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

In the Matter of the Accusation Against:	Case No. 4566
SUPER CARE, INC. DBA SUPERCARE **Gabriel Cassar, President;** **Micheline Cassar, Chief Executive Officer;** **John L. Cassar, Vice President;** **Michael Cassar, Shareholder** **16017 Valley Blvd.** **City of Industry, CA 91745** **Permit No. PHY 45943** **GABRIEL JOHN CASSAR, AKA** **GABRIEL CASSAR** **16017 Valley Blvd.** **City of Industry, CA 91745** **Pharmacist License No. RPH 25650** **KATHERINE THU LE, AKA** **KATHERINE LE** **Pharmacist-in-Charge** **8151 Whitmore Street, #A** **Rosemead, CA 91770** **Pharmacist License No. RPH 57903** **TUAN KIEU NGUYEN** **19563 Cronin Drive** **Rowland Heights, CA 91748** **Pharmacy Technician Registration** **No. TCH 89616** Respondents.	**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.

Super Care, Inc., dba Supercare ("Respondent Pharmacy")

2. On or about July 23, 2002, the Board issued Permit Number PHY 45943 to Super Care, Inc. dba Supercare; Gabriel Cassar, President; Micheline Cassar, Chief Executive Officer; John L. Cassar, Vice President; Michael Cassar, Shareholder; Katherine Le, Pharmacist-in-Charge (collectively "Respondent Pharmacy"). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2014, unless renewed.

Gabriel John Cassar ("Respondent Cassar")

3. On or about June 10, 1968, the Board issued Registered Pharmacist License Number 25650 to Gabriel John Cassar, a.k.a. Gabriel Cassar ("Respondent Cassar"). The License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2015, unless renewed.

Katherine Thu Le ("Respondent Le")

4. On or about November 23, 2005, the Board issued Registered Pharmacist License Number RPH 57903 to Katherine Thu Le, a.k.a. Katherine Le ("Respondent Le"). The License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2015, unless renewed.

Tuan Kieu Nguyen ("Respondent Nguyen")

5. On or about March 10, 2009, the Board issued Pharmacy Technician Registration Number TCH 89616 to Tuan Kieu Nguyen ("Respondent Nguyen"). The Registration 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

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

STATUTORY PROVISIONS

7. Section 4300 of the Code states:

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

8. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

9. Section 4076 of the Code 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:

...

"(9) The expiration date of the effectiveness of the drug dispensed."

10. Section 4084 of the Code provides:

"(a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed."

11. Section 4104 of the Code provides, in pertinent part:

...

"(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy."

12. Section 4116 of the Code provides:

"(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises

described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present."

13. Section 4169 of the Code provides:

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

"(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

. . .

"(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.

"(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label."

14. Section 4301 of the Code 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:

...

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

"(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.

...

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board."

15. Section 4342 of the Code provides:

"(a) The board may institute any action or actions as may be provided by 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 the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

16. California Code of Regulations, title 16 ("CCR"), section 1714 provides:

...

"(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

"(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the

pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container."

17. CCR section 1714.1 provides:

"This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

. . .

"(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours."

18. CCR section 1735.1 provides:

. . .

"(c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label."

19. CCR section 1735.2 provides:

. . .

"(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

. . .

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board Form 17M-39 (Rev. 01/11). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self- assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

20. CCR section 1735.3 provides:

"(a) For each compounded drug product, the pharmacy records shall include:

...

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

...

"(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

"(7) The equipment used in compounding the drug product.

...

"(9) The expiration date of the final compounded drug product.

...

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration."

21. CCR section 1735.4 provides:

. . .

"(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date."

22. CCR section 1735.5 provides:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented."

23. CCR section 1735.6 provides:

"(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of

each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

24. CCR section 1735.7 provides:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel."

25. CCR section 1735.8 provides:

"(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."

26. CCR section 1751.4 provides:

"(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination."

27. CCR section 1751.6 provides:

...

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."

28. CCR section 1793.7 provides:

"(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records."

HEALTH AND SAFETY CODE

29. Health and 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)."

COST RECOVERY PROVISION

30. Section 125.3 of the Code 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.

DRUG CLASSIFICATIONS

31. Xopenex, brand name for Levalbuterol, is a dangerous drug under Code section 4022. It is used as an inhalation therapy for asthma.

32. Symbicort, brand name for Formoterol/Budesonide, is a dangerous drug pursuant to Code section 4022. It is used as an inhalation therapy for asthma.

33. Atrovent Nebules, brand name for Levalbuerol/Ipratropium, is a dangerous drug pursuant to Code section 4022. It is used as an inhalation therapy for asthma.

34. Perforomist, brand name for Formoterol, is a dangerous drug pursuant to Code section 4022. It is a long acting inhalation therapy for asthma.

FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Compounding Training Documentation)

35. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR sections 1735.7, subdivisions (a) and (b), and 1751.6, subdivision (b), in that Respondent Pharmacy failed to maintain written documentation and on-going competency evaluation to demonstrate its staff had the skills and training required to properly and accurately

perform their assigned responsibilities relating to compounding. The circumstances are as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy located in the City of Industry, its Pharmacist-in-Charge Respondent Le failed to maintain training records and documented competency testing for Respondent Pharmacy's licensed employees compounding sterile injectable since October 13, 2009, and failed to maintain training records for the staff compounding inhaled respiratory drugs from powder to solutions.

SECOND CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Misbranded Drugs)

36. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), in conjunction with 4169, subdivision (a)(3), as defined under Health and Safety Code section 111335, in that during the Board's inspection on December 19, 2011, its Pharmacist-in-Charge Respondent Le allowed the selling of misbranded drugs with the expiration dates greater than the ingredients' expiration as shown on the following compounded drug products:

a. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL001 was prepared on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 09/16/11, resulting in one (1) patient receiving an expired drug.

b. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL002 was prepared on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 09/16/11, resulting in six (6) patients receiving an expired drug.

c. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL003 was prepared on 08/10/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's

expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 11/09/11, resulting in eighteen (18) patients receiving an expired drug.

d. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml inhalation solution in Lot #LP013 was prepared on 08/11/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, both the levalbuterol powder and the Ipratropium expiration dates were altered to reflect later dates such that the compound was issued an expiration date of 11/10/11, resulting in ten (10) patients receiving an expired drug.

e. Compounded Formoterol 12mcg/Budesonide 500mcg/2.5ml inhalation solution in Lot #FBB009 was prepared on 11/18/11 with the ingredient polysorbate 80 by Letco listed under Lot #10200811 with an original expiration date of 12/11, but the ingredient's expiration date was altered to reflect a later date, such that the compound was issued an expiration date of 01/17/12, resulting in thirty (30) patients receiving an expired drug.

THIRD CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Complete Self-Assessment)

37. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.2, subdivision (j), in that its Pharmacist-in-Charge Respondent Le failed to complete a self-assessment. The circumstances are as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to compounding orally-inhaled products, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

b. On or about December 10, 2012, during a second Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to compounding, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

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FOURTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Records for Compounded Products)

38. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.3, subdivision (c), in that it failed to maintain proper records for chemical products as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy, Respondent Le failed to maintain the Certificates of Analysis as required for chemicals, bulk drugs substances, drug products, and components used in compounding.

FIFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Compounding Policies and Procedures)

39. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.5, subdivisions (a) and (b), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies and procedures manual related to compounding that establishes procurement procedures, methodologies for formulation and compounding drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

SIXTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Licensed Employee Policies and Procedures)

40. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4104, subdivision (b), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies and procedures manual addressing chemical, mental, or physical impairment, theft, diversion, or self-use of dangerous drugs for the licensed employees.

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SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Facilities and Equipment Records)

41. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.6, subdivisions (a), (b) and (c), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain written documentation for monitoring the safe use of compounding facilities and equipment, failed to maintain written documentation for the calibration or adjustment of the equipment including the scales, incubator, the TPN compounded, and failed to maintain documentation related to the cleaning of the pharmacy's facilities and equipment.

EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Compounding Quality Assurance Plan)

42. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.8, subdivisions (a) and (c), in that during Board inspections at Respondent Pharmacy on December 19, 2011 and December 10, 2012, Respondent Le failed to maintain a written quality assurance plan, and failed to conduct qualitative or quantitative analysis of the pharmacy's compounded drug products to ensure the integrity, potency, quality, and labeled strength.

NINTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)

43. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivision (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or corruption, which attempted to subvert the Board's investigation. The circumstances are as follows:

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a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

TENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Unprofessional Conduct: False Document/Misrepresentation)

44. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivision (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen knowingly made documents which falsely represented the existence or non-existence of facts in an attempt to subvert the Board's investigation. The circumstances are as follows:

a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

ELEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Security of Dangerous Drugs)

45. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4116, subdivision (a), in conjunction with CCR section 1714, subdivision (d), in that Respondent Pharmacy failed to ensure that the area where dangerous drugs was stored, possessed, prepared, manufactured, derived, compounded, disposed or repackaged was restricted to a pharmacist, and that a pharmacist remained present when other individuals were present. The circumstances are as follows:

a. On or about December 10, 2012, during a second Board inspection, Respondent Pharmacy granted the following employees access to the pharmacy where dangerous drugs were stored by using name badge keyless entry during after hours:

(i) Name: "Cleaning Personnel" had access to the pharmacy after closing from "6pm to 2am on Tues/Thurs/Sat."

(ii) Name: "Information Technology" (IT) had 24 hour access to pharmacy "Always On."

(iii) Name: "Managers" had 24 hour access to pharmacy "Always On."

(iv) Name: "Master" had 24 hour access to pharmacy "Always On."

(v) Name: "Pharmacists" had 24 hour access to pharmacy "Always On."

(vi) Name: "Pharmacy Staff" had access to pharmacy "7am-7pm M-F/Sat/Sun."

b. On or about December 10, 2012, during a second Board inspection, before Respondent Le arrived at the pharmacy at 09:35 a.m., there were 6 pharmacy staff inside the pharmacy without a pharmacist present, and 9 pharmacy staff present by 09:35 a.m. when Respondent Le arrived.

TWELFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Operational Standards and Security)

46. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1714, subdivision (e), in that it allowed multiple personnel to have possession of a key to the pharmacy which was not maintained in a tamper evident container. The circumstances are as follows:

a. On or about December 10, 2012, during a second Board inspection, Respondent Le allowed the owners, family members, and/or managers of Respondent Pharmacy to set the "Access Levels" for the scanned name badge keyless entry into the pharmacy without creating a tamper evident process which would restrict entry into the pharmacy to only the pharmacist or during an emergency.

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THIRTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Operations Policy During Pharmacist Absence)

47. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1714.1, subdivision (f), in that on or about December 10, 2012, during a second Board inspection, it failed to maintain written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist.

FOURTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Proper Records of Compounded Drug Products/Supervision)

48. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.3, subdivisions (a)(3), a(4), a(6), a(7), and a(9), in conjunction with CCR section 1793.7, subdivision (b), in that on or about December 10, 2012, during a second Board inspection, Respondent Pharmacy failed to maintain proper records of the compounded drug products, and maintain proper supervision of the pharmacy technicians. The circumstances are as follows:

a. From about November 14, 2012 to about December 7, 2012, Pharmacist-in-Charge Respondent Le allowed pharmacy technician A.Y. to compound non-sterile to sterile filtered unit dose oral inhalation drugs without documenting on the compounding form the manufacturer and Lot numbers for each ingredient, the equipment used in compounding, the expiration date of each ingredient to confirm the final compounded drug product's expiration date.

b. From about November 14, 2012 to about December 7, 2012, pharmacy technician A.Y. did not sign the compounding forms identifying that he compounded the drug products, and Respondent Le did not sign the compounding forms identifying that she reviewed the final drug product, or that she was directly supervising A.Y. in the maintenance of the compounding records. As a result of the lack of supervision, Respondent Le allowed the following to occur:

(i) Two (2) patients received the batch of compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no

record of who compounded the drug or who verified the end product. The drug was dispensed to both patients before completion of an end product testing for sterility.

(ii) Five (5) patients received the batch of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all five (5) patients before completion of an end product testing for sterility.

(iii) Fifty (50) patients received the batch of compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end product testing for sterility.

(iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL012 which was compounded on 12/05/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all seven (7) patients before completion of an end product testing for sterility.

(v) Twenty-nine (29) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for sterility.

(vi) One hundred and forty (140) patients received the batches of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were

compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all one hundred and forty (140) patients before completion of an end product testing for sterility.

FIFTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Ensure Compounding Limitations and Requirements)

49. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.2, subdivision (f), in conjunction with CCR section 1735.1, subdivision (c), in that on or about December 10, 2012, during a second Board inspection, Respondent Pharmacy failed to ensure the integrity, potency, quality, and labeled strength of the compounded drug products until they were dispensed. The circumstances are as follows:

a. Respondent Le conducted quality testing on the end product of the compounded non-sterile to sterile orally inhaled filtered drugs by using a tryptic soy broth medium to confirm the absence of harmful bacteria contaminants. These batches were not quarantined but instead dispensed to patients before the fourteen (14) day testing period for sterility and prior to confirming the "Quality" was sterile for the following batches:

(i) Two (2) patients received the batch of compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12. The drug was dispensed to both patients before completion of an end product testing for sterility.

(ii) Five (5) patients received the batch of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12. The drug was dispensed to all five (5) patients before completion of an end product testing for sterility.

(iii) Fifty (50) patients received the batch of compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end product testing for sterility.

(iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL012 which was compounded on 12/05/12. The drug was dispensed to all seven (7) patients before completion of an end product testing for sterility.

(v) Twenty-nine (29) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for sterility.

(vi) One hundred and forty (140) patients received the batches of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12. The drug was dispensed to all one hundred and forty (140) patients before completion of an end product testing for sterility.

SIXTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Dispensing/Sale of Expired Drug)

50. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(4) as defined under Code section 4076, subdivision (a)(9), in that on or about December 10, 2012, during a second Board inspection, Respondent Le allowed the selling of a compounded drug labeled with an expired date on the 3000ml batch of Levalbuterol 0.63/Ipratropium 0.5mg/3ml under Lot #LP016 which was compounded on 11/23/12 with an expiration date of 01/23/12. This drug was dispensed as follows:

a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;

b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

SEVENTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Include Expiration Date on Labels)

51. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,

during a second Board inspection, Respondent Le allowed the dispensing of misbranded unit-dose containers of the following drugs which contained no expiration dates on the labels:

a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;

b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

d. Compounded Levalbuterol 1mg/3ml.

EIGHTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Purchase of Dangerous Drugs from Unlicensed Entity)

52. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(1), in that on or about December 10, 2012, during a second Board inspection, Board inspectors discovered that Respondent Le purchased Levalbuterol powder from a non-licensed wholesale distributor – Compounding Direct in Quebec Canada, which was manufactured by AARTI Industries without first confirming that the manufacturer was licensed by the Food and Drugs Administration. The circumstances are as follows:

a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct Levalbuterol Powder USP 3x100gms for $4,500.

b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct Levalbuterol Powder USP 3x100gms for $4,500.

NINETEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Embargoed Misbranded Dangerous Drugs)

53. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a) and 4084, subdivisions (a) and (f), in that on or about December 10, 2012, during a second Board inspection, Board inspectors sealed and embargoed the following compounded unit-dose vials for destruction for lacking expiration dates on the labels:

a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

c. 1083 vials of Levalbuterol 1mg/3ml.

TWENTIETH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Failure to Maintain Facility and Equipment Standards)

54. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1751.4, subdivision (d), in that on or about December 10, 2012, during a second Board inspection, Respondent Le advised the Board inspectors that the walls and ceiling in the cleanroom for sterile injectable compounding had not been cleaned, and there was no cleaning record.

TWENTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)

(Drugs Lacking Quality and Strength)

55. Respondent Pharmacy is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4342, subdivision (a), in that on or about December 10, 2012, during a second Board inspection, Board Inspectors discovered drugs maintained at Respondent Pharmacy that did not conform to the standard and tests as to quality and strength, as follows:

a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to identify the date the drug was compounded or the expiration date;

b. Unlabeled Benzalkonium Chloride 17% bottle was in the refrigerator with no label to identify the date the drug was compounded or the expiration date;

c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The solutions expired on 02/24/11 and 05/18/12;

d. The embargoed misbranded compounded drugs which lacked compounding records to determine the quality and strength included:

(i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

(ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

(iii) 1083 vials of Levalbuterol 1mg/3ml.

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TWENTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Compounding Training Documentation)

56. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with CCR sections 1735.7, subdivisions (a) and (b), and 1751.6, subdivision (b), in that Respondent Le failed to maintain written documentation and on-going competency evaluation to demonstrate her staff had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. The circumstances are as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to compounding orally-inhaled products, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

b. On or about December 10, 2012, during a second Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to compounding, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

TWENTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Misbranded Drugs)

57. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(3), as defined under Health and Safety Code section 111335, in that during the Board's inspection on December 19, 2011, she allowed the selling of misbranded drugs with the expiration dates greater than the ingredients' expiration as shown on the following compounded drug products:

a. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL001 was prepared on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 09/16/11, resulting in one (1) patient receiving an expired drug.

b. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL002 was prepared on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 09/16/11, resulting in six (6) patients receiving an expired drug.

c. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL003 was prepared on 08/10/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's expiration dates were altered to reflect later dates, such that the compound was issued an expiration date of 11/09/11, resulting in eighteen (18) patients receiving an expired drug.

d. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml inhalation solution in Lot #LP013 was prepared on 08/11/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an original expiration date in 08/11, both the levalbuterol powder and the Ipratropium expiration dates were altered to reflect later dates such that the compound was issued an expiration date of 11/10/11, resulting in ten (10) patients receiving an expired drug.

e. Compounded Formoterol 12mcg/Budesonide 500mcg/2.5ml inhalation solution in Lot #FBB009 was prepared on 11/18/11 with the ingredient polysorbate 80 by Letco listed under Lot #10200811 with an original expiration date of 12/11, but the ingredient's expiration date was altered to reflect a later date, such that the compound was issued an expiration date of 01/17/12, resulting in thirty (30) patients receiving an expired drug.

TWENTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Complete Self-Assessment)

58. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o) and CCR section 1735.2, subdivision (j), in that she failed to complete a self-assessment. The circumstances are as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to

compounding orally-inhaled products, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

b. On or about December 10, 2012, during a second Board inspection at Respondent Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment prior to compounding, and failed to complete the second section prior to compounding sterile injectable drugs and TPN admixtures.

TWENTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Records for Compounded Products)

59. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.3, subdivision (c), in that she failed to maintain proper records for chemical products as follows:

a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy, Respondent Le failed to maintain the Certificates of Analysis as required for chemicals, bulk drugs substances, drug products, and components used in compounding.

TWENTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Compounding Policies and Procedures)

60. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.5, subdivisions (a) and (b), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies and procedures manual related to compounding that establishes procurement procedures, methodologies for formulation and compounding drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Licensed Employee Policies and Procedures)

61. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4104, subdivision (b), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies

and procedures manual addressing chemical, mental, or physical impairment, theft, diversion, or self-use of dangerous drugs for the licensed employees.

TWENTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Facilities and Equipment Records)

62. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.6, subdivisions (a), (b) and (c), in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain written documentation for monitoring the safe use of compounding facilities and equipment, failed to maintain written documentation for the calibration or adjustment of the equipment including the scales, incubator, the TPN compounded, and failed to maintain documentation related to the cleaning of the pharmacy's facilities and equipment.

TWENTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Compounding Quality Assurance Plan)

63. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.8, subdivisions (a) and (c), in that during Board inspections at Respondent Pharmacy on December 19, 2011 and December 10, 2012, Respondent Le failed to maintain a written quality assurance plan, and failed to conduct qualitative or quantitative analysis of the pharmacy's compounded drug products to ensure the integrity, potency, quality, and labeled strength.

THIRTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)

64. Respondent Le is subject to disciplinary action under Code sections 4301, subdivision (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or corruption, which attempted to subvert the Board's investigation. The circumstances are as follows:

a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the

expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

THIRTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Unprofessional Conduct: False Document/Misrepresentation)

65. Respondent Le is subject to disciplinary action under Code sections 4301, subdivision (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen knowingly made documents which falsely represented the existence or non-existence of facts in an attempt to subvert the Board's investigation. The circumstances are as follows:

a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

THIRTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Security of Dangerous Drugs)

66. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4116, subdivision (a), in conjunction with CCR section 1714, subdivision (d), in that she failed to ensure that the area where dangerous drugs was stored, possessed, prepared, manufactured, derived, compounded, disposed or repackaged was restricted to a pharmacist, and that a pharmacist remained present when other individuals were present. The circumstances are as follows:

a. On or about December 10, 2012, during a second Board inspection, Respondent Pharmacy granted the following employees access to the pharmacy where dangerous drugs were stored by using name badge keyless entry during after hours:

(i) Name: "Cleaning Personnel" had access to the pharmacy after closing from "6pm to 2am on Tues/Thurs/Sat."

(ii) Name: "Information Technology" (IT) had 24 hour access to pharmacy "Always On."

(iii) Name: "Managers" had 24 hour access to pharmacy "Always On."

(iv) Name: "Master" had 24 hour access to pharmacy "Always On."

(v) Name: "Pharmacists" had 24 hour access to pharmacy "Always On."

(vi) Name: "Pharmacy Staff" had access to pharmacy "7am-7pm M-F/Sat/Sun."

b. On or about December 10, 2012, during a second Board inspection, before Respondent Le arrived at the pharmacy at 09:35 a.m., there were 6 pharmacy staff inside the pharmacy without a pharmacist present, and 9 pharmacy staff present by 09:35 a.m. when Respondent Le arrived.

THIRTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Operational Standards and Security)

67. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1714, subdivision (e), in that she allowed multiple personnel to have possession of a key to the pharmacy which was not maintained in a tamper evident container. The circumstances are as follows:

a. On or about December 10, 2012, during a second Board inspection, Respondent Le allowed the owners, family members, and/or managers of Respondent Pharmacy to set the "Access Levels" for the scanned name badge keyless entry into the pharmacy without creating a tamper evident process which would restrict entry into the pharmacy to only the pharmacist or during an emergency.

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THIRTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Operations Policy During Pharmacist Absence)

68. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1714.1, subdivision (f), in that on or about December 10, 2012, during a second Board inspection, she failed to maintain written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist.

THIRTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Proper Records of Compounded Drug Products/Supervision)

69. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.3, subdivisions (a)(3), (4), (6), (7), and (9), in conjunction with CCR section 1793.7, subdivision (b), in that on or about December 10, 2012, during a second Board inspection, Respondent Le failed to maintain proper records of the compounded drug products, and maintain proper supervision of the pharmacy technicians. The circumstances are as follows:

a. From about November 14, 2012 to about December 7, 2012, Respondent Le allowed pharmacy technician A.Y. to compound non-sterile to sterile filtered unit dose oral inhalation drugs without documenting on the compounding form the manufacturer and Lot numbers for each ingredient, the equipment used in compounding, the expiration date of each ingredient to confirm the final compounded drug product's expiration date.

b. From about November 14, 2012 to about December 7, 2012, pharmacy technician A.Y. did not sign the compounding forms identifying that he compounded the drug products, and Respondent Le did not sign the compounding forms identifying that she reviewed the final drug product, or that she was directly supervising A.Y. in the maintenance of the compounding records. As a result of the lack of supervision, Respondent Le allowed the following to occur:

(i) Two (2) patients received the batch of compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no

record of who compounded the drug or who verified the end product. The drug was dispensed to both patients before completion of an end product testing for sterility.

(ii) Five (5) patients received the batch of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all five (5) patients before completion of an end product testing for sterility.

(iii) Fifty (50) patients received the batch of compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end product testing for sterility.

(iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL012 which was compounded on 12/05/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all seven (7) patients before completion of an end product testing for sterility.

(v) Twenty-nine (29) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for sterility.

(vi) One hundred and forty (140) patients received the batches of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were

compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12 without documentation on the compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any of the ingredients used in the compound. There was no record of who compounded the drug or who verified the end product. The drug was dispensed to all one hundred and forty (140) patients before completion of an end product testing for sterility.

THIRTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Ensure Compounding Limitations and Requirements)

70. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1735.2, subdivision (f), in conjunction with CCR section 1735.1, subdivision (c), in that on or about December 10, 2012, during a second Board inspection, Respondent Le failed to ensure the integrity, potency, quality, and labeled strength of the compounded drug products until they were dispensed. The circumstances are as follows:

a. Respondent Le conducted quality testing on the end product of the compounded non-sterile to sterile orally inhaled filtered drugs by using a tryptic soy broth medium to confirm the absence of harmful bacteria contaminants. These batches were not quarantined but instead dispensed to patients before the fourteen (14) day testing period for sterility and prior to confirming the "Quality" was sterile for the following batches:

(i) Two (2) patients received the batch of compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12. The drug was dispensed to both patients before completion of an end product testing for sterility.

(ii) Five (5) patients received the batch of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12. The drug was dispensed to all five (5) patients before completion of an end product testing for sterility.

(iii) Fifty (50) patients received the batch of compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end product testing for sterility.

(iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL012 which was compounded on 12/05/12. The drug was dispensed to all seven (7) patients before completion of an end product testing for sterility.

(v) Twenty-nine (29) patients received the batch of compounded Levalbuterol 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for sterility.

(vi) One hundred and forty (140) patients received the batches of compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12. The drug was dispensed to all one hundred and forty (140) patients before completion of an end product testing for sterility.

THIRTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Dispensing/Sale of Expired Drug)

71. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(4) as defined under Business and Professions Code section 4076, subdivision (a)(9), in that on or about December 10, 2012, during a second Board inspection, Respondent Le allowed the selling of a compounded drug labeled with an expired date on the 3000ml batch of Levalbuterol 0.63/Ipratropium 0.5mg/3ml under Lot #LP016 which was compounded on 11/23/12 with an expiration date of 01/23/12. This drug was dispensed as follows:

a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;

b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

THIRTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Include Expiration Date on Labels)

72. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,

during a second Board inspection, Respondent Le allowed the dispensing of misbranded unit-dose containers of the following drugs which contained no expiration dates on the labels:

a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;

b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

d. Compounded Levalbuterol 1mg/3ml.

THIRTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Purchase of Dangerous Drugs from Unlicensed Entity)

73. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4169, subdivision (a)(1), in that on or about December 10, 2012, during a second Board inspection, Board inspectors discovered that Respondent Le purchased Levalbuterol powder from a non-licensed wholesale distributor – Compounding Direct in Quebec Canada, which was manufactured by AARTI Industries without first confirming that the manufacturer was licensed by the Food and Drugs Administration. The circumstances are as follows:

a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct Levalbuterol Powder USP 3x100gms for $4,500.

b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct Levalbuterol Powder USP 3x100gms for $4,500.

FORTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Embargoed Misbranded Dangerous Drugs)

74. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), in conjunction with 4169, subdivision (a) and 4084, subdivisions (a) and (f), in that on or about December 10, 2012, during a second Board inspection, Board inspectors sealed and embargoed the following compounded unit-dose vials for destruction for lacking expiration dates on the labels:

a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

c. 1083 vials of Levalbuterol 1mg/3ml.

FORTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Failure to Maintain Facility and Equipment Standards)

75. Respondent Le is subject to disciplinary action under Code section 4301, subdivision (o), and CCR section 1751.4, subdivision (d), in that on or about December 10, 2012, during a second Board inspection, Respondent Le advised the Board inspectors that the walls and ceiling in the cleanroom for sterile injectable compounding had not been cleaned, and there was no cleaning record.

FORTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)

(Drugs Lacking Quality and Strength)

76. Respondent Le is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4342, subdivision (a), in that on or about December 10, 2012, during a second Board inspection, Board Inspectors discovered drugs maintained at Respondent Pharmacy that did not conform to the standard and tests as to quality and strength, as follows:

a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to identify the date the drug was compounded or the expiration date;

b. Unlabeled Benzalkonium Chloride 17% bottle was in the refrigerator with no label to identify the date the drug was compounded or the expiration date;

c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The solutions expired on 02/24/11 and 05/18/12;

d. The embargoed misbranded compounded drugs which lacked compounding records to determine the quality and strength included:

(i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;

(ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

(iii) 1083 vials of Levalbuterol 1mg/3ml.

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FORTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)

(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)

77. Respondent Nguyen is subject to disciplinary action under Code sections 4301, subdivision (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or corruption, which attempted to subvert the Board's investigation. The circumstances are as follows:

a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the expiration dates on the ingredients levalbuterol, Ipratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

FORTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)

(Unprofessional Conduct: False Document/Misrepresentation)

78. Respondent Nguyen is subject to disciplinary action under Code sections 4301, subdivision (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician Respondent Nguyen knowingly made documents which falsely represented the existence or non-existence of facts in an attempt to subvert the Board's investigation. The circumstances are as follows:

a. Respondent Le requested Respondent Nguyen to make copies of the original compounding records upon request by the Board Inspector. Respondent Nguyen altered the expiration dates on the ingredients levalbuterol, Ipratropium, polysorbate and citric acid on the pharmacy's compounding records at Respondent Le's request.

b. Complainant refers to and incorporates the allegations contained in the Second Cause for Discipline, as though set forth fully.

DISCIPLINE CONSIDERATIONS

79. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about February 27, 2004, in a prior action, the Board issued Citation Number CI 2002 25346 in the amount of $1,600 for violation of CCR sections 1751.7, subdivisions (a), (d) and (e); 1751.5; 1751.8, subdivision (f), 1716.2, 1714, subdivision (b); 1715 subdivisions (a) and (b); 1793.7, subdivision (b); and Code section 4116. Respondent Pharmacy has fully complied with the Citation.

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 Permit Number PHY 45943, issued to Super Care, Inc. dba Supercare; Gabriel Cassar (President); Micheline Cassar (Chief Executive Officer); John L. Cassar (Vice President); Michael Cassar (Shareholder);

2. Revoking or suspending Pharmacist License No. RPH 25650, issued to Gabriel John Cassar, a.k.a. Gabriel Cassar;

3. Revoking or suspending Pharmacist License No. RPH 57903, issued to Katherine Thu Le, a.k.a. Katherine Le;

4. Revoking or suspending Pharmacy Technician Registration TCH 89616, issued to Tuan Kieu Nguyen;

5. Ordering Super Care, Inc. dba Supercare, Gabriel John Cassar, a.k.a. Gabriel Cassar, Katherine Thu Le, a.k.a. Katherine Le, and Tuan Kieu Nguyen, 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;

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

DATED: 1/17/14

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

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