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

In the Matter of the Accusation Against: **THE COMPOUNDING SHOP CORPORATION, dba THE COMPOUNDING SHOP** **MICHAEL HAULSEE, PRES./PIC** **REBECCA BRADLEY, V.P.** **4000 Park Street North** **St. Petersburg, FL 33709** **Original Non-Resident Pharmacy Permit No. NRP 701** Respondent.	Case No. 5138 **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 ("Board"), Department of Consumer Affairs.

2. On or about February 14, 2006, the Board issued Original Non-Resident Pharmacy Permit Number NRP 701 to The Compounding Shop Corporation ("Respondent"), doing business as The Compounding Shop, with Michael Haulsee as president and pharmacist-in-charge and Rebecca Bradley as vice president. The non-resident pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2015, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

4. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (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 . . .

5. 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.

6. Code section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. 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 . . . .

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7. Code section 4303, subdivision (b), states:

> The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

8. Code section 477, subdivision (b), states that a "license" includes "certificate", "registration" or other means to engage in a business or profession.

9. Code section 4022 states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a --------," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Code section 4112 states, in pertinent part:

> (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.
>
> (b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.
>
> . . . .
>
> (d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section . . .

11. 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".

12. Code section 4127.3, subdivision (a), states:

> Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

13. Health and Safety Code section 109970 states:

> "Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

14. Health and Safety Code section 111250 states that "[a]ny drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

15. Health and Safety Code section 111295 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

FLORIDA STATUTES

16. Florida Statutes section 465.016 states, in pertinent part:

> (1) The following acts constitute grounds for denial of a license or disciplinary action . . .
>
> . . . .
>
> (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893 . . .

17. Florida Statutes, section 499.005, states, in pertinent part:

> It is unlawful for a person to perform or cause the performance of any of the following acts in this state:
>
> (1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use . . .

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18. Florida Statutes, section 499.006, states, in pertinent part:

A drug or device is adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance . . .

COST RECOVERY

19. 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.

DRUG CLASSIFICATIONS

20. "Rhinocort", a brand of budesonide, is indicated for the treatment of nasal congestion. Rhinocort is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

BACKGROUND

21. On and between March 18, 2013, and March 22 2013, the Food and Drug Administration ("FDA") inspected Respondent's pharmacy, The Compounding Shop.

22. On or about March 22, 2013, the FDA posted a Form 483 Inspection Report, listing 12 observations made by FDA representatives during the inspection as to The Compounding Shop's sterile processing (the FDA posted an amended Form 483 Inspection Report pertaining to the inspection on March 25, 2013).

23. On or about May 8, 2013, the FDA posted a news release alerting the public that the FDA's preliminary findings of practices at The Compounding Shop of St. Petersburg, Florida, raised concerns about a lack of sterility assurance for sterile drugs produced at and distributed from the pharmacy. The FDA stated that they had advised The Compounding Shop it was in the best interest of public health to take action to remove all sterile products from the market. The Compounding Shop informed the FDA that it was recalling sterile products and was in the process of notifying customers.

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24. On or about June 25, 2013, the Board's inspector issued a Cease and Desist Order to The Compounding Shop, informing them that the Board had no record of licensure or accreditation that would authorize the pharmacy to ship compounded sterile drug product into California to patients, prescribers, or other recipients. The inspector ordered The Compounding Shop to cease and desist such shipments absent appropriate licensure. The inspector requested that The Compounding Shop provide the Board with, among other things, documentation of all compounded sterile injectable products they had shipped into California since January 1, 2012, and a list of all patients, prescribers or other recipients in California to whom any of The Compounding Shops' recalled or otherwise suspect products were shipped.

25. On or about July 2, 2013, The Compounding Shop's legal representative sent an email to the inspector stating that the pharmacy had voluntarily suspended preparation of any sterile compounded products and that no compounded sterile products were being shipped into California.

26. On or about July 10, 2013, the inspector received various documents from The Compounding Shop's legal representative, including a 14 page Log of Scripts for medications the pharmacy had shipped into California. The log indicated that The Compounding Shop had shipped over 170 prescriptions of compounded sterile injectable medications into California between January 1, 2012, and July 1, 2013.

27. On or about September 3, 2013, the FDA published a Form 483 Inspection Report documenting sterility issues with compounded budesonide that they observed during an inspection of The Compounding Shop. The inspection was conducted between August 23, 2013, and September 3, 2013.

28. On or about September 27, 2013, the FDA published a Safety Alert, warning patients and health care providers that budesonide solution from The Compounding Shop may be contaminated and should not be used or administered to patients. The FDA stated that they had observed a bottle of budesonide solution from The Compounding Shop that contained a visible, white, floating material. The FDA identified the material as a fungus. The FDA expressed their concern that contamination may be present in other budesonide solution products from The

Compounding Shop that may currently be on the market. The FDA explained that drug products that are for oral inhalation, such as the budesonide solution from The Compounding Shop, which is labeled "for inhalation only", are required to be sterile, and that contaminated drug products, whether used by inhalation or otherwise, put patients at risk for infection.

29. That same day (September 27, 2013), the inspector sent a letter to The Compounding Shop, requesting that they halt shipping sterile compounded products, such as budesonide solution for inhalation/irrigation, into California until the sterility issues have been resolved. The inspector also requested documentation of all compounded sterile products that had been shipped to California since January 1, 2013.

30. On or about October 9, 2013, pharmacist-in-charge, Michael Haulsee, sent dispensing information for compounded medications The Compounding Shop had shipped into California between January 1, 2013, and October 4, 2013. The documentation showed that The Compounding Shop had not shipped any medication to California subsequent to April 25, 2013.

CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law or of Applicable State Laws Governing Pharmacy)

31. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated or attempted to violate, directly or indirectly, a provision or term of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) or of the applicable state laws governing pharmacy, as follows:

a. On and between January 1, 2012, and April 15, 2013, Respondent shipped over 170 prescriptions of compounded sterile injectable medications, including Nandrolone Decanoate 200 mg/ml injectable, Testosterone Cyp (Sesame) 200 mg/ml injectable, Nandrolone Decanoate 100 mg/ml injectable, Nandrolone Decanoate 250 mg/ml injectable, Folic Acid/B-12 5mg/100 mcg/ml injectable, and/or Test Cyp/Test Prop Blend 60/60 mg/ml, into the State of California without a sterile compounding license issued by the Board, in violation of Code section 4127.2, subdivision (a).

b. On and between August 23, 2013, and September 3, 2013, Respondent manufactured, sold, delivered, held and/or offered for sale a drug, specifically, budesonide solution, that was

adulterated, as set forth in paragraphs 27 and 28 above, in violation of Health and Safety Code section 111295. Respondent's acts and/or omissions alleged above would constitute grounds for disciplinary action against Respondent in the State of Florida, where Respondent's nonresident pharmacy is permanently located, pursuant to Florida Statutes, section 465.016, subdivision (1)(e), by virtue of Respondent's violation of Florida Statute, section 499.005, subdivision (1).

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 Original Non-Resident Pharmacy Permit Number NRP 701, issued to The Compounding Shop Corporation, doing business as The Compounding Shop;

2. Ordering The Compounding Shop Corporation, doing business as The Compounding Shop, 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;

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

DATED: 7/28/14

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

SA2014114891