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

In the Matter of the Accusation and Petition to Revoke Probation Against: **SANTA CLARA DRUG "THE COMPOUNDING SHOP"** **2453 Forest Avenue** **San Jose, CA 95128** **Retail Pharmacy License No. PHY 51229** **VISHAL B. PUROHIT** **2453 Forest Avenue** **San Jose, CA 95128** **Registered Pharmacist License No. RPH 62617** Respondents.	Case No. 5380 **FIRST AMENDED ACCUSATION AND PETITION TO REVOKE PROBATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this First Amended Accusation and Petition to Revoke Probation 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 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 March 1, 2016, unless renewed.

3. On or about July 28, 2009, the Board 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, 2016, unless renewed.

4. In a disciplinary action entitled "In the Matter of the Accusation Against: Santa Clara Drug "The Compounding Shop" and Vishal B. Purohit," Case No. 4842, the Board of Pharmacy issued a Decision and Order effective August 30, 2013, in which Respondent Pharmacy's License and Respondent Pharmacist's License were revoked. However, the revocations were stayed and Respondents' Licenses were placed on probation for five (5) years with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit A and is incorporated by reference.

JURISDICTION

5. This First Amended Accusation and Petition to Revoke Probation 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.

6. 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.].

7. Code section 4300 provides that every license issued by the Board may be suspended or revoked.

8. 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."

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STATUTORY AND REGULATORY PROVISIONS

9. Code section 4076 states:

"(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:

"…

"(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

"(i) Prescriptions dispensed by a veterinarian.

"(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

"(iii) Dispensed medications for which no physical description exists in any commercially available database.

"…"

10. Code section 4077 states:

"(a) Except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

"…"

11. Code section 4115 states:

"(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

"…

"(f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians

performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

"…"

12. Code section 4169 states:

"(a) A person or entity shall not do any of the following:

"…

"(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

"…"

13. Code section 4301 states:

"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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14. Health & Safety Code section 111255 states:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

15. Health & Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

16. Health & Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

17. Health & Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

18. Health & Safety Code section 11164 states, in pertinent part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

" (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

"…"

19. Health & Safety Code section 11165 states, in pertinent part:

"…

"(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven

days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

"…

"(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

"…

"(5) Quantity of the controlled substance dispensed

"…

"(10) Date of dispensing of the prescription.

"…"

20. 21 U.S.C. § 352 states:

"A drug or device shall be deemed to be misbranded—

"…

"(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

"…"

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21. California Code of Regulations., Title 16, section 1707.1 states:

"(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

"(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

"…

"(B) For each prescription dispensed by the pharmacy:

"1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

"…

"3. The date on which a drug was dispensed or refilled;

"…

"5. The information required by section 1717.

"…"

22. California Code of Regulations., Title 16, section 1707.5 states[1]:

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

"(1) Each of the following 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 10 point sans serif typeface, and listed in the following order:

"(A) Name of the patient

///

[1] Regulation amended on April 1, 2015 to read, 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:… "

"(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.

"…"

23. California Code of Regulations., Title 16, section 1717 states:

"…

"(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

"…

"(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

"…"

24. California Code of Regulations., Title 16, section 1735.8 states:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"…

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

"…"

25. California Code of Regulations., Title 16, section 1773 states:

"(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

"(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

"…

"(6) Not supervise any registered interns nor perform any of the duties of a preceptor;

"…"

26. California Code of Regulations., Title 16, section 1774 states:

"(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

"…

"(4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;

"…

"(b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties."

27. 21 C.F.R. § 1304.11 states:

"…

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

"…"

COST RECOVERY

28. 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.

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FACTUAL BACKGROUND

29. On or about June 3, 2014, two Board Inspectors conducted a routine inspection at Respondent Pharmacy. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) found:

a. Three pharmacy technicians performing pharmacy technician duties when only Respondent Pharmacist was on duty;

b. Prescription containers in the "will call" area that were missing identification codes of the dispensed medications, drug manufacturer information, and contained medication from more than one manufacturer;

c. That Respondents did not provide records and documentation of qualitative and quantitative analysis for the pharmacy's compounded drug preparations;

d. That the most recent biennial inventory of Schedule III to V controlled substances was completed on April 25, 2012;

e. That Respondent Pharmacy failed to inform employees of the its probation status[2]; and

g. That Respondent Pharmacist initialed prescriptions filled by an intern pharmacist and supervised activities performed by an intern pharmacist while he was the only pharmacist on duty[3];

30. On or about March 19, 2015, two Board Inspectors conducted a routine inspection at Respondent Pharmacy. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) found:

a. That the Notice of Probation was posted in a manner that made it unreadable; and

b. That between approximately January 1, 2014 and February 28, 2015,

[2] Respondent Pharmacy did not inform Pharmacist Intern SA, who obtained about 158 hours of pharmacy practice experience between February 26, 2014 and March 27, 2014, that the pharmacy was on probation or of the terms of probation. Similarly, Respondent Pharmacy did not inform volunteer Pharmacy Technician AS, who at the time had volunteered at Respondent Pharmacy two days per week since May 2014, about its probation status.

[3] Respondent Pharmacist supervised the activities performed by intern pharmacist CS while he was the only pharmacist on duty.

Respondents compounded and dispensed prescriptions containing domperidone without having an FDA-approved Investigational New Drug application.

31. On or about July 22, 2015, two Board Inspectors conducted an inspection at Respondent Pharmacy. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) found:

a. That Respondents used non-edible color markers to mark compounded capsules that were to be consumed orally by patients;

b. That Respondents filled and dispensed controlled substances without prescriptions written on California Security Prescription forms;

c. That Respondents failed to maintain an accurate patient medication profile for patient GM[4]; and

d. That Respondents provided the Controlled Substance Utilization Review and Evaluation System (CURES) with inaccurate information related to patient GM's prescription numbers, dispensing dates, and quantity of controlled substance dispensed.

FIRST CAUSE FOR DISCIPLINE

(Exceeding Pharmacist to Technician Ratio)

32. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and/or 4115, subdivision (a) and/or (f)(1) in that, as described in paragraph 29, above, Respondents exceeded the pharmacist to technician ratio.

SECOND CAUSE FOR DISCIPLINE

(Dispensing Dangerous Drugs in Incorrectly Labeled Container)

33. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), 4076, subdivision (a)(11)(A), and/or 4077 subdivision (a), in that, as described in paragraph 29, above, Respondents dispensed drugs in incorrectly labeled containers.

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[4] Patient name withheld to maintain privacy.

THIRD CAUSE FOR DISCIPLINE

(Failure to Label Prescription Containers with Name of Manufacturer)

34. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, title 16, section 1707.5, in that, as described in paragraph 29, above, Respondents failed to include the name of the generic drug manufacturer on prescription container labels.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Implement Quality Assurance For Compounded Drug Products)

35. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, title 16, section 1735.8, subdivision (c), in that, as described in paragraph 29, above, Respondents failed to demonstrate quality assurance in the form of qualitative and quantitative analysis of compounded drug preparations.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Conduct Biennial Inventory)

36. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or 21 C.F.R. § 1304.11(c), in that, as described in paragraph 29, above, Respondents failed to conduct a biennial inventory within the required time frame.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with Conditions of Probation)

37. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1774, subdivision (a)(4), as related to Term and Condition 9 of the Probation Order in Case No. 4842 in that, as described in paragraph 29, above, Respondent Pharmacy did not inform a pharmacist intern and/or a pharmacy technician of its probation status.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Conditions of Probation)

38. Respondent Pharmacist is subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1773, subdivision (a)(6), as

related to Term and Condition 21 of the Probation Order in Case No. 4842, in that, as described in paragraph 29, above, Respondent Pharmacist supervised one or more intern pharmacists while Respondent Pharmacist was on probation.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply with Disciplinary Conditions of Probation Permit)

39. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1774, subdivision (b), in that, as described in paragraph 30, above, Respondents did not place the Notice of Probation in a visible space readable by the public.

NINTH CAUSE FOR DISCIPLINE

(Compounding and Dispensing Misbranded Drug Product)

40. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), Health and Safety Code section 111400, Heath and Safety Code section 111440, and/or 21 U.S.C. § 352(f), in that, as described in paragraph 30, above, Respondents dispensed 48 prescriptions of compounded drug capsules containing domperidone without having an approved Investigational New Drug application on file.

TENTH CAUSE FOR DISCIPLINE

(Commission of Prohibited Acts)

41. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and/or 4169, subdivision (a)(3), and Health and Safety Code section 11335, in that, as described in paragraph 30, above, Respondents purchased domperidone powder and dispensed 48 prescriptions of compounded drug capsules containing domperidone without having an approved Investigational New Drug application on file.

ELEVENTH CAUSE FOR DISCIPLINE

(Dispensing Adulterated Drugs)

42. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o) and/or 4169, subdivision (a)(2) in conjunction with Health and Safety Code section 111255, in that, as described in paragraph 31, above, Respondents dispensed adulterated drugs when they

used non-edible color markers to mark compounded capsules that were to be orally consumed by patients.

TWELFTH CAUSE FOR DISCIPLINE

(Dispensed Controlled Substance Prescription Not Made on Security Form)

43. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or Health and Safety Code section 11164, subdivision (a), in that, as described in paragraph 31, above, Respondents filled and dispensed a prescription for a controlled substance that was not written on a California Security Prescription form.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failed to Maintain Accurate Patient Medication Profile)

44. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, title 16, sections 1707.1, subdivisions (a)(B)(1), (a)(B)(3), and (a)(B)(5), and 1717, subdivision (b)(3), in that, as described in paragraph 31, above, Respondents did not keep an accurate medication profile for patient GM.

FOURTEENTH CAUSE FOR DISCIPLINE

(Reported Inaccurate Information to CURES)

45. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or Health and Safety Code section 11165, subdivision (d)(3), (d)(5), and (d)(10), in that, as described in paragraph 31, above, Respondents reported the wrong prescription numbers, dispensing dates, and quantity of controlled substance dispensed for patient GM to CURES.

PETITION TO REVOKE PROBATION

FIRST CAUSE TO REVOKE RESPONDENT PHARMACY'S PROBATION

(Failure to Give Notice to Employees)

46. At all times after the effective date of the Decision and Order imposing probation of Respondent Pharmacy's license, Term and Condition 9 of that Order required that Respondent Pharmacy provide notice of its probationary status to its employees. Respondent Pharmacy violated this condition of probation.

///

47. At all times after the effective date of the Decision and Order imposing probation of Respondent Pharmacy's license, Term and Condition 11 of that Order required that Respondent Pharmacy to prominently post a probation notice in a place conspicuous and readable to the public. Respondent Pharmacy violated this condition of probation.

FIRST CAUSE TO REVOKE RESPONDENT PHARMACIST'S PROBATION

(Engaged in Supervision)

48. At all times after the effective date of the Decision and Order imposing probation on Respondent Pharmacist's license, Term and Condition 21 of that Order prohibited Respondent from supervising interns and from assuming unauthorized supervision responsibilities. Respondent Pharmacist violated this condition of probation.

OTHER MATTERS – EXTENSION OF PROBATION

49. At all times after the effective date of the Decision and Order imposing probation on Respondents' Licenses, Terms and Conditions 12 and 28 of that Order provided:

> **Violation of Probation.**
> If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed.
> If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction, and the period of probation shall be extended until the petition to revoke probation or accusation is heard and decided.

50. Pursuant to the operation of Terms and Conditions 12 and 28 of the probation order applicable to Respondents' Licenses in Case No. 4248, probation is automatically extended by the filing hereof, and/or by Respondents' failure to comply with the terms and conditions of probation, until such time as this First Amended Accusation and Petition to Revoke Probation is heard and decided, or until the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this First Amended Accusation and Petition to Revoke Probation, 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. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4842 and imposing the disciplinary order that was stayed thereby revoking Retail Pharmacy License Number PHY 51229 issued to Respondent Pharmacy;

4. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4842 and imposing the disciplinary order that was stayed thereby revoking Registered Pharmacist License Number RPH 62617 issued to Respondent Pharmacist;

5. 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; and

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

DATED: 1/14/16

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

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Exhibit A

Decision and Order

Board of Pharmacy Case No. 4842

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** **Retail 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

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on August 30, 2013.

It is so ORDERED on August 30, 2013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
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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** **Retail 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 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Rosailda Perez, Deputy Attorney General.

2. Respondent Santa Clara Drug, "The Compounding Shop" (Respondent Pharmacy) and Respondent Vishal B. Purohit (Respondent Pharmacist) are represented in this proceeding by

attorney Herbert L. Weinberg, whose address is: 1800 Century Park East, 8th Floor, Los Angeles, CA 90067-1501.

3. On or about March 8, 2013, the Board issued Retail Pharmacy License No. PHY 51229 to ERA Pharmacy, Inc., dba Santa Clara Drug, "The Compounding Shop." The Retail Pharmacy License was in full force and effect at all times relevant to the charges brought in Accusation No. 4842 and will expire on September 4, 2013, unless renewed.

4. On or about July 28, 2009, the Board of Pharmacy issued Registered Pharmacist License No. RPH 62617 to Vishal B. Purohit. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 4842 and will expire on November 30, 2014, unless renewed.

JURISDICTION

5. Accusation No. 4842 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on July 26, 2013. Respondents timely filed their Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 4842 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 4842. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California

Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

10. Respondent Pharmacy agrees to withdraw its application for a sterile pharmacy compounding license it filed with the Board on or about November 10, 2012, and that is currently pending with the Board.

CULPABILITY

11. Respondents admit the truth of each and every charge and allegation in Accusation No. 4842.

12. Respondent Pharmacy agrees that its Retail Pharmacy License is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

13. Respondent Pharmacist agrees that his Registered Pharmacist License is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

16. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

17. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER AS TO RESPONDENT PHARMACY

IT IS HEREBY ORDERED that Retail Pharmacy License No. PHY 51229, issued to Respondent Pharmacy, is revoked. However, the revocation is stayed and Respondent Pharmacy is placed on probation for five (5) years on the following terms and conditions:

1. **Obey All Laws**

Respondent Pharmacy shall obey all state and federal laws and regulations.

Respondent Pharmacy shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Retail Pharmacy License No. PHY 51229 or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent Pharmacy shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent Pharmacy shall state in each report, under penalty of perjury, whether there has bee compliance with all the terms and conditions of probation. If, pursuant to term and condition 33, below, Respondent Pharmacist has retained a consulting pharmacist approved by the board or its designee, then any written report submitted to the board pursuant to this provision shall also be executed under penalty of perjury, by the approved consulting pharmacist. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Pharmacy shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent Pharmacy shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Pharmacy shall be jointly and severally liable with Respondent Pharmacist for payment of the Board's costs of investigation and prosecution in the amount of $10,739.00. Respondent Pharmacy shall make said payments following a payment plan approved by the board or its designee. There shall be no

deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent Pharmacy shall not relieve respondent of its responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent Pharmacy shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent Pharmacy shall, at all times while on probation, maintain current licensure with the board. If Respondent Pharmacy submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent Pharmacy 's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent Pharmacy 's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Pharmacy discontinue business, Respondent Pharmacy may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Pharmacy will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent Pharmacy shall relinquish the premises wall

and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent Pharmacy shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent Pharmacy shall also, by the effective date of the decision accepting the surrender, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Pharmacy shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent Pharmacy may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent Pharmacy shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent Pharmacy further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent Pharmacy shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent Pharmacy shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally,

Respondent Pharmacy shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent Pharmacy shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or Respondent Pharmacy's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent Pharmacy shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent Pharmacy shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If Respondent Pharmacy has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Pharmacy violates probation in any respect, the board, after giving Respondent Pharmacy notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Pharmacy during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent Pharmacy's license will be fully restored.

14. **Restricted Practice**

Respondent Pharmacy shall not prepare, oversee or participate in the preparation of injectable sterile products while on probation. Respondent Pharmacy shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

DISCIPLINARY ORDER AS TO RESPONDENT PHARMACIST

IT IS HEREBY ORDERED that Registered Pharmacist License No. RPH 62617 issued to Respondent Pharmacist is revoked. However, the revocation is stayed and Respondent Pharmacist is placed on probation for five (5) years on the following terms and conditions.

15. **Obey All Laws**

Respondent Pharmacist shall obey all state and federal laws and regulations.

Respondent Pharmacist shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Registered Pharmacist License No. RPH 62617 or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

16. **Report to the Board**

Respondent Pharmacist shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent Pharmacist shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

17. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Pharmacist shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

18. **Cooperate with Board Staff**

Respondent Pharmacist shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

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19. **Continuing Education**

Respondent Pharmacist shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

20. **Notice to Employers**

During the period of probation, Respondent Pharmacist shall notify all present and prospective employers of the decision in case number 4842 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Pharmacist's undertaking any new employment, Respondent Pharmacist shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4842, and terms and conditions imposed thereby. It shall be Respondent Pharmacist's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If Respondent Pharmacist works for or is employed by or through a pharmacy employment service, Respondent Pharmacist must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4842 in advance of the Respondent Pharmacist commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Pharmacist undertaking any new employment by or through a pharmacy employment service, Respondent Pharmacist shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number 4842 and the terms and conditions imposed thereby. It shall be Respondent Pharmacist's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of

probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

21. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, Respondent Pharmacist shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

22. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Pharmacist shall be jointly and severally liable with Respondent Pharmacy for payment of the Board's costs of investigation and prosecution in the amount of $10,739.00. Respondent shall make said payments following a payment plan approved by the Board or its designee.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent Pharmacist shall not relieve Respondent Pharmacist of their responsibility to reimburse the board its costs of investigation and prosecution.

23. **Probation Monitoring Costs**

Respondent Pharmacist shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

24. **Status of License**

Respondent Pharmacist shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If Respondent Pharmacist's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

25. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Pharmacist cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Pharmacist may tender their license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Pharmacist will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent Pharmacist's license history with the board.

Upon acceptance of the surrender, Respondent Pharmacist shall relinquish their pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent Pharmacist may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent Pharmacist shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

26. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent Pharmacist shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent

Pharmacist shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

27. **Tolling of Probation**

Except during periods of suspension, Respondent Pharmacist shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent Pharmacist must nonetheless comply with all terms and conditions of probation.

Should Respondent Pharmacist, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Pharmacist's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist, as defined by Business and Professions Code section 4000 et seq., for at least forty (40) hours. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist, as defined by Business and Professions Code section 4000 et seq, for at least forty (40) hours.

28. **Violation of Probation**

If Respondent Pharmacist has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as

deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Pharmacist violates probation in any respect, the board, after giving Respondent Pharmacist notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Pharmacist during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

29. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent Pharmacist's license will be fully restored.

30. **Restricted Practice**

Respondent Pharmacist shall not prepare, oversee or participate in the preparation of injectable sterile products while on probation. Respondent Pharmacist shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

31. **Remedial Education**

Within sixty (60) days of the effective date of this decision, Respondent Pharmacist shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding. The program of remedial education shall consist of at least fifteen (15) hours per year, for five (5) years, at Respondent Pharmacist's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such

remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at their own expense, to take an approved examination to test the respondent's knowledge of the course. If Respondent Pharmacist does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

32. **No New Ownership of Licensed Premises**

Respondent Pharmacist shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent Pharmacist currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent Pharmacist may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

33. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, Respondent Pharmacist shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent Pharmacist may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, Respondent Pharmacist shall retain an independent consultant at his own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by the pharmacy with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the

effective date of this decision. Respondent Pharmacist shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation. The board or its designee may consider a modification of this requirement to require review of pharmacy operations on a quarterly basis.

ACCEPTANCE

I am authorized to sign for Respondent Pharmacy. I have carefully read the Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Retail Pharmacy License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 8/13/13

VISHAL B. PUROHIT, Owner of SANTA CLARA DRUG, "THE COMPOUNDING SHOP"
Respondent Pharmacy

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Registered Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 8/13/13

VISHAL B. PUROHIT
Respondent Pharmacist

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I have read and fully discussed with Respondent Vishal B. Purohit the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 8/14/13

HERBERT L. WEINBERG
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 8/14/13

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Rosailda Perez

ROSAILDA PEREZ
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4842

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Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
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Deputy Attorney General
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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 **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 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.

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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

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

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

In the Matter of the Accusation and Petition to Revoke Probation Against: **SANTA CLARA DRUG "THE COMPOUNDING SHOP"** **2453 Forest Avenue** **San Jose, CA 95128** **Retail Pharmacy License No. PHY 51229** **VISHAL B. PUROHIT** **2453 Forest Avenue** **San Jose, CA 95128** **Registered Pharmacist License No. RPH 62617** Respondents.	Case No. 5380 **ACCUSATION AND PETITION TO REVOKE PROBATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation and Petition to Revoke Probation 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 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 March 1, 2016, unless renewed.

3. On or about July 28, 2009, the Board 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, 2016, unless renewed.

4. In a disciplinary action entitled "In the Matter of the Accusation Against: Santa Clara Drug "The Compounding Shop" and Vishal B. Purohit," Case No. 4842, the Board of Pharmacy issued a Decision and Order effective August 30, 2013, in which Respondent Pharmacy's License and Respondent Pharmacist's License were revoked. However, the revocations were stayed and Respondents' Licenses were placed on probation for five (5) years with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit A and is incorporated by reference.

JURISDICTION

5. This Accusation and Petition to Revoke Probation 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.

6. 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.].

7. Code section 4300 provides that every license issued by the Board may be suspended or revoked.

8. 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."

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STATUTORY AND REGULATORY PROVISIONS

9. Code section 4076 states:

"(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:

"...

"(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

"(i) Prescriptions dispensed by a veterinarian.

"(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

"(iii) Dispensed medications for which no physical description exists in any commercially available database.

"..."

10. Code section 4077 states:

"(a) Except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

"..."

11. Code section 4115 states:

"(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

"...

"(f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians

performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

"..."

12. Code section 4301 states:

"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.

"..."

13. Code section 4169 states:

"(a) A person or entity shall not do any of the following:

"...

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

"..."

14. Health & Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

15. Health & Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

16. Health & Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

17. 21 U.S.C. § 352 states:

"A drug or device shall be deemed to be misbranded—

"...

"(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

"..."

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18. California Code of Regulations., Title 16, section 1707.5 states[1]:

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

"(1) Each of the following 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 10 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.

"..."

19. California Code of Regulations., Title 16, section 1735.8 states:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"...

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

"..."

20. California Code of Regulations., Title 16, section 1773 states:

"(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

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[1] Regulation amended on April 1, 2015 to read, 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:... "

"(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

"...

"(6) Not supervise any registered interns nor perform any of the duties of a preceptor;

"..."

21. California Code of Regulations., Title 16, section 1774 states:

"(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

"...

"(4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;

"...

"(b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties."

22. 21 C.F.R. § 1304.11 states:

"...

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

"..."

COST RECOVERY

23. 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.

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FACTUAL BACKGROUND

24. On or about June 3, 2014, two Board Inspectors conducted a routine inspection at Respondent Pharmacy. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) found:

a. Three pharmacy technicians performing pharmacy technician duties while only Respondent Pharmacist was on duty;

b. Mislabeled prescription containers in the "will call" area that were missing identification codes of the dispensed medications, drug manufacturer information, and had medication from more than one manufacturer;

c. An absence of records and documentation related to quality assurance by way of qualitative and quantitative analysis of its compounded drug products;

d. The most recent biennial inventory of Schedule III to V controlled substances was completed on April 25, 2012;

e. That Respondent Pharmacy failed to inform employees of the its probation status[2]; and

g. That Respondent Pharmacist initialed prescriptions filled by an intern pharmacist and supervised activities performed by an intern pharmacist while he was the only pharmacist on duty[3];

25. On or about March 19, 2015, two Board Inspectors conducted a routine inspection at Respondent Pharmacy. They were met and assisted by Respondent Pharmacist. During the course of that inspection, the Inspector(s) found:

a. The Notice of Probation was posted in such a manner such that it was unreadable; and

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[2]Respondent Pharmacy did not inform Pharmacist Intern SA, who obtained about 158 hours of pharmacy practice experience between February 26, 2014 and March 27, 2014, that the pharmacy was on probation or of the terms of probation. Similarly, Respondent Pharmacy did not inform volunteer Pharmacy Technician AS, who at the time had volunteered at Respondent Pharmacy two days per week since May 2014, about its probation status.

[3] Respondent Pharmacist supervised the activities performed by intern pharmacist CS while he was the only pharmacist on duty.

b. That between approximately January 1, 2014 and February 28, 2015, Respondents compounded and dispensed preparations containing domperidone without having an FDA-approved Investigational New Drug application.

FIRST CAUSE FOR DISCIPLINE

(Exceeding Pharmacist to Technician Ratio)

26. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and/or 4115, subdivision (a) and/or (f)(1) in that, as described in paragraph 24, above, Respondents exceeded the pharmacist to technician ratio.

SECOND CAUSE FOR DISCIPLINE

(Dispensing Dangerous Drugs in Incorrectly Labeled Container)

27. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), 4076, subdivision (a)(11)(A), and/or 4077 subdivision (a), in that, as described in paragraph 24 above, Respondents dispensed drugs in incorrectly labeled containers.

THIRD CAUSE FOR DISCIPLINE

(Failure to Label Prescription Containers with Name of Manufacturer)

28. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, title 16, section 1707.5, in that, as described in paragraph 24 above, Respondents failed to include the name of the generic drug manufacturer on prescription container labels.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Implement Quality Assurance For Compounded Drug Products)

29. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, title 16, section 1735.8, subdivision (c), in that, as described in paragraph 24 above, Respondents failed to demonstrate quality assurance in the form of qualitative and quantitative analysis of compounded drug products.

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FIFTH CAUSE FOR DISCIPLINE

(Failure to Conduct Biennial Inventory)

30. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or 21 C.F.R. § 1304.11(c), in that, as described in paragraph 24 above, Respondents failed to conduct a biennial inventory within the required time frame.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with Conditions of Probation)

31. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1774, subdivision (a)(4), as related to Term and Condition 9 of the Probation Order in Case No. 4842 in that, as described in paragraph 24 above, Respondent Pharmacy did not inform a pharmacist intern and/or a pharmacy technician of its probation status.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Conditions of Probation)

32. Respondent Pharmacist is subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1773, subdivision (a)(6), as related to Term and Condition 21 of the Probation Order in Case No. 4842, in that, as described in paragraph 24 above, Respondent Pharmacist supervised one or more intern pharmacists while on probation.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply with Disciplinary Conditions of Probation Permit)

33. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and/or California Code of Regulations, tile 16, section 1774, subdivision (b), in that, as described in paragraph 25 above, in that Respondents did not place the Notice of Probation in a visible space readable by the public.

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NINTH CAUSE FOR DISCIPLINE

(Compounding and Dispensing Misbranded Drug Product)

34. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), Health and Safety Code section 111400, Heath and Safety Code section 111440, and/or 21 U.S.C. § 352(f), in that, as described in paragraph 25 above, Respondents dispensed 48 prescriptions of compounded drug capsules containing domperidone.

TENTH CAUSE FOR DISCIPLINE

(Commission of Prohibited Acts)

35. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and/or 4169, subdivision (a)(3), and Health and Safety Code section 11335, in that, as described in paragraph 25 above, Respondents purchased domperidone powder and dispensed 48 prescriptions of compounded drug capsules containing domperidone.

PETITION TO REVOKE PROBATION

FIRST CAUSE TO REVOKE RESPONDENT PHARMACY'S PROBATION

(Failure to Give Notice to Employees)

36. At all times after the effective date of Respondent Pharmacy's probation, of the Decision and Order imposing probation of Respondent Pharmacy's license, Term and Condition 9 of that Order required that Respondent Pharmacy provide notice of its probationary status to its employees. Respondent Pharmacy violated this condition of probation.

FIRST CAUSE TO REVOKE RESPONDENT PHARMACIST'S PROBATION

(Engaged in Supervision)

37. At all times after the effective date of the Decision and Order imposing probation on Respondent Pharmacist's license, Term and Condition 21 of that Order prohibited Respondent from supervising interns and from assuming unauthorized supervision responsibilities. Respondent Pharmacist violated this condition of probation.

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OTHER MATTERS – EXTENSION OF PROBATION

38. At all times after the effective date of the Decision and Order imposing probation on Respondents' Licenses, Terms and Conditions 12 and 28 of that Order provided:

> **Violation of Probation.**
> If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed.
> If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction, and the period of probation shall be extended until the petition to revoke probation or accusation is heard and decided.

39. Pursuant to the operation of Terms and Conditions 12 and 28 of the probation order applicable to Respondents' Licenses in Case No. 4248, probation is automatically extended by the filing hereof, and/or by Respondents' failure to comply with the terms and conditions of probation, until such time as this Accusation and Petition to Revoke Probation is heard and decided, or until the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation and Petition to Revoke Probation, 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. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4842 and imposing the disciplinary order that was stayed thereby revoking Retail Pharmacy License Number PHY 51229 issued to Respondent Pharmacy;

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4. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4842 and imposing the disciplinary order that was stayed thereby revoking Registered Pharmacist License Number RPH 62617 issued to Respondent Pharmacist;

5. 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; and

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

DATED: 8/10/15

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

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Exhibit A

Decision and Order

Board of Pharmacy Case No. 4842