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8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Statement of Issues Against:

Case No. 6091

13 **PHARMACY RESOURCES INCORPORATED**
GREGG N. PEDERSON, PRES./PIC
JANET L. PEDERSON, SECTY

STATEMENT OF ISSUES

14 **Non-Resident Sterile Compounding Permit**
15 **Renewal Applicant**

16 Respondent.

17 Complainant alleges:

18 **PARTIES**

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

21 2. On or about September 21, 2016, the Board of Pharmacy, Department of Consumer
22 Affairs, received an application for renewal of Non-Resident Sterile Compounding Permit
23 Number NSC 99697 from Pharmacy Resources Incorporated (Respondent). Gregg N. Pederson,
24 president of the corporation, certified under penalty of perjury to the truthfulness of all
25 statements, answers, and representations in the application. The Board denied the application on
26 November 16, 2016.

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

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

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

6 JURISDICTION

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

10 6. Code section 4300.1 states:

11 The expiration, cancellation, forfeiture, or suspension of a board-issued
12 license by operation of law or by order or decision of the board or a court of law, the
13 placement of a license on a retired status, or the voluntary surrender of a license by a
14 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.

15 STATUTORY PROVISIONS

16 7. Code section 480 states, in pertinent part:

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

19

20 (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.

21 (B) The board may deny a license pursuant to this subdivision only if the
22 crime or act is substantially related to the qualifications, functions, or duties of the
business or profession for which application is made . . .

23 8. Code section 4127.2 states, in pertinent part:

24 (a) A nonresident pharmacy shall not compound sterile drug products for
25 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
26 transferable.

27

28 (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

1 article and any regulations adopted by the board. The nonresident pharmacy shall
2 reimburse the board for all actual and necessary costs incurred by the board in
3 conducting an inspection of the pharmacy at least once annually pursuant to
4 subdivision (v) of Section 4400 . . .

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

7 10. Code section 4301 states, in pertinent part:

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

11

12 (o) Violating or attempting to violate, directly or indirectly, or assisting in
13 or abetting the violation of or conspiring to violate any provision or term of this
14 chapter or of the applicable federal and state laws and regulations governing
15 pharmacy, including regulations established by the board or by any other state or
16 federal regulatory agency . . .

17 11. Code section 4076 states, in pertinent part:

18 (a) A pharmacist shall not dispense any prescription except in a container
19 that meets the requirements of state and federal law and is correctly labeled with all
20 of the following: . . .

21

22 (2) The directions for the use of the drug.

23

24 (8) The quantity of the drug or drugs dispensed . . .

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

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

14 (a) Labels on drug containers dispensed to patients in California shall
15 conform to the following format:

16 (1) Each of the following items, and only these four items, shall be
17 clustered into one area of the label that comprises at least 50 percent of the label.
18 Each item shall be printed in at least a 12-point sans serif typeface, and listed in the
19 following order:

20 (A) Name of the patient.

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

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

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

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

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

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

14

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

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

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

23

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

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

27

28 (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 . . .

1 **FIRST CAUSE FOR DENIAL**

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

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

22 **SECOND CAUSE FOR DENIAL**

23 **(Board Inspection of September 9, 2016/Respondent**

24 **Not in Compliance with the Pharmacy Law)**

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

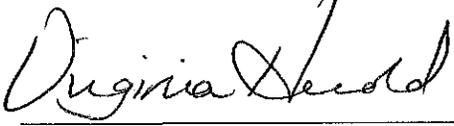
1 That same day, the Board Inspector issued an Inspection Report, finding that Respondent was not
2 in compliance with California Code of Regulations, title 16, sections 1707.5 and 1751.7. The
3 Board Inspector conducted additional investigation and determined that Respondent was also not
4 in compliance with California Code of Regulations, title 16, sections 1735.2, subdivision (h),
5 1735.4, subdivision (a)(3), and 1751.3, subdivision (a)(12), and Code section 4076, subdivisions
6 (a)(2) and (8), as set forth in paragraph 18 above.

7 **PRAYER**

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

- 10 1. Denying the application of Pharmacy Resources Incorporated for renewal of Non-
11 Resident Sterile Compounding Permit Number NSC 99697; and
12 2. Taking such other and further action as deemed necessary and proper.

13
14 DATED: 3/9/18



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

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