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

In the Matter of the Accusation Against: **AMERICAN CUSTOM COMPOUNDING PHARMACY, LLC, DBA AMERICAN CUSTOM COMPOUNDING PHARMACY** **2607 Walnut Hill Lane Ste 220** **Dallas, TX 75229** **Non-Resident Pharmacy Permit No. NRP 1262** **Non-Resident Sterile Compounding Permit No. NSC 99778** Respondents.	Case No. 6017 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia K. 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 November 5, 2012, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 1262 to American Custom Compounding Pharmacy, LLC, doing business as American Custom Compounding Pharmacy. The Non-Resident Pharmacy Permit expired on November 1, 2016, and was cancelled on January 19, 2017.

3. On or about November 8, 2012, the Board of Pharmacy issued Non-Resident Sterile Compounding Permit Number NSC 99778 to American Custom Compounding Pharmacy, LLC, doing business as American Custom Compounding Pharmacy (Respondent). The Non-Resident Sterile Compounding Permit expired on November 1, 2016, and was cancelled on January 19, 2017.

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 unless otherwise indicated.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4127.1(c) of the Code states:

> 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 regulations adopted by the board.

7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

8. Section 4300.1 of the Code 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.

9. Section 4303(b) of the Code states:

> The board may 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.

STATUTORY PROVISIONS

10. Section 4022 of the Code 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.

11. Section 4301 of the Code 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 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.

. . . .

REGULATORY PROVISIONS

12. Title 16, California Code of Regulations, section 1735(a) states in pertinent part:[1]

"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 drug product from chemicals or bulk drug substances

[1] The "compounding" regulations were amended, effective January 1, 2017. This Accusation refers to the version of the regulations in effect at the time of the violations.

. . . .

13. Title 16, California Code of Regulations, sections 1735.2(h) and (j) states:

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

. . .

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. (02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

14. Title 16, California Code of Regulations, section 1751.7 (b) and (c) states:

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulation, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluation, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

. . .

(c) Batch-produced sterile injectable drug products 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.

15. Texas Administrative Code, title 22, Part 15, Chapter 291, Subchapter B, sections 291.36(9) and 291.32(c)(1)(E) provides that all pharmacists on duty at a pharmacy engaged in the compounding of sterile preparations must comply with all state and federal laws or rules governing the practice of pharmacy.

16. Texas Occupations Code, title 3, Chapter 565, Subchapter J, section 565.001(a)(12) provides that the Texas Pharmacy Board may discipline a pharmacy license if the Board finds that the pharmacy has violated any pharmacy or drug statute or rule of Texas, another state or the United States.

COST RECOVERY

17. Section 125.3 of the Code provides, 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.

DRUGS

18. Bacteriostatic sterile water is a dangerous drug pursuant to Business and Professions Code section 4022.

19. Human Chorionic Gonadotropin is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(f)(32) and a dangerous drug pursuant to Business and Professions Code section 4022.

20. Testosterone Cypionate is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(f)(30) and a dangerous drug pursuant to Business and Professions Code section 4022.

21. Sermorelin is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

22. From approximately March 2016 through August 2016, Respondent compounded sterile injectable drug products at its compounding facility in Texas and furnished certain of those drug products to patients in California.

23. Respondent did not test and quarantine, as required prior to dispensing, the following batch-produced sterile products compounded from one or more non-sterile components: Lot #0512016@7 (testosterone cypionate 200mg/ml, Lot #03072016@1 (sermorelin/GHRP-2 9mg/15mg), Lot #03282016@1 (bacteriostatic sterile water), Lot #06082016@2 (HSC 800IU/5ml), Lot #06302016@3 (testosterone cypionate 100 mg/ml) and Lot #06302016@2 (testosterone cypionate 100 mg/ml).

24. From June 29, 2016 through July 26, 2016, Respondent's pharmacist-in-charge did not complete a validation process on aseptic technique prior to compounding thirteen batches of compounded sterile drug products. The pharmacist-in-charge also did not complete a compounding self-assessment when he became the pharmacist-in-charge on June 29, 2016.

25. On March 28, 2016, Respondent compounded bacteriostatic sterile water (lot #03282016@1) and assigned an expiration date equaling 270 days, without conducting or having any stability studies to support the assigned expiration date.

FIRST CAUSE FOR DISCIPLINE

(Failure to Complete Validation Process on Technique)

26. Respondent is subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 21, section 1751.7(b), in that pharmacy staff compounding sterile injectable drugs were not properly trained, as set forth in paragraphs 22 through 25, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Properly Conduct End Product Testing for Sterile Injectable Drug Products)

27. Respondent is subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1751.7(c), in that it failed to properly test and

quarantine sterile injectable drug products, as set forth in paragraphs 22 through 25, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failure to Assign Proper Beyond Use Date)

28. Respondent is subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, section 1735.2(h), in that it did not assign a proper beyond use date for the drugs that were compounded with components set to expire in advance of the beyond use date assigned by Respondent, as set forth in paragraphs 22 through 25, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Self-Assessment Form)

29. Respondent is subject to disciplinary action under section 4301, subdivision (o) for violating California Code of Regulations, title 16, section 1735.2(j), in that Respondent did not complete a self-assessment form prior to compounding drug products, as set forth in paragraphs 22 through 25, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

30. Respondent is subject to disciplinary action under Code section 4301 for unprofessional conduct in that it engaged in the activities described in paragraphs 22 through 25 above, which are incorporated herein by reference.

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 1262, issued to American Custom Compounding Pharmacy, LLC, doing business as American Custom Compounding Pharmacy;

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99778, issued to American Custom Compounding Pharmacy, LLC, doing business as American Custom Compounding Pharmacy;

3. Ordering American Custom Compounding Pharmacy, LLC, doing business as American Custom Compounding Pharmacy 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: 4/24/17

Virginia Herold

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

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