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

In the Matter of the Accusation Against: **PHARMACY RESOURCES INCORPORATED** **GREGG N. PEDERSON, PRES./PIC** **JANET L. PEDERSON, SECTY** **5290 E. Yale Circle, No. 101** **Denver, CO 80222** **Non-Resident Pharmacy Permit No. NRP 1126** **Non-Resident Sterile Compounding Permit No. NSC 99697** Respondent.	Case No. 6021 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (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 October 3, 2011, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 1126 to Pharmacy Resources Incorporated (Respondent), with Gregg N. Pederson (Pederson) as president and pharmacist-in-charge and Janet L. Pederson as secretary. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in the Accusation and will expire on October 1, 2017, unless renewed.

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3. 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 was in full force and effect at all times relevant to the charges brought in the Accusation; however, it expired on October 1, 2016, and has not been renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board) 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:
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> (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.

STATUTORY AND REGULATORY PROVISIONS

7. 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 . . .

8. 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 . . .

9. 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".

10. 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 . . .

11. 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

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compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength."

12. 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 . . .

13. 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:
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> . . . .
>
> (12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration . . .

14. 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 . . .

COST RECOVERY

15. Code section 125.3 provides, in pertinent part, that a 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.

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DRUG CLASSIFICATIONS

16. Glycopyrrolate 0.2 mg/ml is a dangerous drug pursuant to Code section 4022 and is indicated for the reduction of secretions in horses. "Robinul 0.2 mg/ml" is a brand name for Glycopyrrolate.

17. Cimetidine 150 mg/ml is a dangerous drug pursuant to Code section 4022 and is indicated for the treatment of gastric ulcers and melanomas and stomach protection in horses. "Tagamet 300 mg/2ml" is a brand name for Cimetidine.

18. Cacodylate/copper 6 mg/ml is a dangerous drug pursuant to Code section 4022 and is indicated for the treatment of anemia in horses.

19. Methocarbamol 100 mg/ml is a dangerous drug pursuant to Code section 4022 and is indicated for the treatment of muscle spasms in horses.

FACTUAL ALLEGATIONS

20. On or about September 9, 2016, Board Inspector D. P. conducted a non-resident sterile compounding permit renewal inspection at Respondent's pharmacy located in Denver, Colorado, and was assisted by pharmacist-in-charge Pederson. D. P. asked Pederson what risk levels of sterile compounds were dispensed to California patients. Pederson stated that the pharmacy provided mainly non-sterile to sterile (high-risk) veterinary products.

21. D. P. requested various documents from Pederson, including compounding policies and procedures, completed recent patient-specific compounding records with associated prescription labels, quality assurance policies and procedures with documentation of end product testing, non-sterile to sterile compounded product testing documentation, and a list of all compounded preparations provided to California patients during the past year. Pederson told D. P. that his staff kept a log of sterile preparations compounded by the pharmacy and that the California patients could be highlighted on the log for the inspector's review. D. P. was given a log listing veterinary sterile compounded preparations that were supplied to patients with the California patients highlighted.

22. D. P. was also given compounding log worksheets for approximately eight sterile compounded preparations and the related prescriptions, prescription labels, and "soy-logs" (logs

documenting in-house sterility testing of drug products). D. P. found that the prescription labels, including the label for Glycopyrrolate 0.2 mg/ml, were not in compliance with California law. D. P. also found that four sterile compounded injectable preparations, glycopyrrolate, cimetidine, cacodylate/copper, and methocarbamol, were dispensed with beyond use dates (BUD's) greater than 180 days. D. P. requested the validation paperwork for the extended BUD's. D. P. was given a certificate of analysis and a soy log for only one of the four injectable preparations, glycopyrrolate. D. P. was advised that the extended BUD's for the other three drug products were validated some time ago and that the paperwork might not be easy to locate.

23. On and between September 12, 2016 and September 30, 2016, D. P. requested certain documents and information from Pederson, including a list of sterile drug products the pharmacy provided to California patients during the last year; a current copy of the pharmacy's sterile compounding policy and procedures; dispensing records of sterile preparations the pharmacy provided to California patients for the last sixth months; the master formulas, sterility and pyrogens testing data and documentation, and stability studies used to extend the BUD's for glycopyrrolate, cimetidine, cacodylate/copper, and methocarbamol; and the compounding logs, master formulas, prescriptions, labels, and sterility and pyrogens testing data and documentation for certain other compounded products the pharmacy sent to California patients.

24. On and between September 23, 2016 and September 30, 2016, Pederson sent D. P. an Excel spreadsheet listing the sterile compounded prescriptions the pharmacy supplied to California patients, written documentation and justification for the extended BUD's for the four drug preparations, and the pharmacy's compounding policies and procedures.

25. On or about October 5, 2016, D. P. sent Pederson an email stating that she still had not received the sterility and pyrogens data and documentation for glycopyrrolate, cimetidine, cacodylate/copper, and methocarbamol or the compounding logs, master formulas, prescriptions, labels, and sterility and pyrogens testing data and documentation for the other compounded products.

26. On or about October 7, 2016, Pederson provided D. P. with compounding worksheets and prescriptions labels for estrone AQ suspension 5 mg/ml injection, acetyl D glucosamine 50

mg/ml injection, and stanozolol suspension 50 mg/mil injection, and a revised Excel spreadsheet. D. P. found that of the 164 prescriptions listed on the spreadsheet, approximately 72 prescriptions (44%) of sterile compounded products were dispensed prior to the required 14-day quarantine period. D. P. also found that the prescription labels for Estrone, Acetyl D Glucosamine, and Stanozolol were not in compliance with California law and that the three drug products were dispensed with BUD's greater than 180 days.

FIRST CAUSE FOR DISCIPLINE

(Failure to Document Appropriate Beyond Use Date for Compounded Products)

27. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated California Code of Regulations, title 16, section 1735.2, subdivision (h), as follows: Respondent failed to provide the Board with any stability studies to support exceeding the beyond use date of 180 days for the following sterile injectable compounded preparations:

Compounded Preparation	Assigned Lot No.	Date Preparation Compounded	"Validated" BUD Listed on Product Worksheet	Assigned BUD	Actual BUD Days Assigned & Documented	Listed Label. Expiration Date
Glycopyrrolate .2 mg/ml inj.	050816	08/05/16	270 days	05/05/17	274 days	APR '17
Cimetidine 150 mg/ml inj.	070916	09/07/16	360 days	09/07/17	366 days	AUG '17
Caco-6-Copper 6 mg/ml inj.	040816	08/03/16	240 days	04/03/17	244 days	MAR '17
Methocarbamol 100 mg/ml inj.	270716	07/27/16	360 days	04/19/17 (component expiration date)	236 days	APR '17
Estrone AQ susp 5 mg/ml inj.	060716	07/06/16	360 days	04/02/17 (component expiration date)	271 days	MAR '17
Glycopyrrolate .2 mg/ml inj.	050816	08/05/16	270 days	05/05/17	274 days	APR '17

Compounded Preparation	Assigned Lot No.	Date Preparation Compounded	"Validated" BUD Listed on Product Worksheet	Assigned BUD	Actual BUD Days Assigned & Documented	Listed Label. Expiration Date
Stanozolol susp. 50 mg/ml inj.	210416	04/21/16	360 days	01/09/17 (component expiration date)	274 days	DEC '16

SECOND CAUSE FOR DISCIPLINE

(Failure to Quarantine Batch-Produced Sterile Injectable Drug Products)

28. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), as follows:

a. Respondent dispensed the following sterile injectable compounded preparations, compounded from one or more non-sterile ingredients and in quantities greater than one dose, prior to documented end-product testing confirming sterility and acceptable levels of pyrogens, specifically, endotoxin testing:

Compounded Preparation	Lot #	Quantity Compounded	Date Compounded	Date Dispensed	Endotoxin Indication on Compounding Worksheet
Glycopyrrolate .2 mg/ml inj.	050816	262 ml into 12 20 ml vials	08/05/16	08/05/16	"N/A"
Cimetidine 150 mg/ml inj.	070916	260 ml into 8 30 ml vials	09/06/16	09/06/16	No endotoxin requirement listed

b. Respondent dispensed the following sterile injectable compounded preparations, compounded from one or more non-sterile ingredients and in quantities greater than one dose, prior to the 14-day quarantine period and completion of the end product testing confirming sterility and acceptable levels of pyrogens:

Rx Number	Date Written	Date Compounded	Date Dispensed	Patient Name	Compounded Preparation	Vial Quantity/ Quantity Dispensed
66854	08/29/16	08/30/16	08/30/16	Armored Car	Estrone 5 mg/ml	100 ml/13 vials

Rx Number	Date Written	Date Compounded	Date Dispensed	Patient Name	Compounded Preparation	Vial Quantity/ Quantity Dispensed
66853	08/29/16	08/30/16	08/30/16	Award It	Estrone 5 mg/ml	100 ml/13 vials
66760	8/23/16	8/12/16	8/23/16	Madame Strips	Estrone 5 mg/ml	100 ml/13 vials
66618	08/12/16	8/12/16	8/12/16	Weird Haircut Steh	Tranexamic Acid 10%	100 ml/6 vials
65623	06/07/16	8/09/16	8/09/16	Zen	Ketoprofen 10%/L-Arginine 7%	100 ml/12 vials
66520	08/05/16	08/05/16	08/05/16	Raphael	Glycopyrrolate 0.mg/ml	20 ml/12 vials
66409	08/01/16	08/01/16	08/01/16	Travel Fighter	L-Arginine 10%	100 ml/13 vials
66481	08/04/16	08/04/16	8/04/16	Sunfeet	Acety D Glucosamine 100 mg/ml	50 ml/8 vials
66384	07/29/16	07/29/16	07/29/16	Velocity	Aminocaproic Acid 25%	100 ml/6 vials
66385	07/29/16	07/29/16	07/29/16	Westbrook	Estrone 5 mg/ml	100 ml/13 vials
66386	07/29/16	07/29/16	07/29/16	Magical Tech	Estrone 5 mg/ml	100 ml/13 vials
61677	08/03/15	07/29/16	07/29/16	Fancy Pants	Acety D Glucosamine 100 mg/ml	50 ml/8 vials
66355	07/28/16	07/28/16	07/28/16	Edgy Girl	Estrone 5 mg/ml	100 ml/13 vials
66019	07/05/16	07/06/16	07/06/16	Check's in the Mail	Estrone 5 mg/ml	100 ml/13 vials
66020	07/05/16	07/06/16	07/06/16	Pandora	Estrone 5 mg/ml	100 ml/13 vials
66021	07/05/16	07/06/16	07/06/16	Alaskan Fun	Estrone 5 mg/ml	100 ml/13 vials

THIRD CAUSE FOR DISCIPLINE

(Failure to Label Patient-Specific Sterile Compounded Prescriptions with the Required Elements)

29. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated 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), as follows: Respondent failed to label California patient-specific sterile compounded prescriptions, specifically, prescriptions for Glycopyrrolate 0.2 mg/ml injection, Estrone AQ suspension 5 mg/ml injection, Acetyl D Glucosamine 50 mg/ml injection, and Stanozolol suspension 50 mg/ml injection, with the directions for use of the preparation, the total quantity of the drug or drugs dispensed, and/or the intended rate of administration. Further, Respondent failed to use the California patient-centered format on the labels.

MATTERS IN AGGRAVATION

30. To determine the degree of discipline to be assessed against Respondent, if any, Complainant alleges as follows:

a. On or about January 20, 2016, the Board issued Citation and Fine No. CI 2015 66540 against Respondent's Non-Resident Pharmacy Permit for violating California Code of Regulations, title 16, section 1735.2, subdivision (j) (failure to complete compounding self-assessment). The Board ordered Respondent to pay a fine of $500 by February 19, 2016. Respondent paid the citation in full.

b. On or about January 20, 2016, the Board issued Citation and Fine No. CI 2015 68710 against Respondent's Non-Resident Sterile Compounding Permit for violating California Code of Regulations, title 16, section 1735.2, subdivision (j) (failure to complete compounding self-assessment).

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 1126, issued to Pharmacy Resources Incorporated;

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99697, issued to Pharmacy Resources Incorporated;

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3. Ordering Pharmacy Resources Incorporated 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: 1/3/18

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

SA2016104808