

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

In the Matter of the Accusation Against:

**SUPER CARE, INC. DBA SUPERCARE
Gabriel Cassar, President;
Micheline Cassar, Chief Executive Officer;
John L. Cassar, Vice President;
Michael Cassar, Shareholder
Permit No. PHY 45943**

**GABRIEL JOHN CASSAR, AKA
GABRIEL CASSAR
Pharmacist License No. RPH 25650**

**KATHERINE THU LE, AKA
KATHERINE LE
Pharmacist-in-Charge
Pharmacist License No. RPH 57903**

**TUAN KIEU NGUYEN
Pharmacy Technician REgistration
No. TCH 89616**

Respondents.

Case No. 4566

OAH No. 2014030278

**STIPULATED SURRENDER OF
LICENSE AND ORDER**

As to: TUAN KIEU NGUYEN

DECISION AND ORDER

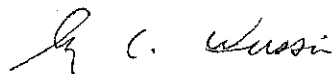
The attached Stipulated Settlement and Disciplinary Order for Surrender and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on December 24, 2014.

It is so ORDERED on December 17, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STAN C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 ARMANDO ZAMBRANO
Supervising Deputy Attorney General
3 LINDA L. SUN
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Attorneys for Complainant
7

8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:
11 **SUPER CARE, INC, DBA SUPERCARE**
12 **Gabriel Cassar, President;**
13 **Micheline Cassar, Chief Executive Officer;**
14 **John L. Cassar, Vice President;**
15 **Michael Cassar, Shareholder**
16 **16017 Valley Blvd.**
17 **City of Industry, CA 91745**
18 **Permit No. PHY 45943**

19 **GABRIEL JOHN CASSAR, AKA**
20 **GABRIEL CASSAR**
21 **16017 Valley Blvd.**
22 **City of Industry, CA 91745**
23 **Pharmacist License No. RPH 25650**

24 **KATHERINE THU LE, AKA**
25 **KATHERINE LE**
26 **Pharmacist-in-Charge**
27 **13089 Peyton Dr., #C383**
28 **Chino Hills, CA 91709**
Pharmacist License No. RPH 57903

TUAN KIEU NGUYEN
19563 Cronin Drive
Rowland Heights, CA 91748
Pharmacy Technician Registration
No. TCH 89616

Respondents.

Case No. 4566
OAH No. 2014030278
STIPULATED SURRENDER OF
LICENSE AND ORDER
As to: **TUAN KIEU NGUYEN**

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

3 **PARTIES**

4 1. Virginia Herold (Complainant) is the Executive Officer of the Board. She brought
5 this action solely in her official capacity and is represented in this matter by Kamala D. Harris,
6 Attorney General of the State of California, by Linda L. Sun, Deputy Attorney General.

7 2. Tuan Kieu Nguyen (Respondent) is representing himself in this proceeding and has
8 chosen not to exercise his right to be represented by counsel.

9 3. On or about March 10, 2009, the Board issued Pharmacy Technician License No.
10 TCH 89616 to Respondent. The Pharmacy Technician License was in full force and effect at all
11 times relevant to the charges brought in Accusation No. 4566 and will expire on November 30,
12 2014, unless renewed.

13 **JURISDICTION**

14 4. Accusation No. 4566 was filed before the Board and is currently pending against
15 Respondent. The Accusation and all other statutorily required documents were properly served
16 on Respondent on January 29, 2014. Respondent timely filed his Notice of Defense contesting
17 the Accusation. A copy of Accusation No. 4566 is attached as Exhibit A and incorporated by
18 reference.

19 **ADVISEMENT AND WAIVERS**

20 5. Respondent has carefully read, and understands the charges and allegations in
21 Accusation No. 4566. Respondent also has carefully read, and understands the effects of this
22 Stipulated Surrender of License and Order.

23 6. Respondent is fully aware of his legal rights in this matter, including the right to a
24 hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at
25 his own expense; the right to confront and cross-examine the witnesses against him; the right to
26 present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel
27 the attendance of witnesses and the production of documents; the right to reconsideration and
28

1 court review of an adverse decision; and all other rights accorded by the California
2 Administrative Procedure Act and other applicable laws.

3 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
4 every right set forth above.

5 **CULPABILITY**

6 8. Respondent admits the truth of each and every charge and allegation in Accusation
7 No. 4566 pertaining to him, agrees that cause exists for discipline and hereby surrenders his
8 Pharmacy Technician License No. TCH 89616 for the Board's formal acceptance.

9 9. Respondent understands that by signing this stipulation he enables the Board to issue
10 an order accepting the surrender of his Pharmacy Technician License without further process.

11 **CONTINGENCY**

12 10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
13 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
14 communicate directly with the Board regarding this stipulation and surrender, without notice to or
15 participation by Respondent. By signing the stipulation, Respondent understands and agrees that
16 he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board
17 considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order,
18 the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this
19 paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not
20 be disqualified from further action by having considered this matter.

21 11. The parties understand and agree that Portable Document Format (PDF) and facsimile
22 copies of this Stipulated Surrender of License and Order, including Portable Document Format
23 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

24 12. This Stipulated Surrender of License and Order is intended by the parties to be an
25 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
26 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
27 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order
28

1 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
2 executed by an authorized representative of each of the parties.

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

5 **ORDER**

6 IT IS HEREBY ORDERED that Pharmacy Technician License No. TCH 89616, issued to
7 Respondent Tuan Kieu Nguyen, is surrendered and accepted by the Board of Pharmacy.

8 1. The surrender of Respondent's Pharmacy Technician License and the acceptance of
9 the surrendered license by the Board shall constitute the imposition of discipline against
10 Respondent. This stipulation constitutes a record of the discipline and shall become a part of
11 Respondent's license history with the Board of Pharmacy.

12 2. Respondent shall lose all rights and privileges as a pharmacy technician in California
13 as of the effective date of the Board's Decision and Order.

14 3. Respondent shall cause to be delivered to the Board his pocket license and, if one was
15 issued, his wall certificate on or before the effective date of the Decision and Order.

16 4. If Respondent ever files an application for licensure or a petition for reinstatement in
17 the State of California, the Board shall treat it as an application for a new license. Respondent
18 may not apply for any license, permit, or registration from the Board for three (3) years from the
19 effective date of this decision. Respondent stipulates that should he apply for any license from the
20 Board on or after the effective date of this Decision, all allegations set forth in Accusation No.
21 4566 be deemed to be true, correct and admitted by Respondent when the Board determines
22 whether to grant or deny the application. Respondent shall satisfy all requirements applicable to
23 that license as of the date the application is submitted to the Board, including, but not limited to
24 certification by a nationally recognized body prior to the issuance of a new license. Respondent is
25 required to report this surrender as disciplinary action.

26 5. Respondent shall pay the agency its costs of investigation and enforcement in the
27 amount of \$2,000.00 prior to issuance of a new or reinstated license.

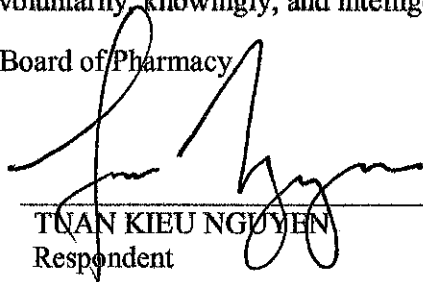
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ACCEPTANCE

I have carefully read the Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have on my Pharmacy Technician License. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy

DATED: 9/29/14


TUAN KIEU NGUYEN
Respondent

ENDORSEMENT

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

Dated:

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

11-67-14


LINDA L. SUN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4566

1 KAMALA D. HARRIS
Attorney General of California
2 ARMANDO ZAMBRANO
Supervising Deputy Attorney General
3 LINDA L. SUN
Deputy Attorney General
4 State Bar No. 207108
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
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6 Facsimile: (213) 897-2804
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10 In the Matter of the Accusation Against:

Case No. 4566

11 **SUPER CARE, INC. DBA SUPERCARE**
12 **Gabriel Cassar, President;**
13 **Micheline Cassar, Chief Executive Officer;**
14 **John L. Cassar, Vice President;**
15 **Michael Cassar, Shareholder**
16017 Valley Blvd.
City of Industry, CA 91745
Permit No. PHY 45943

A C C U S A T I O N

16 **GABRIEL JOHN CASSAR, AKA**
17 **GABRIEL CASSAR**
16017 Valley Blvd.
City of Industry, CA 91745
18 **Pharmacist License No. RPH 25650**

19 **KATHERINE THU LE, AKA**
20 **KATHERINE LE**
Pharmacist-in-Charge
8151 Whitmore Street, #A
21 **Rosemead, CA 91770**
22 **Pharmacist License No. RPH 57903**

23 **TUAN KIEU NGUYEN**
19563 Cronin Drive
Rowland Heights, CA 91748
24 **Pharmacy Technician Registration**
25 **No. TCH 89616**

26 Respondents.
27
28

1 Complainant alleges:

2 **PARTIES**

3 1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity
4 as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

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

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

11 Gabriel John Cassar ("Respondent Cassar")

12 3. On or about June 10, 1968, the Board issued Registered Pharmacist License Number
13 25650 to Gabriel John Cassar, a.k.a. Gabriel Cassar ("Respondent Cassar"). The License was in
14 full force and effect at all times relevant to the charges brought herein and will expire on August
15 31, 2015, unless renewed.

16 Katherine Thu Le ("Respondent Le")

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

21 Tuan Kieu Nguyen ("Respondent Nguyen")

22 5. On or about March 10, 2009, the Board issued Pharmacy Technician Registration
23 Number TCH 89616 to Tuan Kieu Nguyen ("Respondent Nguyen"). The Registration was in full
24 force and effect at all times relevant to the charges brought herein and will expire on November
25 30, 2014, unless renewed.

26 **JURISDICTION**

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

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

8 13. Section 4169 of the Code provides:

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

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

12 ...

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

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

18 14. Section 4301 of the Code states:

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

21 Unprofessional conduct shall include, but is not limited to, any of the following:

22 ...

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

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

28 ...

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

6 17. CCR section 1714.1 provides:

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

11 ...

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

18 18. CCR section 1735.1 provides:

19 ...

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

23 19. CCR section 1735.2 provides:

24 ...

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

28 ...

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

12 20. CCR section 1735.3 provides:

13 “(a) For each compounded drug product, the pharmacy records shall
14 include:

15 ...

16 “(3) The identity of the pharmacy personnel who compounded the drug
17 product.

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

19 ...

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

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

26 ...

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

28 ...

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

6 21. CCR section 1735.4 provides:

7 ...

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

12 22. CCR section 1735.5 provides:

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

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

20 23. CCR section 1735.6 provides:

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

25 “(b) Any equipment used to compound drug products shall be stored, used, and
26 maintained in accordance with manufacturers’ specifications.

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

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

3 24. CCR section 1735.7 provides:

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

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

10 25. CCR section 1735.8 provides:

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

14 ...

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

19 26. CCR section 1751.4 provides:

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

23 27. CCR section 1751.6 provides:

24 ...

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

1 28. CCR section 1793.7 provides:

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

5 **HEALTH AND SAFETY CODE**

6 29. Health and Safety Code section 111335 states:

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

9 **COST RECOVERY PROVISION**

10 30. Section 125.3 of the Code states, in pertinent part, that the Board may request the
11 administrative law judge to direct a licentiate found to have committed a violation or violations of
12 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
13 enforcement of the case.

14 **DRUG CLASSIFICATIONS**

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

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

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

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

23 **FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

24 **(Failure to Maintain Compounding Training Documentation)**

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

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

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

8 **SECOND CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

9 **(Misbranded Drugs)**

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

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

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

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

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

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

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

13 **THIRD CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

14 **(Failure to Complete Self-Assessment)**

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

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

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

26 ///

27 ///

28 ///

1 **FOURTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Records for Compounded Products)**

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

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

9 **FIFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

10 **(Failure to Maintain Compounding Policies and Procedures)**

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

18 **SIXTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

19 **(Failure to Maintain Licensed Employee Policies and Procedures)**

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

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1 **SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Facilities and Equipment Records)**

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

10 **EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

11 **(Failure to Maintain Compounding Quality Assurance Plan)**

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

18 **NINTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

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

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

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

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

7 **TENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

8 **(Unprofessional Conduct: False Document/Misrepresentation)**

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

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

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

21 **ELEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

22 **(Failure to Maintain Security of Dangerous Drugs)**

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

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

4 (i) Name: "Cleaning Personnel" had access to the pharmacy after closing from
5 "6pm to 2am on Tues/Thurs/Sat."

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

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

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

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

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

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

16 **TWELFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

17 **(Failure to Maintain Operational Standards and Security)**

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

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

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1 **THIRTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Operations Policy During Pharmacist Absence)**

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

7 **FOURTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

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

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

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

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

25 (i) Two (2) patients received the batch of compounded Levalbuterol
26 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12
27 without documentation on the compounding records of any of the drug manufacturers, lot
28 numbers, or expiration dates for any of the ingredients used in the compound. There was no

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

3 (ii) Five (5) patients received the batch of compounded Formoterol
4 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12
5 without documentation on the compounding records of any of the drug manufacturers, lot
6 numbers, or expiration dates for any of the ingredients used in the compound. There was no
7 record of who compounded the drug or who verified the end product. The drug was dispensed to
8 all five (5) patients before completion of an end product testing for sterility.

9 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
10 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without
11 documentation on the compounding records of any of the drug manufacturers, lot numbers, or
12 expiration dates for any of the ingredients used in the compound. There was no record of who
13 compounded the drug or who verified the end product. The drug was dispensed to thirty-three
14 (33) of the fifty (50) patients before completion of an end product testing for sterility.

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

21 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
22 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the
23 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
24 of the ingredients used in the compound. There was no record of who compounded the drug or
25 who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29)
26 patients before completion of an end product testing for sterility.

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

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

6 **FIFTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

7 **(Failure to Ensure Compounding Limitations and Requirements)**

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

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

18 (i) Two (2) patients received the batch of compounded Levalbuterol
19 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12.
20 The drug was dispensed to both patients before completion of an end product testing for sterility.

21 (ii) Five (5) patients received the batch of compounded Formoterol
22 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12.
23 The drug was dispensed to all five (5) patients before completion of an end product testing for
24 sterility.

25 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
26 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The
27 drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end
28 product testing for sterility.

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

4 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
5 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to
6 nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for
7 sterility.

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

12 **SIXTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

13 **(Dispensing/Sale of Expired Drug)**

14 50. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
15 subdivisions (j) and (o), and 4169, subdivision (a)(4) as defined under Code section 4076,
16 subdivision (a)(9), in that on or about December 10, 2012, during a second Board inspection,
17 Respondent Le allowed the selling of a compounded drug labeled with an expired date on the
18 3000ml batch of Levalbuterol 0.63/Ipratropium 0.5mg/3ml under Lot #LP016 which was
19 compounded on 11/23/12 with an expiration date of 01/23/12. This drug was dispensed as
20 follows:

- 21 a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;
22 b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

23 **SEVENTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

24 **(Failure to Include Expiration Date on Labels)**

25 51. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
26 subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code
27 section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,
28

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

- 3 a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;
- 4 b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 5 c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 6 d. Compounded Levalbuterol 1mg/3ml.

7 **EIGHTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

8 **(Purchase of Dangerous Drugs from Unlicensed Entity)**

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

- 16 a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct
17 Levalbuterol Powder USP 3x100gms for \$4,500.
- 18 b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct
19 Levalbuterol Powder USP 3x100gms for \$4,500.

20 **NINETEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

21 **(Embargoed Misbranded Dangerous Drugs)**

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

- 27 a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 28 b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

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

2 **TWENTIETH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

3 **(Failure to Maintain Facility and Equipment Standards)**

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

9 **TWENTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

10 **(Drugs Lacking Quality and Strength)**

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

- 15 a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to
16 identify the date the drug was compounded or the expiration date;
- 17 b. Unlabeled Benzalkonium Chloride 17% bottle was in the refrigerator with no label to
18 identify the date the drug was compounded or the expiration date;
- 19 c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The
20 solutions expired on 02/24/11 and 05/18/12;
- 21 d. The embargoed misbranded compounded drugs which lacked compounding records
22 to determine the quality and strength included:
- 23 (i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 24 (ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 25 (iii) 1083 vials of Levalbuterol 1mg/3ml.

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1 **TWENTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

2 **(Failure to Maintain Compounding Training Documentation)**

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

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

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

17 **TWENTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)**

18 **(Misbranded Drugs)**

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

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

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

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

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

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

21 **TWENTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

22 **(Failure to Complete Self-Assessment)**

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

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

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

7 **TWENTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

8 **(Failure to Maintain Records for Compounded Products)**

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

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

15 **TWENTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

16 **(Failure to Maintain Compounding Policies and Procedures)**

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

23 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

24 **(Failure to Maintain Licensed Employee Policies and Procedures)**

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

3 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

4 **(Failure to Maintain Facilities and Equipment Records)**

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

12 **TWENTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

13 **(Failure to Maintain Compounding Quality Assurance Plan)**

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

20 **THIRTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

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

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

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

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

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

5 **THIRTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)**

6 **(Unprofessional Conduct: False Document/Misrepresentation)**

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

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

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

19 **THIRTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

20 **(Failure to Maintain Security of Dangerous Drugs)**

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

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

4 (i) Name: "Cleaning Personnel" had access to the pharmacy after closing from
5 "6pm to 2am on Tues/Thurs/Sat."

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

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

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

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

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

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

16 **THIRTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)**

17 **(Failure to Maintain Operational Standards and Security)**

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

21 The circumstances are as follows:

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

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1 **THIRTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

2 **(Failure to Maintain Operations Policy During Pharmacist Absence)**

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

7 **THIRTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

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

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

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

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

24 (i) Two (2) patients received the batch of compounded Levalbuterol
25 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12
26 without documentation on the compounding records of any of the drug manufacturers, lot
27 numbers, or expiration dates for any of the ingredients used in the compound. There was no
28

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

3 (ii) Five (5) patients received the batch of compounded Formoterol
4 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12
5 without documentation on the compounding records of any of the drug manufacturers, lot
6 numbers, or expiration dates for any of the ingredients used in the compound. There was no
7 record of who compounded the drug or who verified the end product. The drug was dispensed to
8 all five (5) patients before completion of an end product testing for sterility.

9 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
10 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without
11 documentation on the compounding records of any of the drug manufacturers, lot numbers, or
12 expiration dates for any of the ingredients used in the compound. There was no record of who
13 compounded the drug or who verified the end product. The drug was dispensed to thirty-three
14 (33) of the fifty (50) patients before completion of an end product testing for sterility.

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

21 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
22 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the
23 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
24 of the ingredients used in the compound. There was no record of who compounded the drug or
25 who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29)
26 patients before completion of an end product testing for sterility.

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

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

6 **THIRTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

7 **(Failure to Ensure Compounding Limitations and Requirements)**

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

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

18 (i) Two (2) patients received the batch of compounded Levalbuterol
19 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12.
20 The drug was dispensed to both patients before completion of an end product testing for sterility.

21 (ii) Five (5) patients received the batch of compounded Formoterol
22 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12.
23 The drug was dispensed to all five (5) patients before completion of an end product testing for
24 sterility.

25 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
26 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The
27 drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end
28 product testing for sterility.

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

4 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
5 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to
6 nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for
7 sterility.

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

12 **THIRTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

13 **(Dispensing/Sale of Expired Drug)**

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

- 21 a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;
22 b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

23 **THIRTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

24 **(Failure to Include Expiration Date on Labels)**

25 72. Respondent Le is subject to disciplinary action under Code sections 4301,
26 subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code
27 section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,
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1 during a second Board inspection, Respondent Le allowed the dispensing of misbranded unit-dose
2 containers of the following drugs which contained no expiration dates on the labels:

- 3 a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;
- 4 b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 5 c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 6 d. Compounded Levalbuterol 1mg/3ml.

7 **THIRTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

8 **(Purchase of Dangerous Drugs from Unlicensed Entity)**

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

- 16 a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct
17 Levalbuterol Powder USP 3x100gms for \$4,500.
- 18 b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct
19 Levalbuterol Powder USP 3x100gms for \$4,500.

20 **FORTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

21 **(Embargoed Misbranded Dangerous Drugs)**

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

- 27 a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 28 b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

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

2 **FORTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)**

3 **(Failure to Maintain Facility and Equipment Standards)**

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

9 **FORTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

10 **(Drugs Lacking Quality and Strength)**

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

- 15 a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to
16 identify the date the drug was compounded or the expiration date;
- 17 b. Unlabeled Benzaikonium Chloride 17% bottle was in the refrigerator with no label to
18 identify the date the drug was compounded or the expiration date;
- 19 c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The
20 solutions expired on 02/24/11 and 05/18/12;
- 21 d. The embargoed misbranded compounded drugs which lacked compounding records
22 to determine the quality and strength included:
- 23 (i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 24 (ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 25 (iii) 1083 vials of Levalbuterol 1mg/3ml.

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1 **FORTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)**

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

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

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

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

15 **FORTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)**

16 **(Unprofessional Conduct: False Document/Misrepresentation)**

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

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

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

1 **DISCIPLINE CONSIDERATIONS**

2 79. To determine the degree of discipline, if any, to be imposed on Respondent
3 Pharmacy, Complainant alleges that on or about February 27, 2004, in a prior action, the Board
4 issued Citation Number CI 2002 25346 in the amount of \$1,600 for violation of CCR sections
5 1751.7, subdivisions (a), (d) and (e); 1751.5; 1751.8, subdivision (f), 1716.2, 1714, subdivision
6 (b); 1715 subdivisions (a) and (b); 1793.7, subdivision (b); and Code section 4116. Respondent
7 Pharmacy has fully complied with the Citation.

8 **PRAYER**

9 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
10 and that following the hearing, the Board of Pharmacy issue a decision:

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

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

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

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

20 5. Ordering Super Care, Inc. dba Supercare, Gabriel John Cassar, a.k.a. Gabriel Cassar,
21 Katherine Thu Le, a.k.a. Katherine Le, and Tuan Kieu Nguyen, to pay the Board of Pharmacy the
22 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
23 Professions Code section 125.3;

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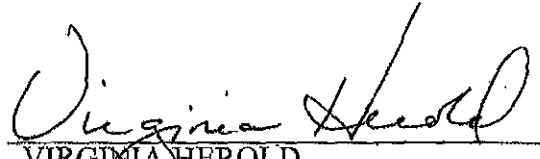
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6. Taking such other and further action as deemed necessary and proper.

DATED: 1/17/14


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

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