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

In the Matter of the Accusation Against: **APS PHARMACY** **Jaime Alberto Rios, President** **Michele Ann Lagamba, Secretary** **George Chrysakis, Pharmacist-in-Charge** 34911 US Hwy 19N, Ste 600 Palm Harbor, FL 34684 **Nonresident Sterile Compounding Permit Number NSC 99796** **Nonresident Pharmacy Permit No. NRP 1286** Respondent.	Case No. 7119 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about October 3, 2021, Complainant Anne Sodergren, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed Accusation No. 7119 against Drug Depot Inc., dba APS Pharmacy, Drug Depot Inc., dba APS Pharmacy (Respondent) before the Board of Pharmacy. (Accusation attached as Exhibit A.)

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2. On or about May 20, 2013, the Board of Pharmacy (Board) issued Nonresident Sterile Compounding Permit No. NSC 99796 to Respondent. The Nonresident Sterile Compounding Permit expired on May 14, 2020, and has not been renewed.

3. On or about May 16, 2013, the Board of Pharmacy issued Nonresident Pharmacy Permit No. NRP 1286 to Respondent. The Nonresident Pharmacy Permit expired on May 14, 2020, and has not been renewed.

4. On or about October 12, 2021, Respondent was served by Certified and First Class Mail copies of the Accusation No. 7119, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondent's address of record which, pursuant to Business and Professions Code section 4100, is required to be reported and maintained with the Board. Respondent's address of record was and is: 34911 US Hwy 19N. Ste. 600, Palm Harbor, FL 34684. On or about November 9, 2021, the above documents were also served by Certified and First Class Mail to 6213 Laferre Lane, Hillard, OH 43026.

5. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505(c) and/or Business and Professions Code section 124.

6. Government Code section 11506(c) states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

7. The Board takes official notice of its records and the fact that Respondent filed a Notice of Defense within 15 days after service upon them of the Accusation, and on or about January 2, 2022 withdrew their Notice of Defense, waiving their right to a hearing on the merits of Accusation No. 7119.

8. California Government Code section 11520(a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

9. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 7119, finds that the charges and allegations in Accusation No. 7119, are separately and severally, found to be true and correct by clear and convincing evidence.

10. The Board finds that the actual costs for Investigation and Enforcement are $14,415.00 as of February 4, 2022.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent Drug Depot Inc., dba APS Pharmacy, Drug Depot Inc., dba APS Pharmacy has subjected its Nonresident Sterile Compounding Permit No. NSC 99796 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board of Pharmacy is authorized to revoke Respondent's Nonresident Sterile Compounding Permit based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. Failure to Maintain Safe Environment for Compounding of Sterile Drug Products (BPC § 4301, subd. (o); Regulation section 1751.4, subsection (a));

b. Failure to Maintain Facility Standards for Sterile Compounding (BPC § 4301, subd. (o); Regulation section 1751.4, subsection (f));

c. Failure to Provide Documentation to Support Extension of Beyond Use Date for Sterile Drug Preparation (BPC § 4301, subd. (o); Regulation section 1735.2, subsection (i)(3));

d. Failure to Maintain the Quality of a Compounded Sterile Preparation (BPC § 4301, subd. (j); Regulation section 1735.1, subsection (ae)); and

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e. Adulterated Preparations (BPC § 4301, subd. (j), 4169, subd. (a)(2), Health and Safety Code § 111295, and Health and Safety Code § 111250.)

ORDER

IT IS SO ORDERED that Nonresident Sterile Compounding Permit No. NSC 99796, and Nonresident Pharmacy Permit No. NRP 1286, issued to Respondent Drug Depot Inc., dba APS Pharmacy, Drug Depot Inc., dba APS Pharmacy, are revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective at 5:00 p.m. on April 27, 2022.

It is so ORDERED on March 28, 2022.

Seung W. Oh, Pharm.D.
Board President
FOR THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

35890621.DOCX
DOJ Matter ID:SA2021301248

Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

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

In the Matter of the Accusation Against**:** **APS PHARMACY** **Jaime Alberto Rios, President** **Michele Ann Lagamba, Secretary** **George Chrysakis, Pharmacist-in-Charge** 34911 US Hwy 19N, Ste 600 Palm Harbor, FL 34684 **Nonresident Sterile Compounding Permit Number NSC 99796** **Nonresident Pharmacy Permit No. NRP 1286** Respondent.	Case No. 7119 **ACCUSATION**

PARTIES

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

2. On or about May 16, 2013, the Board of Pharmacy issued Nonresident Pharmacy Permit Number NRP 1286 to APS Pharmacy (Respondent). The Nonresident Pharmacy Permit was cancelled on May 14, 2020, and has not been renewed.

3. On or about May 20, 2013, the Board of Pharmacy issued Nonresident Sterile Compounding Permit Number NSC 99796 to APS Pharmacy (Respondent). The Nonresident Sterile Compounding Permit was cancelled on May 14, 2020, and has not been renewed.

JURISDICTION

4. This Accusation 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

5. Code section 4300 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:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

6. Code section 4300.1 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.

7. Code section 4307 states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any

conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

8. Code section 4301 states:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(j) The violation of any of the statutes of this state, or 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 . . . .

. . . .

9. Code section 4302 states, in pertinent part:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

10. Code section 4169 states, in pertinent part:

(a) A person or entity shall not do any of the following:

…

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

REGULATORY PROVISIONS

11. California Code of Regulations (Regulation), title 16, section 1735 states, in pertinent part:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

12. Regulation section 1735.1 states, in pertinent part:

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

. . .

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those

listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

13. Regulation section 1735.2, states, in pertinent part:

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

14. Regulation section 1751 states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

15. Regulation section 1751.4 states, in pertinent part:

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

. . .

(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.

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(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.

16. Regulation section 1751.8, states, in pertinent part:

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

HEALTH AND SAFETY CODE PROVISION

17. Health and Safety Code section 111295 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

18. Health and Safety Code section 111250 states: "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

COST RECOVERY

19. Section 125.3 of the Code states, 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.

FACTUAL ALLEGATIONS

20. On March 11, 2019, APS Pharmacy, a Nonresident pharmacy/sterile pharmacy, located in Palm Harbor, Florida, was inspected by a Board inspector for a Nonresident sterile compounding license renewal. The pharmacy compounds high risk drug products.

21. During the inspection, certification reports for the pharmacy's designated compounding areas revealed that the non-hazardous compounding room pressure differential and

air changes was noted to "not meet the requirement of USP797." The hazardous compounding buffer room report states that HEPA filters number 1 and 6 failed the leak test. The pharmacy's compounding environment returned to within specifications on March 11, 2019, for the first time since January 24, 2019. The pharmacy continued to compound drugs in this environment during the period that the environment did not meet specifications.

22. The United States Pharmacopeia (USP) and National Formulary (NF) are the official standards for all prescription and over the counter medicines, dietary supplements and other health care products manufactured and sold in the United States[1]. USP drug Monographs set forth the quality expectations of a medicine and how to test the medicine and its ingredients to meet the quality expectations[2].

23. On February 27, 2020, APS Pharmacy, was inspected by a Board inspector for its annual onsite sterile compounding inspection.

24. The inspections and subsequent investigations revealed the following violations of California pharmacy laws related to sterile compounding of drugs

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Safe Environment for Compounding of Sterile Drug Products)

25. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subd. (o) for violating pharmacy regulations described in Regulation section 1751.4, subsection (a), and Respondent's compounding policies and procedures, in that in and between January 24, 2019 and March 11, 2019, Respondent compounded and dispensed approximately 1,947 prescriptions to California patients when the pharmacy ante room and non-hazardous buffer where the prescriptions were prepared had HEPA filters which failed to meet certification requirements, per certification reports for the designated compounding areas, and before certification of the new HEPA filters on March 11, 2019, as further explained in paragraph 20, above.

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[1] https://www.pharmaceutical-business-review.com/products/usp-bp-ep-jp-nf-chemicals.
[2] https://www.usp.org/about/public-policy/overview-of-monographs.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Facility Standards for Sterile Compounding)

26. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subd. (o) for violating pharmacy regulations described in Regulation section 1751.4, subsection (f), and the pharmacy's compounding policies and procedures, in that in and between January 24, 2019 and March 11, 2019, Respondent compounded and dispensed approximately 1,947 prescriptions to California patients when the pharmacy ante room and non-hazardous buffer where the prescriptions were prepared had HEPA filters which failed to meet certification requirements, and before certification of the new HEPA filters on March 11, 2019, as further explained in paragraph 20, above.

THIRD CAUSE FOR DISCIPLINE

(Failure to Provide Documentation to Support Extension of Beyond Use Date for Sterile Drug Preparation)

27. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subd. (o) for violating pharmacy regulations described in Regulation section 1735.2, subsection (i)(3), as follows:

a. In or about and between March 1, 2018 and March 11, 2019, Respondent dispensed approximately 52 prescriptions to California patients from 24 compounded sterile preparations lot batches of Glutamine/Arginine/Carnitine (GAC) that were assigned a 90 day room temperature Beyond Use Date (BUD), which exceeded the required BUD maximum of 24 hours at room temperature required by CCR section 1751.8, subsection (c), without documentation from container closure integrity and stability studies supporting the BUD extension to 90 days.

b. In or about and between March 12, 2019 and February 26, 2020, Respondent dispensed approximately 2,115 prescriptions to California patients. Thirty-eight prescriptions for Glutamine/Arginine/Carnitine were assigned a 90-day BUD without supporting BUD extension from container closure integrity and stability studies, and 2077 prescriptions from Human Chorionic Gonadotropin with Theanine with a 95-day BUD without supporting BUD extension from stability studies.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain the Quality of a Compounded Sterile Preparation)

28. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subd. (o) for violating pharmacy regulations described in CCR section 1735.1, subsection (ae), as follows:

a. In or about and between February 11, 2019 and March 11, 2019, Respondent compounded and dispensed approximately 1,314 compounded drug preparations with bulk ingredients made from one or more substances intended for dietary use only, or not approved for compounding by the FDA, or which lacked compliance with United States Pharmacopeia standards, thus rendering the compounded drug product lacking in quality.

b. In or about and between March 12, 2019 and February 26, 2020, Respondent compounded and dispensed approximately 2,440 compounded drug preparation, including 363 prescriptions of Glutathione, and 2,077 prescriptions of Human Chorionic Gonadotropin with Theanine, with bulk ingredients made from one or more substances intended for dietary use only or not approved for compounding by the FDA, or lacked compliance with USP standards, thus rendering the compounded drug product lacking in quality.

FIFTH CAUSE FOR DISCIPLINE

(Adulterated Preparations)

29. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subd. (j) for violating statutes regulating controlled substances and dangerous drugs as they relate to adulterated preparations described in Code section 4169, subd. (a)(2) and Health and Safety Code section 111295, and defined in Health and Safety Code section 111250, as follows:

a. In or about and between February 11, 2019 and March 11, 2019, Respondent dispensed approximately 1,314 compounded drug preparations with bulk ingredients made from one or more substances intended for dietary use only, or not approved for compounding by the FDA, or which lacked compliance with USP standards, therefore adulterating the compounded sterile preparation.

b. In or about and between March 12, 2019 and February 26, 2020, Respondent compounded and dispensed at least 2,440 compounded drug preparations, including 363 prescriptions of Glutathione and 2,077 prescriptions of Human Chorionic Gonadotropin with Theanine, with bulk ingredients made from one or more substances intended for dietary use only, or not approved for compounding by the FDA, or which lacked compliance with USP standards, therefore adulterating the compounded sterile preparation.

DISCIPLINE CONSIDERATIONS

30. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about July 28, 2017, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 74158 for two violations of Code section 4301, subdivisions (n). Respondent was ordered to pay a fine in the amount of $5000, and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth. The bases of the citation are as follows:

a. On or about February 24, 2016, the Oklahoma Board of Pharmacy placed Respondent on probation for three years and fined it $15,000 after discovering that between October 1, 2013 and May 31, 2015, Respondent was not continuously licensed yet shipped 1,002 prescriptions to Enhance Spa, which were controlled substances; mailed patient-specific drugs to addresses other than the patient's home or work; and compounded medications in strength that were already commercially available.

b. On or about March 8, 2016, the Iowa Board of Pharmacy cited Respondent and ordered it to pay $2,500 after discovering that Respondent did not have an active license between January 1, 2014 and September 7, 2014, yet Respondent shipped approximately 100 prescriptions into Iowa.

OTHER MATTERS

31. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1286 issued to APS Pharmacy, then it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit

Number NRP 1286 is placed on probation; or, 2) if the pharmacy permit is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

32. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1286 issued to APS Pharmacy, then Nonresident Sterile Compounding Permit Number NSC 99796, issued to APS Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit Number NRP 1286 is placed on probation; or, 2) if Nonresident Pharmacy Permit Number NRP 1286 is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

33. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1286 issued to APS Pharmacy, then Jaime Alberto Rios, President, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit Number NRP 1286 is placed on probation; or, 2) if Nonresident Pharmacy Permit Number NRP 1286 is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

34. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1286 issued to APS Pharmacy, then Michele Ann Lagamba, Secretary, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit Number NRP 1286 is placed on probation; or, 2) if Nonresident Pharmacy Permit Number NRP 1286 is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

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:

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1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1286, issued to APS Pharmacy;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 99796, issued to APS Pharmacy;

3. Prohibiting Nonresident Pharmacy Permit Number NRP 1286, issued to APS Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any California Pharmacy licensee;

4. Prohibiting Nonresident Sterile Compounding Permit Number NSC 99796, issued to APS Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any California Pharmacy licensee;

5. Prohibiting Jamie Alberto Rio, President, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any California Pharmacy licensee;

6. Prohibiting Michele Ann Lagamba, Secretary, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any California Pharmacy licensee;

7. Ordering APS Pharmacy, Jaime Alberto Rios and Michele Ann Lagamba 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,

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

DATED: 10/3/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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