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

In the Matter of the Statement of Issues Against: **PHARMACY RESOURCES INCORPORATED; GREGG N. PEDERSON, PRESIDENT/PHARMACIST-IN-CHARGE** **Non-Resident Sterile Compounding Permit Renewal Applicant** Respondent.	Case No. 6091 **WITHDRAWAL OF STATEMENT OF ISSUES**

On March 28, 2018, Pharmacy Resources Incorporated, and Gregg N. Pederson, President/Pharmacist-in-Charge (Respondent) withdrew their appeal and request for a hearing of the denial of their application for Renewal of Non-Resident Sterile Compounding Permit by the Board of Pharmacy. Accordingly, Statement of Issues No. 6091, filed against Respondent, is withdrawn without prejudice and the denial of their application is affirmed. The earliest date on which Respondent may reapply for a Renewal of Non-Resident Sterile Compounding Permit is one year after the effective date of the denial.

That effective date is the issue date of this Withdrawal of Statement of Issues.

DATED: 4/10/18

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

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

In the Matter of the Statement of Issues Against: **PHARMACY RESOURCES INCORPORATED** **GREGG N. PEDERSON, PRES./PIC** **JANET L. PEDERSON, SECTY** **Non-Resident Sterile Compounding Permit Renewal Applicant** Respondent.	Case No. 6091 **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 September 21, 2016, the Board of Pharmacy, Department of Consumer Affairs, received an application for renewal of Non-Resident Sterile Compounding Permit Number NSC 99697 from Pharmacy Resources Incorporated (Respondent). Gregg N. Pederson, president of the corporation, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on November 16, 2016.

3. On or about October 3, 2011, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 1126 to Respondent with Gregg N. Pederson as president and pharmacist-

in-charge and Janet L. Pederson as secretary. The Non-Resident Pharmacy Permit will expire on October 1, 2017, unless renewed.

4. On or about November 3, 2011, the Board of Pharmacy issued Non-Resident Sterile Compounding Permit Number NSC 99697 to Respondent. The Non-Resident Sterile Compounding permit expired on October 1, 2016, and has not been renewed.

JURISDICTION

5. 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.

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.

STATUTORY PROVISIONS

7. Code section 480 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)(A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.
>
> (B) 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 business or profession for which application is made . . .

8. Code section 4127.2 states, in pertinent part:

> (a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.
>
> . . . .
>
> (c) A license to compound sterile drug products 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. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400 . . .

9. Code section 4300, subdivision (c), provides, in pertinent part, that the Board may refuse a license to any applicant guilty of unprofessional conduct.

10. Code section 4301 states, in pertinent part:

> 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:
>
> . . . .
>
> (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 . . .

11. Code section 4076 states, in pertinent part:

> (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following: . . .
>
> . . . .
>
> (2) The directions for the use of the drug.
>
> . . . .
>
> (8) The quantity of the drug or drugs dispensed . . .

12. Code section 4127.2, subdivision (a), states that "[a] nonresident pharmacy shall not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable".

13. California Code of Regulations, title 16, section 1707.5 states, in pertinent part:

> (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
>
> (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
>
> (A) Name of the patient.

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription . . .

14. California Code of Regulations, title 16, section 1735.2, subdivision (h), states that "[a]ll chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength."

15. California Code of Regulations, title 16, section 1735.4 states, in pertinent part:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

. . . .

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included . . .

16. California Code of Regulations, title 16, section 1751.3 states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

. . . .

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration . . .

17. California Code of Regulations, title 16, section 1751.7 states, in pertinent part:

. . . .

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients . . . shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations . . .

FIRST CAUSE FOR DENIAL

(Acts Warranting Denial of Application: Accusation No. (insert assigned case no.)

18. Respondent's application for renewal of Non-Resident Sterile Compounding Permit Number NSC 99697 is subject to denial pursuant to Code sections 4300, subdivision (c), and 480, subdivision (a)(3)(A), in that Respondent committed acts which are grounds for revocation of Non-Resident Pharmacy Permit Number NRP 1126 and Non-Resident Sterile Compounding Permit Number NSC 99697 pursuant to Code section 4301, subdivision (o), as set forth in Accusation No. 6021 filed on January 3, 2018, which is currently pending. Respondent is alleged to have failed to provide the Board with any stability studies to support exceeding the beyond use date of 180 days for certain sterile injectable compounded preparations, in violation of California Code of Regulations, title 16, section 1735.2, subdivision (h); to have dispensed certain sterile injectable compounded preparations prior to documented end-product testing confirming sterility and acceptable levels of pyrogens (specifically, endotoxin testing), and to have dispensed certain sterile injectable compounded preparations prior to the 14-day quarantine period and completion of the end product testing confirming sterility and acceptable levels of pyrogens, in violation of California Code of Regulations, title 16, section 1751.7, subdivision (e)(1); and to have failed to label patient-specific sterile compounded prescriptions with the required elements (directions for use of the preparation, the total quantity of the drug or drugs dispensed, and/or the intended rate of administration) and use the California patient-centered format on the labels, in violation of Code section 4076, subdivisions (a)(2) and (8), and California Code of Regulations, title 16, sections 1707.5, subdivision (a)(1), 1735.4, subdivision (a)(3), and 1751.3, subdivision (a)(12).

SECOND CAUSE FOR DENIAL

(Board Inspection of September 9, 2016/Respondent Not in Compliance with the Pharmacy Law)

19. Respondent's application for renewal of Non-Resident Sterile Compounding Permit Number NSC 99697 is subject to denial pursuant to Code section 4127.2, subdivision (c), as follows: On or about September 9, 2016, a Board Inspector conducted a non-resident sterile compounding permit renewal inspection at Respondent's pharmacy located in Denver, Colorado.

That same day, the Board Inspector issued an Inspection Report, finding that Respondent was not in compliance with California Code of Regulations, title 16, sections 1707.5 and 1751.7. The Board Inspector conducted additional investigation and determined that Respondent was also not in compliance with California Code of Regulations, title 16, sections 1735.2, subdivision (h), 1735.4, subdivision (a)(3), and 1751.3, subdivision (a)(12), and Code section 4076, subdivisions (a)(2) and (8), as set forth in paragraph 18 above.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Denying the application of Pharmacy Resources Incorporated for renewal of Non-Resident Sterile Compounding Permit Number NSC 99697; and

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

DATED: 3/9/18

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

SA2017106466