



175146



1008



PH02928



0801R

DO NOT FOLD OR STAPLE ABOVE THIS LINE

Nevada State Board of Pharmacy - 431 W Plumb Lane • Reno, NV 89509 • bop.nv.gov

Renewal Application - PHARMACY

For the period of November 1, 2014 to October 31, 2016

Money Order ONLY (NO BUSINESS or PERSONAL CHECKS, NO CASH)\$500.00 (postmarked on or before 10/31/2014) **OR** \$750.00 (postmarked after 10/31/2014)

Please make any changes to name or address next to the old information

LICENSE: PH02928**SUPER CARE PHARMACY**

16017 VALLEY BLVD,

La Puente, CA 91744

RENEW BY MAIL

1. Complete this form
2. Sign and date this form
3. Send payment with this form (do **NOT** staple)
4. Mail **original** form and payment to address above
5. **NO COPIES OR STAMPS ACCEPTED**

<OR>

RENEW ONLINE

1. Go to <http://bop.nv.gov>
2. Click "Applications" then, "License Renewal"
3. Follow instructions
4. Use **USER ID:** ph48hw57
PASSWORD: wud763
***New Users: once logged in, when asked for OLD password, use the above password, then change**

Section 1: Since your last renewal or recent licensure has any owner or shareholder: (Fill in completely) **Yes No**

1. Been charged, arrested or convicted of a felony or misdemeanor in any state?..... ☐ ☒
2. Been the subject of a board citation or an administrative action whether completed or pending in any state?..... ☒ ☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?..... ☒ ☐

If you marked YES to any of the questions (1-3) above, include the following information & provide documentation:

Board Administrative Action:	State	Date:	Case #:
Accusation Pending	CA	01/17/14	4566
Criminal Action:	State	Date:	Case #:
NIA	_____	_____/_____/____	_____

Section 2: CAUTIONS

- (1.) Nevada has **no grace period**. All applications postmarked by the US Postal Service after October 31, 2014 that are NOT accompanied by the late fee, will be returned and will be assessed the late fee, delaying processing.
- (2.) Any application that is not 100% complete will be returned and will not be considered to have been received.
Only completed applications will be processed.
- (3.) If you have a Nevada State Business license, please provide the # _____

Section 3:

It is a violation of Nevada Statute to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

Signature: _____

Date: 10 / 30 / 14



March 16, 2016

Nevada State Board of Pharmacy
431 Plumb Lane
Reno, NV 89509

**Reference: Non-Resident Pharmacy License
PH02928**

SuperCare Pharmacy, license number PHY45943 is on probation with the California State Board of Pharmacy as of January of 2015.

More than 2 years ago an onsite pharmacy board inspection occurred and at that time our pharmacy was sterile compounding. The issues included failure to maintain adequate or accurate records, violations of state statutes and regulations, expired drugs found in inventory, inadequate security and mislabeling. All of these issues involved the compounding process. Due to not effectively meeting the USP 797 regulations, SuperCare ceased compounding.

There were also issues that the pharmacist in charge, Katherine Le and a pharmacy technician, Tuan Nguyen provided false information to the state board inspector during the course of the inspection. The pharmacist in charge and the pharmacy technician involved were both terminated.

SuperCare Pharmacy currently provides retail and mail order prescription services and no compounding. As a stipulation of continued licensure, the California Board of Pharmacy requires notice be provided to all employees and probation status be posted in the location. This notice was included with training provided to employees in 2015. Quarterly self-assessments must be completed and be submitted to the board. The pharmacy board also completes inspections on a quarterly basis. Self-Assessments submitted to the board have been accepted and inspections completed have shown compliance.

Regards,

Susean Nichols, Corporate Compliance Officer

8345 East Firestone Blvd., Suite 210
Downey, CA 90241
800-206-4880 | supercarehealth.com

**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;
Michelline 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. 57903

TUAN KIEU NGUYEN
Pharmacy Technician Registration
No. TCH 89616

Respondents.

Case No. 4566

OAH No. 2014030278

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

As to: **SUPER CARE, INC. DBA**
SUPERCARE, PERMIT No.
PHY 45943

DECISION AND ORDER

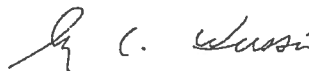
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on February 4, 2015.

It is so ORDERED on January 28, 2015.

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
Deputy Attorney General
4 State Bar No. 207108
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-6375
6 Facsimile: (213) 897-2804
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:

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

OAH No. 2014030278

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

As to: SUPER CARE, INC. DBA
SUPERCARE, Permit No. PHY 45943

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
Pharmacist License No. RPH 57903

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

25
26 Respondents.
27
28

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 of Pharmacy
5 ("Board"). She brought this action solely in her official capacity and is represented in this matter
6 by Kamala D. Harris, Attorney General of the State of California, by Linda L. Sun, Deputy
7 Attorney General.

8 2. Respondent Super Care, Inc., dba Supercare; Gabriel Cassar, President; Micheline
9 Cassar, Chief Executive Officer; John L. Cassar, Vice President; Michael Cassar, Shareholder;
10 Katherine Le, Pharmacist-in-Charge (collectively "Respondent Pharmacy" or "Respondent") is
11 represented in this proceeding by attorney Tony J. Park, Esq., whose address is: 6789 Quail Hill
12 Parkway, #405, Irvine, CA 92603.

13 3. On or about July 23, 2002, the Board issued Permit Number PHY 45943 to
14 Respondent Pharmacy. The Permit was in full force and effect at all times relevant to the charges
15 brought herein and will expire on July 1, 2015, unless renewed.

16 **JURISDICTION**

17 4. Accusation No. 4566 was filed before the Board and is currently pending against
18 Respondent Pharmacy. The Accusation and all other statutorily required documents were
19 properly served on Respondent Pharmacy on January 29, 2014. Respondent Pharmacy timely
20 filed its Notice of Defense contesting the Accusation.

21 5. A copy of Accusation No. 4566 is attached as Exhibit A and incorporated herein by
22 reference.

23 **ADVISEMENT AND WAIVERS**

24 6. Respondent Pharmacy has carefully read, fully discussed with counsel, and
25 understands the charges and allegations in Accusation No. 4566. Respondent Pharmacy has also
26 carefully read, fully discussed with counsel, and understands the effects of this Stipulated
27 Settlement and Disciplinary Order.
28

1 7. Respondent Pharmacy is fully aware of its legal rights in this matter, including the
2 right to a hearing on the charges and allegations in the Accusation; the right to be represented by
3 counsel at its own expense; the right to confront and cross-examine the witnesses against them;
4 the right to present evidence and to testify on its own behalf; the right to the issuance of
5 subpoenas to compel the attendance of witnesses and the production of documents; the right to
6 reconsideration and court review of an adverse decision; and all other rights accorded by the
7 California Administrative Procedure Act and other applicable laws.

8 8. Respondent Pharmacy voluntarily, knowingly, and intelligently waives and gives up
9 each and every right set forth above.

10 CULPABILITY

11 9. Respondent Pharmacy admits the truth of each and every charge and allegation in
12 Accusation No. 4566.

13 10. Respondent Pharmacy agrees that its Permit is subject to discipline and they agree to
14 be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

15 CONTINGENCY

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

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Permit No. PHY 45943 issued to Respondent Pharmacy is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

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

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

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Pharmacy's permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

1 **2. Report to the Board**

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

10 **3. Interview with the Board**

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

16 **4. Cooperate with Board Staff**

17 Respondent Owner shall cooperate with the Board's inspection program and with the
18 Board's monitoring and investigation of Respondent Pharmacy's compliance with the terms and
19 conditions of their probation. Failure to cooperate shall be considered a violation of probation.

20 **5. Reimbursement of Board Costs**

21 As a condition precedent to successful completion of probation, Respondent Owner shall
22 pay to the Board its costs of investigation and prosecution in the amount of \$6,310.80 (six
23 thousand three hundred ten dollars and eighty cents). The costs may be paid on a payment plan
24 approved by the Board. There shall be no deviation from the payment plan schedule absent prior
25 written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed
26 shall be considered a violation of probation.

27 The filing of bankruptcy by Respondent Owner shall not relieve Respondent Pharmacy of
28 their responsibility to reimburse the Board its costs of investigation and prosecution.

1 **6. Probation Monitoring Costs**

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

6 **7. Status of License**

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

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

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

18 Following the effective date of this decision, should Respondent Owner discontinue
19 business, Respondent Owner may tender the premise's license to the Board for surrender. The
20 Board or its designee shall have the discretion whether to grant the request for surrender or take
21 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of
22 the license, Respondent will no longer be subject to the terms and conditions of probation.

23 Upon acceptance of the surrender, Respondent Owner shall relinquish the premises wall
24 and renewal license to the Board within ten (10) days of notification by the Board that the
25 surrender is accepted. Respondent Owner shall further submit a completed Discontinuance of
26 Business form according to Board guidelines and shall notify the Board of the records inventory
27 transfer.

28 ///

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

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

15 Respondent Owner further stipulates that he or she shall reimburse the Board for its costs of
16 investigation and prosecution prior to the acceptance of the surrender.

17 9. Notice to Employees

18 Respondent Owner shall, upon or before the effective date of this decision, ensure that all
19 employees involved in permit operations are made aware of all the terms and conditions of
20 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
21 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
22 remain posted throughout the probation period. Respondent Owner shall ensure that any
23 employees hired or used after the effective date of this decision are made aware of the terms and
24 conditions of probation by posting a notice, circulating a notice, or both. Additionally,
25 Respondent Owner shall submit written notification to the Board, within fifteen (15) days of the
26 effective date of this decision, that this term has been satisfied. Failure to submit such
27 notification to the Board shall be considered a violation of probation.

28 ///

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

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

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

12 **11. Posted Notice of Probation**

13 Respondent Owner shall prominently post a probation notice provided by the Board in a
14 place conspicuous and readable to the public. The probation notice shall remain posted during
15 the entire period of probation.

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

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

21 **12. Violation of Probation**

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

27 If Respondent Owner violates probation in any respect, the Board, after giving Respondent
28 Owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary

1 order that was stayed. Notice and opportunity to be heard are not required for those provisions
2 stating that a violation thereof may lead to automatic termination of the stay and/or revocation of
3 the license. If a petition to revoke probation or an accusation is filed against Respondent
4 Pharmacy during probation, the Board shall have continuing jurisdiction and the period of
5 probation shall be automatically extended until the petition to revoke probation or accusation is
6 heard and decided.

7 **13. Completion of Probation**

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

10 **14. Community Services Program**

11 Within sixty (60) days of the effective date of this decision, Respondent Owner shall submit
12 to the Board or its designee, for prior approval, a community service program in which
13 Respondent shall provide free brown-bag events to the community for at least twenty (20) days
14 per year for the first two (2) years of probation.

15 Within thirty (30) days of Board approval thereof, Respondent Owner shall submit
16 documentation to the Board demonstrating commencement of the community service program.
17 Respondent Owner shall report on progress with the community service program in the quarterly
18 reports.

19 Failure to timely submit, commence, or comply with the program shall be considered a
20 violation of probation.

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

1 ACCEPTANCE

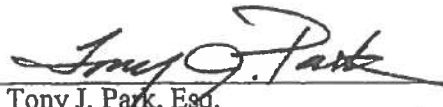
2 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
3 discussed it with my attorney, Tony J. Park, Esq.. I understand the stipulation and the effect it
4 will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order
5 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
6 Board of Pharmacy.

7
8 DATED: 12-9-2014


9 OWNER, SUPER CARE, INC. DBA SUPERCARE
Respondent

10 I have read and fully discussed with Respondent Super Care, Inc. dba Supercare; Gabriel
11 Cassar; Micheline Cassar; John L. Cassar; Michael Cassar; Katherine Le; the terms and
12 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
13 I approve its form and content.

14 DATED: 12/09/2014


15 Tony J. Park, Esq.
Attorney for Respondent

16
17 ENDORSEMENT

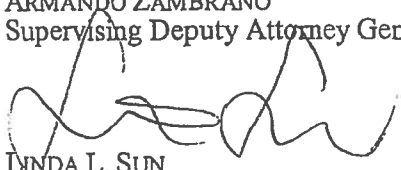
18 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
19 submitted for consideration by the Board of Pharmacy.

20
21 Dated:

1/5/2015

Respectfully submitted,

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


24
25 LINDA L. SUN
Deputy Attorney General
26 Attorneys for Complainant

27 LA2013508981
28 51646049.doc

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
Telephone: (213) 897-6375
6 Facsimile: (213) 897-2804
Attorneys for Complainant
7

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

11 In the Matter of the Accusation Against:

Case No. 4566

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

A C C U S A T I O N

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

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

22 **TUAN KIEU NGUYEN**
23 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.

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

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

3 ...

4 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
5 violation of or conspiring to violate any provision or term of this chapter or of the applicable
6 federal and state laws and regulations governing pharmacy, including regulations established by
7 the board or by any other state or federal regulatory agency.

8 ...

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

11 15. Section 4342 of the Code provides:

12 "(a) The board may institute any action or actions as may be provided by law and that, in
13 its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that
14 do not conform to the standard and tests as to quality and strength, provided in the latest edition
15 of the United States Pharmacopoeia or the National Formulary, or that violate any provision of
16 the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of
17 Division 104 of the Health and Safety Code)."

18 REGULATORY PROVISIONS

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

20 ...

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

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

25 ///

26 ///

27 ///

28 ///

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:

26 ///

27 ///

28 ///

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.

27 ///

28 ///

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 (c), 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.

26 ///

27 ///

28 ///

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
28

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
28

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.

27 ///

28 ///

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,
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 **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 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.

26 ///

27 ///

28 ///

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
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
22
24
22
22
22
22
22

2
3
4
5
6
7

8

9
10

- 11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

24

2.

2.

2

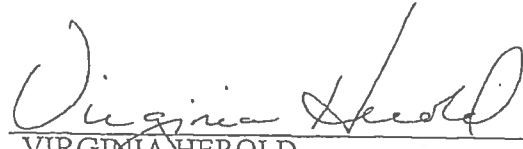
2

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

LA2013508981
51364520.doc

Blank