KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
ROSAILDA PEREZ
Deputy Attorney General
State Bar No. 284646
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1618
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against: **SANTA CLARA DRUG "THE COMPOUNDING SHOP"** **2453 Forest Avenue** **San Jose, CA 95128** **Pharmacy License No. PHY 51229** **VISHAL B. PUROHIT** **2453 Forest Avenue** **San Jose, CA 95128** **Registered Pharmacist License No. RPH 62617** Respondents.	Case No. 4842 **ACCUSATION**

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 March 8, 2013, the Board of Pharmacy issued Retail Pharmacy License Number PHY 51229 to ERA Pharmacy Inc., dba Santa Clara Drug "The Compounding Shop" (Respondent Pharmacy). The Retail Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on September 4, 2013, unless renewed.

3. On or about July 28, 2009, the Board of Pharmacy issued Registered Pharmacist

License Number RPH 62617 to Vishal B. Purohit (Respondent Pharmacist). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2014, unless renewed.

JURISDICTION

4. This Accusation is brought before the 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 4011 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. Code section 4300 provides that every license issued by the Board may be suspended or revoked.

7. Code section 4300.1 provides that 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

8. Code section 4081 provides, in pertinent part that:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and

Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

"..."

9. Code section 4113, subdivision (c), provides that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

10. Code section 4127.1 provides, in pertinent part, that unless exempted due to accreditation by a private accreditation agency approved by the Board, a pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the Board pursuant to this section, that the license shall be renewed annually and is not transferable, and that a license to compound injectable sterile drug products may not be issued or renewed until the location has been inspected by the Board and found in compliance.

11. Code section 4301 provides, in pertinent part that:

"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:

"...

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

"...

"(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.

"..."

12. Code section 4332 makes it unlawful for any person to fail, neglect, or refuse to

maintain the records required by section 4081 or, when called upon by an authorized officer or a member of the board, to refuse to produce or provide the records within a reasonable time, or to willfully produce or furnish records that are false.

13. Code section 4342, subdivision (a), states that the Board may institute any action or actions as may be provided by the law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law.

14. California Code of Regulations, title 16, section 1714 provides, in pertinent part, that each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed.

15. California Code of Regulations, title 16, section 1715 requires, in pertinent part, that the pharmacist-in-charge of each pharmacy complete, using a form specified by the regulation and available from the Board, a self-assessment of the pharmacy's compliance with federal and state pharmacy law before July 1 of each odd-numbered year and within thirty (30) days whenever a new pharmacy permit has been issued, there is a change in the pharmacist-in-charge, or there is a change in the licensed location of the pharmacy. Each pharmacy self-assessment form shall be kept on file in the pharmacy for three (3) years from the date of completion.

16. California Code of Regulations, title 16, section 1735.2, subdivision (j), states, in pertinent part, that prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies using a form specified by the regulation and available from the Board, and that the self-assessment form shall be thereafter completed before July 1 of each odd-numbered year, and within thirty (30) days of the start of a new pharmacist-in-charge or issuance of a new pharmacy license.

17. California Code of Regulations, title 16, section 1735.3 lists records that are required to be created and maintained in a readily retrievable form by the pharmacy for three (3) years, for each compounded drug product prepared by a pharmacy; subdivisions (a)(5) and (a)(6) thereof require that for each compounded drug product pharmacy records include the quantity of each

component used in compounding the drug product ((a)(5)) and the manufacturer and lot number of each component, unless the manufacturer name is demonstrably unavailable in which case the name of the supplier may be substituted ((a)(6)).

18. California Code of Regulations, title 16, section 1751.1 lists additional records that are required to be created and maintained in a readily retrievable form by the pharmacy for three (3) years, for each sterile injectable compounded drug product prepared by a pharmacy; subdivision (b)(6) thereof requires that for sterile products compounded from one or more non-sterile ingredients, a pharmacy keep records of preparation including the master worksheet, the preparation work sheet, and records of end-product evaluation results.

19. California Code of Regulations, title 16, section 1751.7 requires, in pertinent part, that a pharmacy engaged in compounding sterile injectable drug products maintain, as part of its written policies and procedures, a written quality assurance plan including, inter alia, a periodic sampling plan for examination of end product, and further requires that 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.

COST RECOVERY

20. Code section 125.3 states, 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.

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

21. Code section 4022 states, in pertinent part, that:

"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."

22. **Alprostadil** is a dangerous drug as designated by Code section 4022.

FACTUAL BACKGROUND

23. On or about June 18, 2013, two Board Inspectors inspected Respondent Pharmacy after receiving a complaint against Respondent Pharmacy alleging a contaminated sterile environment, use of expired ingredients in compounding drug products, and failure to perform qualitative and quantitative testing on sterile compounded products. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) discovered:

a. That Respondents had been engaged in sterile injectable drug compounding in and/or between March and June 2013, despite the pharmacy's lack of licensure to do so;

b. That Respondents had compounded multiple batch-produced sterile injectable drug products from one or more non-sterile ingredients between April and June 2013, and released those products for sale and/or patient administration, without first quaranting those drug products until receipt of results of end product testing for sterility and pyrogens;

c. That Respondents had compounded multiple batch-produced sterile injectable drug products from one or more non-sterile ingredients between April and June 2013 for which there were no records of end product testing for sterility and pyrogens;

d. That Respondents had inadequate compounding records, including that there were no compounding records available for alprostadil aliquots lot number 90000ALIQ used in sterile injectable compounded products between April and June 2013;

e. That Respondents had not completed a new pharmacy self-assessment form or a compounding self-assessment form since the new pharmacy permit was issued or there was a change in the pharmacist-in-charge; and

f. That Respondents kept multiple expired medications throughout the pharmacy's extemporaneous compounding area, sterile injectable product compounding area,

main pharmacy dispensing area, and in an unclean refrigerator.

FIRST CAUSE FOR DISCIPLINE

(Unlicensed Activity)

24. Respondents are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or 4127.1, in that, as described in paragraph 24 above, Respondents compounded sterile injectable drug products from about March 2013 through June 2013 without having obtained a sterile compounding license from the Board.

SECOND CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Injectable Compounding Quality Assurance and Process)

25. Respondents are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.7, in that, as described in paragraph 24 above, Respondents compounded multiple batch-produced sterile injectable drug products from one or more non-sterile ingredients and released them for sale to physicians for office use without first quarantining the sterile injectable drugs for end product testing for sterility and pyrogens.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Injectable Recordkeeping Requirements)

26. Respondents are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or California Code of Regulations, title 16, sections 1735.3, and/or 1751.1, in that, as described in paragraph 24 above, Respondents failed to make and keep records that included the master work sheet, the preparation work sheet, and records of end-product evaluation results for multiple batch-produced sterile injectable drug products that were compounded from one or more non-sterile ingredients, including the alprostadil aliquots, lot number 90000ALIQ, used in sterile injectable compounded products between April 2013 and June 2013.

///

///

///

FOURTH CAUSE FOR DISCIPLINE

(Failure to Complete Pharmacy Self-Assessment)

27. Respondents are subject to discipline pursuant Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or California Code of Regulations section 1715, in that, as described in paragraph 24 above, the Respondent Pharmacist did not complete a self-assessment within 30 days of the new pharmacy permit being issued or when Respondent Pharmacist became the new Pharmacist-in-Charge.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Self-Assessment)

28. Respondents are subject to discipline pursuant Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or California Code of Regulations section 1735.2, in that Respondent Pharmacist did not complete a self-assessment form for compounding pharmacies prior to compounding drugs in the pharmacy.

SIXTH CAUSE FOR DISCIPLINE

(Drugs Lacking Quality/Strength)

29. Respondents are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o), and/or 4113, subdivision (c), and/or 4342, subdivision (a), and/or California Code of Regulations, title 16, section 1714, in that, as described in paragraph 24 above, there were multiple expired drugs throughout the pharmacy in violation of operational standards.

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 Retail Pharmacy License Number PHY 51229, issued to ERA Pharmacy Inc., dba Santa Clara Drug "The Compounding Shop" (Respondent Pharmacy);

2. Revoking or suspending Registered Pharmacist License Number RPH 62617, issued to Vishal B. Purohit (Respondent Pharmacist);

3. Ordering Respondents 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;

4. Taking such other and further action as is deemed necessary and proper.

DATED: 7/24/13

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

SF2013405145
20712674.doc