Order restricting Respondent's distribution of sterile compounded products into South Carolina pending further order of the Board. Respondent hereby petitions the Board for relief from this Order.

i. Prior to registering with FDA as an Outsourcing Facility, following an FDA inspection initiated on October 15, 2013, FDA issued a warning letter to Respondent.

j. Arkansas Board of Pharmacy has taken no action in this matter, and Respondent's permit remains in good standing.

3. Since resuming operations in December of 2016, Respondent was inspected by a hospital collective and received a score of 97/100. The Board further finds that Respondent has implemented procedures to remedy the deficiencies noted by the FDA.

CONCLUSIONS OF LAW

1. Respondent was properly served with the Notice of Hearing.

2. The Board has jurisdiction in this matter.

3. Respondent acknowledged in the MOA that Respondent's conduct admitted in the MOA constitutes violations of S.C. Code Ann. §§40-43-86(DD)(5) and (EE), as well as 40-43-140(A)(1)(a). The Board adopts this conclusion.

4. Upon finding that a licensee's conduct is grounds for discipline under any of the provisions of S.C. Code Ann. §§ 40-1-110 or 40-43-10 *et seq.*, the Board has the authority to issue a public reprimand, impose a fine, place a licensee on probation or restrict the individual's license, suspend the license for a definite or indefinite time, prescribe conditions to be met during probation, restriction, or suspension including but not limited to completion of additional education, a supervisory period, continuing education programs, or permanently revoke the individual's license to practice pharmacy or registration as a pharmacy technician in this State. Additionally, S.C. Code Regs. 99-46

(2012, as amended) provides that upon determination by the Board that one or more grounds for disciplining a licensee or permittee exist, the Board may impose a fine of $500 per violation, not to exceed a total of $25,000 per action, plus the costs of the disciplinary action.

5. In this case, the Board concludes that Respondent may resume shipping compounded drugs into South Carolina subject to its compliance with certain conditions. First, Respondent's permit shall be placed on a probationary status for a minimum of two years. Prior to resuming shipping, Respondent must provide an inspection by the Arkansas Board of Pharmacy, which must be approved by the Board Administrator. Further, Respondent must provide an FDA End of Inspection ("EIR") Report indicating no further disciplinary action taken by the FDA. During Respondent's probationary period, Respondent must report any and all correspondence with the FDA to the Board Administrator. Respondent must reappear before the Board to have the probation lifted.

6. The sanctions and conditions imposed by this Order are within the scope of those permitted by S.C. Code Ann. §§ 40-1-120 and 40-43-150 (2011) and are designed not to punish the Respondent but to protect the life, health and welfare of the people at large.

IT IS THEREFORE ORDERED:

1. The Board accepts the MOA and finds that Respondent violated the Pharmacy Practice Act.

2. The Petition to resume shipping compounded products is granted, subject to Respondent's submission to, and approval by, the Board Administrator of a new Arkansas inspection report. Upon receipt and approval of the same, the license shall be immediately placed on a probationary status for a period of two years, subject to the following conditions of probation: 1) Respondent must provide the Board with an FDA EIR Report indicating no further violations; 2) Respondent shall submit all correspondence, documentation, etc. received by the FDA to the Board; and 3) Respondent must reappear before the Board to have its permit removed from probationary status.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

Carole Small Russell

Carole Small Russell, R.Ph.
Board Chair

September 19, 2017

South Carolina Department of Labor, Licensing and Regulation

STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

CANTRELL DRUG COMPANY INC

PY . 10776

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, September 19, 2017, served the Final Order 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 following address:

CANTRELL DRUG COMPANY INC
7321 CANTRELL RD
LITTLE ROCK AR 72207

JONATHAN A. WALLACE, ESQUIRE
715 KING STREET
CHARLESTON, SC 29403

Karen Y Newton

Karen Y. Newton
Administrative Coordinator
SC Department of Labor, Licensing
and Regulation

KENTUCKY BOARD OF PHARMACY

Matt Bevin
Governor

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
http://pharmacy.ky.gov

Board Members
Deborah L. Brewer, R.Ph.
Brian C. DeWire, DC, Consumer
Scott A. Greenwell, Pharm.D.
Cathy Hanna, Pharm.D.
Craig Martin, Pharm D.
Ron Poole, R.Ph.

Executive Director
B. Steven Hart, R.Ph.

February 22, 2017

James McCarley Jr
7700 Northshore Place
North Little Rock AR 72118

Re: Case No. 17-0202

Dear Pharmacist,

This letter follows a recent investigation by Board staff.

The purpose of this letter is to offer you an opportunity to informally resolve this matter through an Agreed Order prior to the filing of a formal Complaint. Find enclosed a proposed Agreed Order setting forth terms I believe the Board will accept.

Review the proposed Agreed Order carefully. Feel free to consult with legal counsel. If acceptable, sign and return the Agreed Order to the Board office by March 22, 2017. Upon receipt, the proposed Agreed Order will be signed by the Board President, and a copy will be sent to you.

If this proposed Agreed Order is unacceptable and you in good faith believe this matter can be resolved, please feel free to contact me during normal business hours.

Should you fail to respond by returning the proposed Agreed Order or contacting me by March 22, 2017, your case will be referred to the Office of the Attorney General to conduct an administrative hearing.

Sincerely,

Steve Hart, R.Ph.
Executive Director

Enclosure

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 17-0202

IN RE: PHARMACIST LICENSE NO. 013447 HELD BY James McCarley Jr

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("Board") and James McCarley Jr ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is a pharmacist in the Commonwealth of Kentucky, having been assigned pharmacist license no. 013447.

(3)(a) Respondent self-reported completion of only 10 of 15 required hours of continuing education for the year 2016, in violation of 201 KAR 2:015, Section 5.

(b) The above actions subject Respondent to discipline pursuant to KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter 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 $250.00, payable on or before March 22, 2017. 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) On or before March 22, 2017, Respondent shall submit to the Board office proof of no less than ten (10) continuing education hours, which programs shall not be used in any way to satisfy Respondent's continuing education requirements for renewal.

(C) By entering into this Agreed Order, Respondent expressly acknowledges that the Respondent was fully and completely informed of Respondent's right to due process, that the Respondent fully understands those rights, and that the Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(D) 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.

Scott Greenwell, President
Kentucky Board of Pharmacy

Date

James McCarley Jr, Respondent

3-15-17
Date

U.S. Department of Justice

United States Attorney
Eastern District of Arkansas

Post Office Box 1229
425 W. Capitol Avenue, Suite 500
Little Rock, Arkansas 72203

501-340-2600
FAX 501-340-2730

September 21, 2004

Mr. John Gilbert
Hyman, Phelps & McNamara
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-5929

RE: *U.S. v. Cantrell Drive Store, Dell McCarley*

Dear Mr. Gilbert:

Enclosed please find one executed copy of the Settlement Agreement. Thank you for your assistance in this matter.

Sincerely,
H.E. (BUD) CUMMINS
United States Attorney

By A. DOUG CHAVIS
Assistant U.S. Attorney

ADC/kim

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

UNITED STATES OF AMERICA

V. USAO: 2004V00173

CANTRELL DRUG STORE
DELL MCCARLEY

SETTLEMENT AGREEMENT

This Settlement Agreement is made and entered into this 20 day of September, 2004, by and among the United States of America, acting through the United States Attorney for the Eastern District of Arkansas (hereinafter referred to as "USAO""), and Cantrell Drug Company.

PREAMBLE

WHEREAS, the United States contends that Cantrell Drug Company has violated 21 U.S.C. § 828(a), § 829(a) and § 842(a)(1), (a)(2) and (a)(5);

WHEREAS, the Cantrell Drug Company denies it has violated any provision of Title 21 U.S.C.

WHEREAS, the parties desire to reach an agreement that would settle, compromise and resolve the United States' claims under Title 21 U.S.C. in order to avoid the expense and uncertainty of litigation.

TERMS OF AGREEMENT

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the parties agree as

follows:

1. Cantrell Drug Company agrees to pay $30,000 (hereinafter the Settlement Amount), Said settlement amount shall be paid within 30 days of the date of this Agreement and paid as follows:

A $10,000 check within 30 days of the date of the execution of this Settlement Agreement, a $10,000 check within 120 days of the date of the execution of this Settlement Agreement and a $10,000 check within 210 days of the date of the execution of this Settlement Agreement. Said checks shall be delivered to the office of the U.S. Attorney, Attn: Kim Squires, Legal Assistant, 425 W. Capitol, Suite 500, Little Rock, AR 72201.

Cantrell Drug Company also agrees to submit, within 30 days, an application with the U.S. Drug Enforcement Administration, for a manufacturer's registration.

2. In consideration of the agreements and payments set forth herein, the United States hereby releases and will be deemed to have released Cantrell Drug Company together with its owners, officers, employees, successors and assigns (hereinafter referred to as the "released persons and entities"), from any claims which the United States has or may have against the released persons arising from claims that may have occurred prior to and up to the date of this agreement under 21 U.S.C. § 828(a), § 829(a) and § 842(a)(1), (a)(2) and (a)(5).

3. The releases provided for in this Agreement shall not include releases from claims arising under Title 26 of the United States Code (Internal Revenue Code) and the regulations promulgated thereunder.

4. Each party to this Agreement shall bear its own costs.

5. It is understood and agreed that this Settlement Agreement is in compromise of disputed claims and that it shall not be construed as an admission of or evidence of liability or wrongdoing on the part of any of the released entities.

6. This document contains the complete agreement between the parties with respect to the matters herein.

7. This Agreement may be executed in identical counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

8. This Agreement may be modified only by a written document signed by all of the parties. No waiver of this Agreement or of any of the promises, obligations, terms or conditions hereof shall be valid unless it is written and signed by the party against whom the waiver is to be enforced.

9. If any part or any provision of this Agreement shall be finally determined to be invalid or unenforceable under applicable law by a court of proper jurisdiction, that part shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining part of said provision or the remaining provision of this Agreement.

10. Each person who signs this Agreement in a representative capacity represents that he or she is duty authorized to do so.

11. This Agreement is effective upon the date of the signature of the last signatory.

IN WITNESS WHEREOF, we have hereunder set our hand as of the date first above written.

On behalf of the United States of America, the Department of Justice, and acting through the United States Attorney for the Eastern District of Arkansas:

H.E. (BUD) CUMMINS,
United States Attorney

9-20-04
Date

By: A. Doug Chavis
Assistant United States Attorney

On behalf of Cantrell Drug Company.

9-17-04
Date

Dell McCarley, President
Cantrell Drug Company

9/16/04
Date

John Gilbert
Attorney for Cantrell Drug Company
Hyman, Phelps & McNamara
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-5929

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
SUMMER D. HARO
Deputy Attorney General
State Bar No. 245482
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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **CANTRELL DRUG COMPANY** **7321 Cantrell Road, Suite 300-400** **Little Rock, AR 72207** **Non-Resident Pharmacy Permit No. NRP 1071** **Non-Resident Sterile Compounding Permit No. NSC 99637** Respondent.	Case No. 6279 **ACCUSATION**

Complainant Virginia Herold ("Complainant") alleges:

PARTIES

1. Complainant brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs ("Board").

2. On or about October 7, 2010, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 1071 to Cantrell Drug Company ("Respondent"). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2018, unless renewed.

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3. On or about November 3, 2010, the Board of Pharmacy issued Non-Resident Sterile Compounding Permit Number NSC 99637 to Respondent. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on October 1, 2017, and has not been renewed.

JURISDICTION

4. 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.

5. Section 4300 of the Code states in pertinent part:

> (a) Every license issued may be suspended or revoked.
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> (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:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
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> . . .
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> (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.

6. 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.

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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:

. . .

(c) Gross negligence.

. . .

(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.

UNITED STATES CODE

8. United States Code, title 21, section 353b, states:

(a) In general. Sections 502(f)(1), 505, and 582 [*21 USCS §§ 352(f)(1), 355*, and *360eee-1*] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting. The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances. The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in *section 207.3(a)(4) of title 21, Code of Federal* Regulations (or any successor regulation)), unless--

(A)

(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by-

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal

Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E [*21 USCS § 356e*] at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 [*21 USCS § 360*] (including a foreign establishment that is registered under section 510(i)) [*21 USCS § 360(i)*]; and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances) If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective. The drug does not appear on a list published by the Secretary 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.

(5) Essentially a copy of an approved drug. The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding. The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use. In the case of a drug that is

compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505-1 [*21 USCS § 355-1*], or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) Prohibition on wholesaling. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph 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 503(b)(1) [*21 USCS § 353(b)(1)*].

(9) Fees. The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K [*21 USCS § 379j-62*].

(10) Labeling of drugs.

(A) Label. The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug--

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(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—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) 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); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information. The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement. The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs.

(1) Registration of outsourcing facilities.

(A) Annual registration. Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510 [*21 USCS § 360*]), and a point of contact email address; and

(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 506E [*21 USCS § 356e*] during the subsequent calendar year.

(B) Availability of registration for inspection; list.

(i) Registrations. The Secretary shall make available for inspection, to any person so requesting, any

registration filed pursuant to this paragraph.

(ii) List. The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

(2) Drug reporting by outsourcing facilities.

(A) In general. Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

(B) Form. Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

(C) Confidentiality. Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

(3) Electronic registration and reporting. Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

(4) Risk-based inspection frequency.

(A) In general. Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 704 [*21 USCS § 374*]; and

(ii) shall not be eligible for the exemption under section 704(a)(2)(A) [*21 USCS § 374(a)(2)(A)*].

(B) Risk-based schedule. The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors. In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 [*21 USCS § 374*] within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E [*21 USCS § 356e*].

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting. Outsourcing facilities shall submit adverse event reports to the Secretary 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).

(c) Regulations.

(1) In general. The Secretary shall implement the list described in subsection (a)(6) through regulations.

(2) Advisory committee on compounding. Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) Interim list.

(A) In general. Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such subsection by—

(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

(ii) providing a period of not less than 60 calendar days for comment on the notice; and

(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

(B) Sunset of notice. Any notice provided under subparagraph (A) shall not be effective after the earlier of—

(i) the date that is 5 years after the date of enactment of the Compounding Quality Act [enacted Nov. 27, 2013]; or

(ii) the effective date of the final regulations issued to implement subsection (a)(6).

(4) Updates. The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d) Definitions. In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) 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) [*21 USCS § 353(b)*] and not subject to approval in an application submitted under section 505 [*21 USCS § 355*], unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E [*21 USCS § 356e*] at the time of compounding, distribution, and dispensing; 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) [*21 USCS § 353(b)*] and not subject to approval in an application submitted under section 505 [*21 USCS § 355*], 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.

(3) The term "approved drug" means a drug that is approved under section 505 [*21 USCS § 355*] and does not appear on the list described in subsection (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) (A) The term "outsourcing facility" means 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.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

(5) The term "sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law". (*sic*)

(d) (*sic*) Obligation to pay fees. Payment of the fee under section 744K [*21 USCS § 379j-62*], as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

CODE OF FEDERAL REGULATIONS

9. Code of Federal Regulations, title 21, part 211.22, states in pertinent part:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

. . .

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed

10. Code of Federal Regulations, title 21, part 211.42, states in pertinent part:

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

(2) Holding rejected components, drug product containers, closures, and labeling before disposition;

(3) Storage of released components, drug product containers, closures, and labeling;

(4) Storage of in-process materials;

(5) Manufacturing and processing operations;

(6) Packaging and labeling operations;

(7) Quarantine storage before release of drug products;

(8) Storage of drug products after release;

(9) Control and laboratory operations;

(10) Aseptic processing, which includes as appropriate:

(i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;

(ii) Temperature and humidity controls;

(iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;

(iv) A system for monitoring environmental conditions;

(v) A system for cleaning and disinfecting the room and

equipment to produce aseptic conditions;

(vi) A system for maintaining any equipment used to control the aseptic conditions.

11. Code of Federal Regulations, title 21, part 211.113, states:

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

12. Code of Federal Regulations, title 21, part 211.125, states in pertinent part:

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations.

(b) Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records.

(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2).(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2). Labeling reconciliation is also waived for 360 [degrees] wraparound labels on portable cryogenic medical gas containers.

(d) All excess labeling bearing lot or control numbers shall be destroyed.

(e) Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification.

(f) Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed.

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13. Code of Federal Regulations, title 21, part 211.130, states:

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

(a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products.

(b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.

(c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

(d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record.

(e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

14. Code of Federal Regulations, title 21, part 211.165, states:

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.

(c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed.

(d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.

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(e) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

(f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant critieria.

15. Code of Federal Regulations, title 21, part 211.166, states:

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

(b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

(c) For homeopathic drug products, the requirements of this section are as follows:

(1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use.

(2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.

(d) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section.

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16. Code of Federal Regulations, title 21, part 211.192, states:

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

CALIFORNIA CODE OF REGULATIONS

17. California Code of Regulations, title 16, section 1735.2, states in pertinent part:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any. Instructions for storage and handling of the compounded drug preparation.

. . .

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-

in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

18. California Code of Regulations, title 16, section 1751.4, states in pertinent part:

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

. . .

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

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COST RECOVERY

19. Code section 125.3 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.

STATEMENT OF FACTS

20. Respondent's facility in Little Rock, Arkansas, is a 503b Food and Drug Administration ("FDA") registered outsourcer, compounding non-sterile to sterile single API[1] products and limited non-sterile (i.e. suppositories) for shipment within Arkansas and out-of-state to licensed healthcare facilities.

21. From on or about September 14, 2016, to on or about October 14, 2016, the FDA performed an inspection at Respondent's registered outsourcing facility. Pursuant to that inspection, the FDA made the following observations and found that Respondent did not comply with Code of Federal Regulations, title 21, part 211, and United States Code, title 21, section 353b:

a. OBSERVATION 1: Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. (C.F.R., tit. 21, §211.42(c))

b. OBSERVATION 2: Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed. (C.F.R., tit. 21, §§211.165 and 211.113)

///

[1] United States Code, title 21, section 379j-41(2) provides that an "API" is an Active Pharmaceutical Ingredient, which is "(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended (i) to be used as a component of a drug; and (ii) 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 human body; or (B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A)."

c. OBSERVATION 3: Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products. (C.F.R., tit. 21, §211.42(c))

d. OBSERVATION 4: Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed. (C.F.R., tit. 21, §211.165)

e. OBSERVATION 5: There is no written testing program designed to assess the stability characteristics of drug products. (C.F.R., tit. 21, §211.166)

f. OBSERVATION 6: Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release. (C.F.R., tit. 21, §211.165)

g. OBSERVATION 7: Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. (C.F.R., tit. 21, §211.42(c))

h. OBSERVATION 8: Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. (C.F.R., tit. 21, §211.42(c))

i. OBSERVATION 9: The building lacks adequate space for the orderly placement of equipment and materials to prevent mix- ups between different components, drug product containers, labeling, inprocess materials and drug products and to prevent contamination. (C.F.R., tit. 21, §211.42(b))

j. OBSERVATION 10: There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. (C.F.R., tit. 21, §211.192)

k. OBSERVATION 11: The labels of Respondent's outsourcing facility's drug products are deficient. (C.F.R., tit. 21, §§211.125 and 211.130)

22. On or about November 17, 2016, Respondent notified the Board that it was recalling a select number of sterile products due to a lack of sterility assurance.

23. On or about November 18, 2016, Respondent provided the Board with an unredacted version of the FDA's form 483, containing the FDA's observations and required corrective actions from the FDA's inspection that occurred from approximately September 14, 2016, to October 14, 2016, set forth above in paragraph 21 and its subparts. That same day, Respondent also provided the Board with Respondent's redacted response to the FDA's form 483, dated

November 4, 2016. In that response Respondent represented that it had corrected the FDA's Observations, including Observation numbers 1, 2, 7, and 11.

24. On or about November 21, 2016, the FDA posted a MedWatch which stated that Respondent had expanded its recall to all unexpired sterile drugs products within expiry.

25. From on or about June 12, 2017, to on or about June 29, 2017, the FDA performed an inspection at Respondent's registered outsourcing facility. Pursuant to that inspection, the FDA made the following observations and found that Respondent did not comply with Code of Federal Regulations, title 21, part 211, and United States Code, title 21, section 353b:

a. OBSERVATION 1: The quality control unit lacks authority to fully investigate errors that have occurred. (C.F.R., tit. 21, §211.22(a))

b. OBSERVATION 2: The responsibilities and procedures applicable to the quality control unit are not fully followed. (C.F.R., tit. 21, §211.22(d))

c. OBSERVATION 3: Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. This was a repeat observation from the FDA inspection that had been conducted on or about October 14, 2016. (C.F.R., tit. 21, §211.42(c))

d. OBSERVATION 4: There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. (C.F.R., tit. 21, §211.192)

e. OBSERVATION 5: Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed. This was a repeat observation from the FDA inspection that had been conducted on or about October 14, 2016. (C.F.R., tit. 21, §211.165)

f. OBSERVATION 6: Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. This was a repeat observation from the FDA inspection that was conducted on or about October 14, 2016. (C.F.R., tit. 21, §211.42(c))

g. OBSERVATION 7: There is no written testing program designed to assess the stability characteristics of drug products. (C.F.R., tit. 21, §211.166)

h. OBSERVATION 8: The labels of Respondent's outsourcing facility's drug products are deficient. This is a repeat observation from the FDA inspection that was conducted on or about October 14, 2016. (C.F.R., tit. 21, §§211.125 and 211.130)

26. On or about July 17, 2017, the Board received FDA form 483, containing the FDA's required corrective actions from the FDA's inspection that occurred from approximately June 12, 2017 to June 29, 2017, which included the FDA's observations set forth above in paragraph 25.

27. On or about July 18, 2017, the Board received a list of products that Respondent shipped into California from January 1, 2017, to July 17, 2017, which included twenty-eight (28) different drugs, and a total of 47,711 units of those drugs.

28. On or about July 25, 2017, the Board received Respondent's reply to the FDA's form 483 for the FDA inspection that occurred in June 2017. In that reply, Respondent stated that it had voluntarily and temporarily ceased production, that it was in the process of recalling all unexpired, sterile products, that it had contracted with third-parties for its microbiology lab, that it had hired a full-time microbiologist, and that it disagreed with the FDA's Observation 3 because at least one of the two sensors for the batches was within range at any given time.

29. On or about July 25, 2017, Respondent notified the Board that it was recalling all unexpired lots of sterile drug products.

30. On or about July 31, 2017, Respondent notified the Board that it had shipped only non-patient-specific products into California.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply With Statutes and Regulations Re. Dangerous Drugs and Pharmacy Practice)

31. Respondent is subject to disciplinary action under Code sections 4301(j) and (o) in that Respondent violated the statutes of the United States regulating dangerous drugs and pharmacies including United States Code, title 21, section 353b, and Code of Federal Regulations, title 21, sections 211.22(a), 211.22(d), 211.42(b), 211.42(c), 211.113, 211.125, 211.130, 211.165, 211.166, 211.192, as set forth above in paragraphs 20-30.

SECOND CAUSE FOR DISCIPLINE

(Gross Negligence)

32. Respondent is subject to disciplinary action under Code section 4301(c) in that Respondent committed gross negligence by representing to the Board on or about November 18, 2016, that Respondent was in compliance with the statutes and regulations of the United States

regulating dangerous drugs and pharmacy practice, because Respondent had corrected the FDA's observations from its September-October 2016 inspection, including the FDA's Observation numbers 1, 2, 7, and 11, when in fact Respondent was not in compliance with those statutes and observations because Respondent had not corrected those observations, as set forth above in paragraphs 21, 23, and 25.

MATTER IN AGGRAVATION

33. On or about August 9, 2017, Inspector L.P. conducted the annual sterile compounding inspection at Respondent's facilities. Pursuant to that inspection, Inspector L.P. found that Respondent committed the following violations of laws, rules, and regulations of the Board:

a. At the time of inspection, the compounding area buffer cleanroom contained exposed paper and post it notes adjacent to the compounding hoods. (Cal. Code Reg., tit. 16, §1751.4(c))

b. At the time of inspection, the pharmacy had recently moved the primary engineering controls into the secondary engineering control (buffer room) and began production in the space without having retested the secondary engineering controls. (Cal. Code Reg., tit. 16, §1751.4(f))

c. At the time of inspection, the pharmacist in charge had changed more than 30 days from the date of inspection but the new pharmacist in charge had not completed a compounding self-assessment. (Cal. Code Reg., tit. 16, §1735.2(k))

d. At the time of the inspection, the pharmacy master formula did not contain the rationale for the beyond use date assigned to each preparation. (Cal. Code Reg., tit. 16, §1735.2(e)(3))

e. At the time of the inspection, the pharmacy was cleaning ceilings, walls, floors, and doors using a contact time for LPH of 5 minutes when the manufacturer recommended contact time was a minimum of 10 minutes. (Code §4036.5)

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 Non-Resident Pharmacy Permit Number NRP 1071, issued to Cantrell Drug Company.

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99637, issued to Cantrell Drug Company;

3. Ordering Cantrell Drug Company 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,

4. Taking such other and further action as deemed necessary and proper.

DATED: 1/18/18

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2017109479
33215493.docx

NABP
National Association of Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Dawn Bibbs-Morrissey, Accreditation Manager

DATE: June 14, 2018

RE: Disqualified VAWD Accreditation

The National Association of Boards of Pharmacy® (NABP®) understands that many states confirm a facility's Verified-Accredited Wholesale Distributors® (VAWD®) accreditation status when making licensure decisions for that facility. To help facilitate this process, NABP would like to update the boards of pharmacy that NABP has taken the following action:

Name	Address	Action	Effective Date
Cantrell Drug Company	7321 Cantrell Rd, Ste 300-400 Little Rock, AR 72207	Disqualified	Immediately

If you would like additional information or have any questions, please feel free to contact VAWD by calling 847/391-4539 or via email at vawd@nabp.pharmacy. You can also contact me at 847/391-4510 or via email at dbibbs-morrissey@nabp.pharmacy.

Thank you.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Josh Bolin, Associate Executive Director
Kevin McGlynn, Accreditation Director

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: PharMEDium Services, LLC

Physical Address: 913 North Davis Avenue

City: Cleveland State: MS Zip Code: 38732

Telephone: (662) 846-5969 Fax: (662) 846-2614

Toll Free Number: (800) 523-7749 (Required per NAC 639.708)

E-mail: Bwomack@pharmedium.com Website: http://pharmedium.com

Supervising Pharmacist: Barrett Karl Manning Nevada License #: pending

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

100781

FEI Number (From FDA application): 961740623

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Barrett Karl Manning Nevada License Number: pending

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☒ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Brenda Womack

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

Brenda Womack, General Manager

Print Name of Authorized Person

4-6-18

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: 610-727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

Include 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.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

MISSISSIPPI BOARD OF PHARMACY

6360 I 55 North, Suite, 400, Jackson, Mississippi 39211
Phone 601-899-8880: Fax 601-899-8891

December 12, 2017

To Whom It May Concern:

The Mississippi Board of Pharmacy issued a Sterile Product Outsourcer Permit (Permit Number 13625/13.5) to Pharmedium Services, LLC, 913 North Davis Avenue, Cleveland, Mississippi, on August 18, 2014. This permit is current and in good standing and expires on December 31, 2019. There are no records of complaints or disciplinary action taken against this permit.

The Sterile Product Outsourcer Facilities are subject to the jurisdiction of the Food and Drug Administration and Drug Enforcement Administration.

If you have questions concerning this matter, please contact me at 601-899-8880.

Sincerely,

Cheri Atwood
Director of Compliance
Mississippi Board of Pharmacy

MISSISSIPPI
Board of Pharmacy

This is to certify that

PharMEDium Services, LLC

913 North Davis Avenue
Cleveland, MS 38732

is duly permitted as a:

Permit No.:
13625/13.5

Permit Holder:
Manning, Barrett K.

Sterile Product Outsourcer

This permit is not transferable or assignable.

Issued: 8/18/2014
Renewed: 11/2/2017
Expires: 12/31/2019

Frank Yarnell
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: PharMEDium Services, LLC

Physical Address: 36 Stults Road

City: Dayton State: NJ Zip Code: 08810

Telephone: (609) 819-4100 Fax: (609) 655-7628

Toll Free Number: 800-523-7749 (Required per NAC 639.708)

E-mail: Wkelso@pharmedium.com Website: www.pharmedium.com

Supervising Pharmacist: Walter Kelso Nevada License #: pending

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

100780

FEI Number (From FDA application): 079939389

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Walter Kelso Nevada License Number: pendind

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☒ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Walter T. Kelso RPh.

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

Walter Kelso, General Manager

Print Name of Authorized Person

9/5/18

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: PharMEDium Services, LLC

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: (610) 727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

Include 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.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

PHARMEDIUM SERVICES, LLC
0600175624

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 July 23, 2003.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

NATIONAL REGISTERED AGENTS, INC. OF NJ
820 BEAR TAVERN RD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 6th day of April, 2018

Elizabeth Maher Muoio
Acting State Treasurer

Certificate Number : *6087323868*

Verify this certificate *online at*

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: PharMEDium Services, LLC

Physical Address: 6100 Global Drive

City: Memphis State: TN Zip Code: 38141

Telephone: (901) 547-3900 Fax: (901) 367-6896

Toll Free Number: 800-523-7749 (Required per NAC 639.708)

E-mail: Emack@pharmedium.com Website: http://pharmedium.com

Supervising Pharmacist: Erica Mack Nevada License #: pending

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

100779

FEI Number (From FDA application): 961740649

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Erica Mack Nevada License Number: pending

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: n/a

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☒ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

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

Bruce Bagley, Interim General Manager

Print Name of Authorized Person

6 APR 2016

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: (610) 727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

Include 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.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

State of Tennessee
Department of Health

10688793
23804

TENNESSEE BOARD OF PHARMACY
OUTSOURCERS
PHARMEDIUM SERVICES, LLC
6100 GLOBAL DR.
MEMPHIS TN 38141

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004338
EXPIRATION DATE: 09/30/2019

CONTROLLED SUBSTANCE REGISTRATION

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

COMMISSIONER

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: PharMEDium Services, LLC

Physical Address: 12620 W. Airport Boulevard, Suite 130

City: Sugar Land State: TX Zip Code: 77478

Telephone: (281) 491-1900 Fax: (281) 491-1902

Toll Free Number: (800) 523-7749 (Required per NAC 639.708)

E-mail: Bbagley@pharmedium.com Website: www.pharmedium.com

Supervising Pharmacist: Bamidele Dauda Abdullahi Nevada License #: ~~N/A~~ pending

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

100782

FEI Number (From FDA application): 961740664

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Bamidele Dauda Abdullahi Nevada License Number: **

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☒ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

**Application by Reciprocation as a Pharmasict is being completed. Pharmacist license number in the state of TX is 54260.

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

Bruce Bagley, General Manager
Print Name of Authorized Person

14 MAR 2019
Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 227 Washington Street

City: Conshohocken State: PA Zip: 19428

Telephone: (610) 727-7000 Fax: (800) 640-5221

Contact Person: _____

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

Include 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.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

- 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.state.tx.us/fdlicense.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Food and Drug Licensing Group at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: https://reglicensing.questionpro.com. 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.

PHARMEDIUM SERVICES LLC
TWO CONWAY PARK 150 N FIELD DR STE 350
LAKE FOREST IL 60045

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

PHARMEDIUM SERVICES LLC

12620 W AIRPORT BLVD STE 130
SUGAR LAND, TX 77478

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 # 1000284
Expires: October 28, 2019

NON-TRANSFERABLE

Commissioner

509775

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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.
Non-Patient Specific

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Publicly 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: SCA Pharmaceuticals LLC

Physical Address: 755 Rainbow Road, Ste. B

City: Windsor State: CT Zip Code: 06095

Telephone: 877-550-5059 Fax: 860-831-1101

Toll Free Number: 877-550-5059 (Required per NAC 639.708)

E-mail: ldenton@scausa.net Website: www.scausa.net

Supervising Pharmacist: Cindy Mitman Nevada License #: 19891

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500.00

FEI Number (From FDA application): 90-0622763

Please provide the name of the facility as registered with the FDA and the registration number:
SCA Pharmaceuticals LLC #080545245

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Cindy Mitman Nevada License Number: 19891

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: n/a

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
Our 8821 Knoedle Ct., Little Rock, AR location was issued an FDA warning letter on June 25, 2015 our corrective actions were deemed acceptable by the FDA. Please see attached.

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

James Milton Boyer, CEO
Print Name of Authorized Person

1/12/18
Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: SCA Pharmaceuticals Holdings LLC

Address: 601 Lexington Avenue, 55th Floor

City: New York State: NY Zip: 10022

Telephone: 877-550-5059 Fax: 860-831-1101

Contact Person: Chris Musser

For any corporation non publicly traded, disclose the following:

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

a) EHP-SCA, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

b) EHP-SCA CO-INVEST, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

c) EHP CO-INVEST, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

d) SCA HOLDINGS, LLC 8821 Knoedl Court, Little Rock, Arkansas 72205
Name Address

2) Provide the number of shares issued by the corporation. 17,952,500

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 10/20/2016

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

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions regarding this registration can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information current. The email on your account will be used for all correspondence from this office.

You can update your address and email address or print a duplicate certificate by logging into your account with your User Id and Password at www.elicense.ct.gov. If you need your User Id and/or Password, please email dcp.online@ct.gov.

Mailing address:

SCA PHARMACEUTICALS LLC
755 RAINBOW RD STE B
WINDSOR, CT 06095-1024

Email on file to be used for receiving all notices from this office:

ldenton@scausa.net

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

SCA PHARMACEUTICALS LLC
755 RAINBOW RD STE B
WINDSOR, CT 06095-1024

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: Yes **Rx Legend Drugs: Yes** **Non Rx Legend Drugs: No** **Medical Devices: No** **Cosmetics: No**

Medical Gases/Oxygen: No **Durable Medical Equipment (DME): No** **Number of Chemists: 8**

Registration #: CSM.0001141
Effective Date: 07/01/2018
Expiration Date: 06/30/2019

verify online at www.elicense.ct.gov

Michelle Seagull

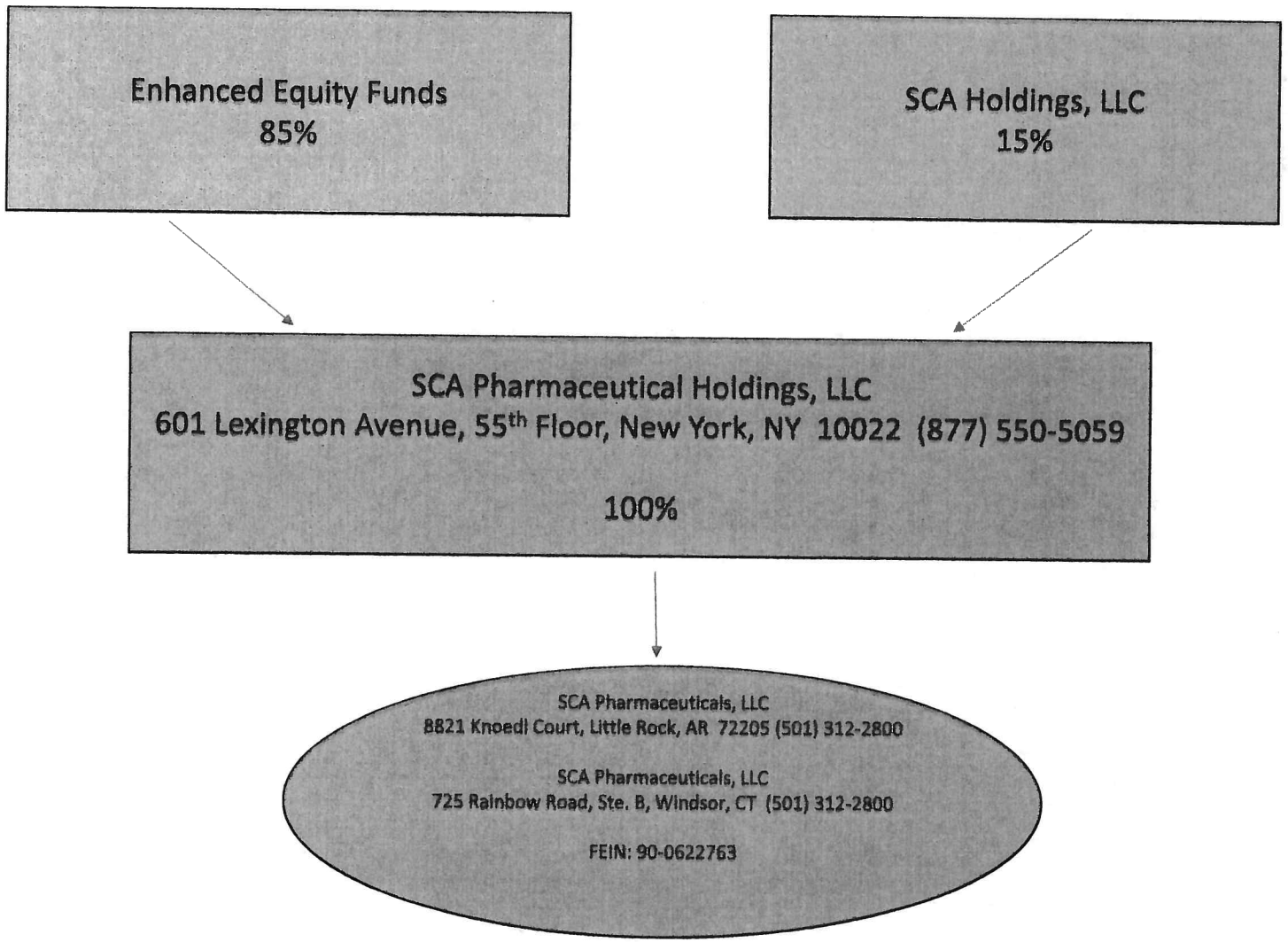
Michelle Seagull, Commissioner

SCA PHARMACEUTICALS

SCA Pharmaceuticals. LLC
Officers List

James Milton Boyer, CEO
Symmes Circle
Arlington, MA 02474
706-459-4448

Office: 501-312-2800 • Toll Free: 877-550-5059 • Fax: 501-312-2805
8821 Knoedl Court, Little Rock, Arkansas 72205 • **www.scausa.net**


Enhanced Equity Funds
85%
SCA Holdings, LLC
15%
SCA Pharmaceutical Holdings, LLC
601 Lexington Avenue, 55th Floor, New York, NY 10022 (877) 550-5059
100%
SCA Pharmaceuticals, LLC
8821 Knoedl Court, Little Rock, AR 72205 (501) 312-2800
SCA Pharmaceuticals, LLC
725 Rainbow Road, Ste. B, Windsor, CT (501) 312-2800
FEIN: 90-0622763

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

June 25, 2015

2015-DAL-WL-19

WARNING LETTER

UPS OVERNIGHT

Roy Eugene Graves, Chief Executive Officer
SCA Pharmaceuticals, LLC
8821 Knoedl Court
Little Rock, AR 72205-4600

Dear Mr. Graves:

You registered 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 December 13, 2013, and again on December 22, 2014. From March 17 to April 1, 2014, FDA investigators inspected your facility, SCA Pharmaceuticals, Inc., located at 8821 Knoedl Court, Little Rock, AR 72205-4600. During the inspection, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the investigators observed that your firm failed to perform adequate investigations of sterility failures, batches found to contain particulates, and daily pressure differentials that were out-of-specification. Investigators also observed that your firm does not perform adequate environmental monitoring of the ISO 5 areas or endotoxin testing on all your sterile drug products. In addition, the investigators observed that you failed to meet the conditions under section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain requirements under the FDCA. FDA issued a FDA 483 to your facility on April 1, 2014. FDA acknowledges receipt of your facility's response, dated April 22, 2014. FDA also acknowledges your action in January 2015 to voluntarily recall two lots of Glycopyrrolate Injection, 1 mg/5 mL Syringes, which were labeled with an expiration date that was unclear.

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

Based on this inspection, it appears your facility is producing drugs that violate the FDCA.

A. Compounded Drugs under the FDCA

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title I of the DQSA, the Compounding Quality Act (CQA), added a new section 503B to the FDCA. Under section 503B(b), 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 can qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.

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 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.

B. Violations of the FDCA

FDA investigators observed significant CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA.

In addition, the FDA investigators observed that your facility failed to meet the conditions of section 503B. For example, during the inspection, the FDA investigators noted:

1. Some of your facility's drug products do not include the following statements on the label: "This is a compounded drug," "Not for resale," and the 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 report to FDA in December 2013 and in June 2014 identifying the drug products that you compounded during the previous 6-month period (section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]).

Because your compounded drug products have not met all of the conditions in section 503B, they are not eligible for the exemptions under section 503B from the FDA approval requirements in 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.[2] In addition, the mislabeled drug products that you distributed and subsequently recalled are also misbranded under section 502(a) of the FDCA [21 U.S.C. § 352(a)].

Specific violations are described below.

Adulterated Drug Products

FDA investigators noted CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

2. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

3. Your firm does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product (21 CFR 211.167(a)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a draft guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.* This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

---

[2] See, e.g., section 503B(a)(11) of the FDCA [21 U.S.C. § 353b(a)(11)].

Misbranded Drug Products

You compound drug products that are intended for conditions that are 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, and they are not exempt from the requirements of section 502(f)(1) of the FDCA (*see, e.g.*, 21 CFR 201.115).

In addition, in January 2015, you voluntarily recalled two lots of Glycopyrrolate Injection, 1 mg/5 mL Syringes, which were labeled with an unclear expiration date. A printing error caused an overlap in the "y" and "3," making the actual "Use By 3/2015" date on the drug product labels appear to read "Use By 8/2015." Under section 502(a) of the FDCA, a drug product is misbranded if its labeling is false or misleading in any particular. Because the labeling of these drug products was false, they are misbranded under section 502(a) of the FDCA.

It is 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 report to FDA upon initial registration as an outsourcing facility in December 2013 and again in June 2014, identifying the drug products that you compounded during the previous 6-month period (section 503B(b)(2) of the FDCA [21 U.S.C. § 353b(b)(2)]). 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)].

C. Corrective Actions

In your April 22, 2014, response to the Form FDA 483 you described certain corrective actions you took in response to the Form FDA 483 observations. Although several of your proposed corrective actions appear adequate, others are deficient. For example, your written response stated that you have "invested in new equipment in order to perform the traditional 14 day sterility testing." However, your plan is to use this equipment only to "facilitate the root causes of sterility failures that would lead to adequate corrective/preventive actions, follow-up (verification) and conclusions throughout the entire facility" and not as your primary test method for sterility testing. Your firm has not shown that the sterility test method routinely used for release is adequate for its intended use. In addition, you stated that you plan to perform air monitoring and work surface sampling on a daily basis. It is not clear if your firm intends

to perform air monitoring during dynamic conditions and work surface sampling immediately following production.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation. You should fully implement necessary corrections in order to ensure that the drug products produced by your firm conform to the basic quality standards that ensure safety, identity, strength, quality, and purity.

D. 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 the violations identified above 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 the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. FDA intends to re-inspect your facility to verify corrective actions have been completed.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If the corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be completed. Your written notification should refer to the Warning Letter Number above (2015-DAL-WL-19). Please address your reply to Rose Ashley, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact Rose Ashley at (210) 308-1407.

Sincerely,

, Acting DD

Reynaldo R. Rodriguez, Jr.
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cc:

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