BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **PHARMEDIUM SERVICES, LLC** **Sugar Land, Texas** **Applicant for Nonresident Outsourcing Facility Registration** Respondent.	Case No. 6465

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 2, 2019.

It is so ORDERED on June 3, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Victor Law, R.Ph.
Board President

XAVIER BECERRA
Attorney General of California
LINDA K. SCHNEIDER
Senior Assistant Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **PHARMEDIUM SERVICES, LLC** **Sugar Land, Texas** **Applicant for Nonresident Outsourcing Facility Registration** Respondent.	Case No. 6465 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibilities of the Board of Pharmacy of the Department of Consumer Affairs (Board), the parties hereby agree to the following Stipulated Settlement and Disciplinary Order for Public Reproval to be submitted for adoption in final disposition of the Statement of Issues.

PARTIES

1. Anne Sodergren (Complainant), Interim Executive Officer of the Board, continues this action solely in her official capacity and is represented by Xavier Becerra, Attorney General of the State of California, Joshua A. Room, Supervising Deputy Attorney General.

2. Respondent PharMEDium Services, LLC in Sugar Land, Texas (Respondent)[1] is represented in this proceeding by attorney Jonathan Klein, of Klein, Hockel, Iezza & Patel P.C., 455 Market Street, Suite 1480, San Francisco, CA 94105-2442 (telephone (415) 951-0535).

[1] The Statement of Issues erroneously identified Respondent as "Amerisource Bergen Corporation dba PharMEDium Services, LLC." Amerisource Bergen is Respondent's owner.

JURISDICTION

3. On or about March 2, 2017, the Board of Pharmacy, Department of Consumer Affairs received an Application for a Nonresident Outsourcing Facility License from Respondent. On or about December 22, 2017, the Board issued Temporary Nonresident Outsourcing Facility Permit Number NSF 110 to Respondent. The Board denied the Application on or about March 20, 2018. Respondent timely requested a hearing. The Temporary Permit expired March 31, 2018.

4. Statement of Issues No. 6465 was filed before the Board and is currently pending against Respondent. The Statement of Issues and all other statutorily required documents were properly served on Respondent on July 5, 2018. A copy of Statement of Issues No. 6465 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Statement of Issues No. 6465. Respondent has also carefully read, fully discussed with counsel, and understands, the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Statement of Issues; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands and agrees that the charges and allegations in Statement of Issues No. 6465, if proven at a hearing, constitute cause for denying its license Application.

///

9. For the purpose of resolving the Statement of Issues without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Statement of Issues, and that Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Application for a Nonresident Outsourcing Facility License is subject to denial, and agrees to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

///

14. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that, upon subsequent receipt of an updated, complete, and accurate version thereof that reflects all changes in ownership or management that have taken place since its original submission, the Application for a Nonresident Outsourcing Facility License submitted by PharMEDium Services, LLC in Sugar Land, Texas (Respondent) shall be granted. Upon successful completion of all licensing requirements, including successful submission of all updated, complete and accurate application materials and supporting documentation required by Board staff and successful completion of a 2019 pre-licensure inspection by Board investigators, a license shall be issued to Respondent. Said license shall be publicly reproved by the Board under Business and Professions Code section 495 in resolution of Statement of Issues No. 6465, attached as exhibit A.

IT IS FURTHER HEREBY ORDERED that Respondent shall henceforth comply with all applicable requirements of federal current good manufacturing practices (CGMPs) with regard to any products or preparations shipped into or within California, including but not limited to:

1. Respondent shall refrain from preparing compounds containing **cefazolin** or any other beta-lactam drugs in the same primary engineering control (PEC) or in the same room as any other drug preparations, and shall ensure that any such drug preparation with similar risks from cross-contamination and hypersensitivity reactions is compounded using a separate air handling system and separately stored;
2. Respondent shall appropriately sample and test all compounding components, containers, and closures, rely only on current supplier reports of analysis, and maintain current container and closure integrity studies on site;
3. Respondent shall ensure that all compounded drug preparations bear expiration dates or beyond use dates that comply with applicable law, and which are supported by appropriate stability studies, method suitability testing, and other scientific support;

4. Respondent shall ensure visual testing of all drug preparations, and use of a black and white board with a light for this purpose; and

5. Respondent shall identify and retain reserve samples representative of each lot in each shipment of each active ingredient, and store same under conditions consistent with product labeling and in the same immediate container-closure system.

Failure to meet any of these requirements with regard to any products or preparations shipped into or within California after the effective date of this decision shall be deemed unprofessional conduct and cause for further discipline against Respondent.

IT IS FURTHER HEREBY ORDERED that Respondent shall, within six (6) months of issuance of the license, undergo an inspection by an external entity approved in advance by the Board for this purpose, to determine compliance with all above requirements as well as all applicable requirements of state and federal law. A copy of the inspection report shall be provided to the Board immediately upon completion. Failure to timely: submit a proposed entity to the Board for approval; undergo the inspection; or provide the inspection report, shall be deemed unprofessional conduct and cause for further discipline against Respondent.

///

///

///

///

///

///

///

///

///

///

///

///

ACCEPTANCE

I am authorized to sign for Respondent PharMEDium Services, LLC in Sugar Land, Texas. I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with Respondent's attorney, Jonathan Klein. I understand the stipulation and the effect it will have on the Application for a Nonresident Outsourcing Facility License and subsequently-issued Nonresident Outsourcing Facility License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 02-MAY-2019

Scott Aladeen, President, for
PHARMEDIUM SERVICES, LLC
Sugar Land, Texas
Respondent

I have read and fully discussed with Respondent and its representative(s) the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/2/19

JONATHAN KLEIN
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/2/19

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
LINDA K. SCHNEIDER
Senior Assistant Attorney General

JOSHUA A. ROOM
Supervising Deputy Attorney General
Attorneys for Complainant

SF2018200705
21379100.doc

Exhibit A

Statement of Issues No. 6465

XAVIER BECERRA
Attorney General of California
LINDA K. SCHNEIDER
Senior Assistant Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **PHARMEDIUM SERVICES, LLC** **Applicant for Nonresident Outsourcing Facility Registration** Respondent.	Case No. 6465 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about March 2, 2017, the Board of Pharmacy, Department of Consumer Affairs received an Application for a Nonresident Outsourcing Facility License from Amerisource Bergen Corporation dba PharMEDium Services, LLC in Sugar Land, Texas (Respondent). On or about January 30, 2017, Jennifer Adams, President of PharMEDium Services, LLC in Sugar Land, Texas, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. On or about December 22, 2017, the Board issued Temporary Nonresident Outsourcing Facility Permit Number NSF 110 to Respondent. On or about February 27, 2018, Respondent received an Order to Cease and Desist from the Board. The Board denied the Application on or about March 20, 2018. The Temporary Permit expired March 31, 2018.

JURISDICTION

3. This Statement of Issues is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

5. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.

6. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

7. Section 480 of the Code states, in pertinent part:

"(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

. . .

"(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the . . . [license]."

8. Section 4300, subdivision (c), of the Code states in pertinent part:

> (c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy. . . .

9. Section 4129, subdivision (a), of the Code states:

"(a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California."

10. Section 4129.2 of the Code states, in pertinent part:

"(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. . . ."

REGULATORY PROVISIONS

11. 21 C.F.R. § 211.1(a) specifies that Part 211 contains the federal current good manufacturing practices for drug products for administration to humans or animals.

12. 21 C.F.R. § 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. . . .

(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.

(d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use."

13. 21 C.F.R. § 211.46 states, in pertinent part:

"(a) Adequate ventilation shall be provided.

. . .

(d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use."

14. 21 C.F.R. § 211.84 states, in pertinent part:

"(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

(b) Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by § 211.170.

. . .

(d) Samples shall be examined and tested as follows:

(1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used.

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

(3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.

(4) When appropriate, components shall be microscopically examined.

(5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination.

(6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.

. . ."

15. 21 C.F.R. § 211.94 states, in pertinent part:

"(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated.

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures.

. . ."

16. 21 C.F.R. § 211.137 states, in pertinent part:

"(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

. . ."

17. 21 C.F.R. § 211.160, subdivision (a), states:

"(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such . . . shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified."

18. 21 C.F.R. § 211.166 states, in pertinent part:

"(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.

. . ."

19. 21 C.F.R. § 211.170 states, in pertinent part:

"(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. . . .

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. . . ."

20. 21 C.F.R. § 211.188 states, in pertinent part:

"Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

(1) Dates;

(2) Identity of individual major equipment and lines used;

(3) Specific identification of each batch of component or in-process material used;

(4) Weights and measures of components used in the course of processing;

(5) In-process and laboratory control results;

(6) Inspection of the packaging and labeling area before and after use;

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(8) Complete labeling control records, including specimens or copies of all labeling used;

(9) Description of drug product containers and closures;

(10) Any sampling performed;

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

(12) Any investigation made according to § 211.192.

(13) Results of examinations made in accordance with § 211.134."

FACTUAL BACKGROUND

21. Between on or about October 9, 2017 and October 11, 2017, Respondent was the subject of a Board pre-licensure inspection pursuant to its Application for a Nonresident Outsourcing Facility License. In the course of that inspection, and/or subsequently, Board inspectors discovered several deviations from current federal current good manufacturing practices (CGMPs). An Order to Cease and Desist was issued to Respondent. The Temporary Nonresident Outsourcing Facility Permit issued to Respondent has since expired.

CAUSE FOR DENIAL OF APPLICATION

(Non-Compliance with CGMPs and/or California Compounding Regulations)

22. Respondent's Application for a Nonresident Outsourcing Facility License is subject to denial under section(s) 480, subdivision (a)(3), section 4300, subdivision (c), section 4129.1, and/or section 4129.2 of the Code, in that Respondent, in the following ways, failed to comply with current federal CGMPs:

a. Respondent produced compounds containing **cefazolin**, a beta-lactam drug similar to penicillin and with similar risks from cross-contamination and hypersensitivity reactions that penicillin can trigger, in the same room and in the same primary engineering control (PEC) as other compounds, failing to comply with 21 C.F.R. § 211.42(c) and/or (d);

b. These compounds containing **cefazolin** were produced in the same room with a total of twenty-four (24) PECs utilizing a shared air handling system, and were stored alongside other compounds, failing to comply with 21 C.F.R. § 211.46(a) and/or (d);

c. Components, containers, and/or closures were not adequately sampled and tested prior to use, failing to comply with 21 C.F.R. § 211.84(a) and/or (b);

d. Components for compounded products were not adequately tested prior to the compounding process, and/or Respondent relied on out-of-date supplier reports of analysis and/or qualifications, failing to comply with 21 C.F.R. § 211.84(d);

e. No container and/or closure integrity studies were available for review, failing to comply with 21 C.F.R. § 211.94(a) and/or (d);

f. Compounded preparations bore expiration dates not supported by appropriate stability studies/scientific support, failing to comply with 21 C.F.R. § 211.137;

g. Respondent did not have appropriate specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms developed by an appropriate organizational unit and reviewed and approved by an appropriate quality control unit, e.g., Respondent's testing plan did not require visual inspection of each drug preparation and use of a black and white board with a light, failing to comply with 21 C.F.R. § 211.160;

h. Compounded preparations bore expiration dates not supported by appropriate stability studies/scientific support, failing to comply with 21 C.F.R. § 211.166;

i. Respondent did not appropriately identify and retain reserve samples representative of each lot in each shipment of each active ingredient, and/or store same under conditions consistent with product labeling and in the same immediate container-closure system, failing to comply with 21 C.F.R. § 211.170; and/or

j. Respondent failed to appropriately include in batch production and control records statement(s) of actual yield and statement(s) of percentage of theoretical yield at appropriate phases of processing, failing to comply with 21 C.F.R. § 211.188(b)(7).

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. Denying the Application for a Nonresident Outsourcing Facility License received from Amerisource Bergen Corporation dba PharMEDium Services, LLC (Respondent);

2. Taking such other and further action as is deemed necessary and proper.

DATED: 7/5/18

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

SF2018200705
21171704.doc