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

11 In the Matter of the Accusation Against:

Case No. 6187

12 **LIMAS PROFESSIONAL PHARMACY 1,**
13 **ROBERT BREDE LIMA, OWNER AND**
14 **CHIEF EXECUTIVE OFFICER, and**
15 **RAMONA LIMA, OWNER AND**
16 **SECRETARY**
2097 Harrison Avenue
Eureka, CA 95501

SUPPLEMENTAL ACCUSATION

17 **Original Permit No. PHY 43124**
18 **Original Sterile Compounding Permit No.**
19 **LSC 100544**

20 **RAMONA LIMA**
2097 Harrison Avenue
Eureka, CA 95501

21 **Pharmacist License No. RPH 46446**

22 Respondents.

23
24 Complainant alleges:

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Supplemental Accusation solely in her
27 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
28 Affairs.

1 11. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be
2 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
3 to the practice of pharmacy."

4 12. California Code of Regulations, title 16, section 1735.7, subdivision (b) states: "The
5 pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy
6 personnel involved in compounding, and shall maintain documentation of any and all training
7 related to compounding undertaken by pharmacy personnel."

8 13. California Code of Regulations, title 16, section 1751.1 provides, in pertinent part:
9 "(a) In addition to the records required by section 1735.3, any pharmacy engaged in any
10 compounding of sterile drug preparations shall maintain the following records, which must be
11 readily retrievable, within the pharmacy:

12 ...

13 "(9) Other facility quality control records specific to the pharmacy's policies and
14 procedures (e.g., cleaning logs for facilities and equipment)."

15 14. California Code of Regulations, title 16, section 1751.4 provides, in pertinent part:
16 "(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a
17 sporicidal agent is required to be used at least monthly.

18 "(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor
19 shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall
20 occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters."

21 15. California Code of Regulations, title 16, section 1751.7, subdivision (d) states: "Re-
22 evaluation of garbing and gloving competency shall occur at least every 12 months for personnel
23 compounding products made from sterile ingredients and at least every six months for personnel
24 compounding products from non-sterile ingredients."

25 COSTS

26 16. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
27 administrative law judge to direct a licentiate found to have committed a violation or violations of
28 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and

1 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
2 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
3 included in a stipulated settlement.

4 **FACTUAL BACKGROUND**

5 17. On or about November 8, 2017, a Board inspector completed an annual sterile
6 compounding license inspection at Respondent Pharmacy. During the inspection, the inspector
7 asked Respondent Ramona Lima to provide daily logs for the cleaning of all required surfaces in
8 the sterile compounding room. Respondent Ramona Lima was unable to produce any daily
9 cleaning logs.

10 18. Respondent Pharmacy's personnel, including Respondent Ramona Lima, compound
11 products made from sterile ingredients and products made from non-sterile ingredients. In
12 reviewing Respondent Pharmacy's employee quality assurance and process validation
13 documentation, the inspector determined that Respondent Pharmacy did not perform a six-month
14 re-evaluation of garbing and gloving competency for Respondent Ramona Lima for compounding
15 products from non-sterile ingredients.

16 19. The inspector further determined that Respondent Pharmacy did not maintain on-
17 going competency evaluations or documentation of compounding-related training for two
18 compounding technicians employed by Respondent Pharmacy.

19 **FIRST CAUSE FOR DISCIPLINE**

20 **(Failure to Maintain On-Going Competency Evaluations and Documentation of**
21 **Compounding-Related Training)**

22 20. Respondents' licenses and permits are subject to disciplinary action under sections
23 4301, subdivision (o) and 4113, subdivision (c) of the Code, in that Respondents did not maintain
24 on-going competency evaluations or documentation of compounding-related training for
25 pharmacy personnel involved in compounding, as required by California Code of Regulations,
26 title 16, sections 1735.7, subdivision (b). The circumstances of Respondents' conduct are set
27 forth above in paragraph 19.

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1 **SECOND CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Daily Cleaning Logs)**

3 21. Respondents' licenses and permits are subject to disciplinary action under sections
4 4301, subdivision (o) and 4113, subdivision (c) of the Code, in that Respondents did not maintain
5 daily cleaning logs of ISO Class 5 surfaces, work table surfaces, carts, counters, or the cleanroom
6 floor, as required by California Code of Regulations, title 16, sections 1751.1, subdivision (a)(9)
7 and 1751.4, subdivision (d)(1). The circumstances of Respondents' conduct are set forth above in
8 paragraph 17.

9 **THIRD CAUSE FOR DISCIPLINE**

10 **(Failure to Perform Re-Evaluation of Garbing and Gloving Competency)**

11 22. Respondents' licenses and permits are subject to disciplinary action under sections
12 4301, subdivision (o) and 4113, subdivision (c) of the Code, in that Respondent Pharmacy did not
13 perform a six-month re-evaluation of garbing and gloving competency for personnel
14 compounding products from non-sterile ingredients, as required by California Code of
15 Regulations, title 16, section 1751.7, subdivision (d). The circumstances of Respondents'
16 conduct are set forth above in paragraph 18.

17 **OTHER MATTERS**

18 23. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number
19 PHY 43124 issued to Respondent Pharmacy while Robert Brede Lima was an officer or owner of
20 Respondent Pharmacy and had knowledge of or knowingly participated in any conduct for which
21 Original Permit Number PHY 43124 was disciplined, Robert Brede Lima shall be prohibited
22 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
23 of a licensee for five years if Original Permit Number PHY 43124 is placed on probation or until
24 Original Permit Number PHY 43124 is reinstated if it is revoked.

25 24. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number
26 PHY 43124 issued to Respondent Pharmacy while Ramona Lima was an officer or owner of
27 Respondent Pharmacy and had knowledge of or knowingly participated in any conduct for which
28 Original Permit Number PHY 43124 was disciplined, Ramona Lima shall be prohibited from

1 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
2 licensee for five years if Ramona Lima is denied a license, if Pharmacist License Number RPH
3 46446 issued to Ramona Lima is revoked or under suspension, or if Original Permit Number
4 PHY 43124 is placed on probation, or until Original Permit Number PHY 43124 or Pharmacist
5 License Number RPH 46446 are reinstated if they are revoked.

6 **PRAYER**

7 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
8 Supplemental Accusation, and that following the hearing, the Board of Pharmacy issue a
9 decision:

- 10 1. Revoking or suspending Original Permit Number PHY 43124 issued to Limas
11 Professional Pharmacy 1, Robert Brede Lima, Owner and Chief Executive Officer, and Ramona
12 Lima, Owner and Secretary;
- 13 2. Revoking or suspending Original Sterile Compounding Permit Number LSC 100544
14 issued to Limas Professional Pharmacy 1, Robert Brede Lima, Owner and Chief Executive
15 Officer, and Ramona Lima, Owner and Secretary;
- 16 3. Revoking or suspending Pharmacist License Number RPH 46446 issued to Ramona
17 Lima;
- 18 4. Prohibiting Robert Brede Lima from serving as a manager, administrator, owner,
19 member, officer, director, associate, or partner of a licensee for five years if Original Permit
20 Number PHY 43124 is placed on probation or until Original Permit Number PHY 43124 is
21 reinstated if it is revoked;
- 22 5. Prohibiting Ramona Lima from serving as a manager, administrator, owner, member,
23 officer, director, associate, or partner of a licensee for five years if Ramona Lima is denied a
24 license, if Pharmacist License Number RPH 46446 issued to Ramona Lima is revoked or under
25 suspension, or if Original Permit Number PHY 43124 is placed on probation, or until Original
26 Permit Number PHY 43124 or Pharmacist License Number RPH 46446 are reinstated if they are
27 revoked;

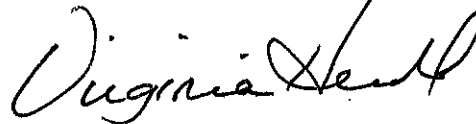
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1 6. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
2 investigation and enforcement of this case pursuant to Business and Professions Code section
3 125.3; and

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

5
6 DATED:

5/23/18



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

10 OK2017901366

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A C C U S A T I O N

17 **Original Permit No. PHY 43124**
18 **Original Sterile Compounding Permit No.**
19 **LSC 100544**

20 **RAMONA LIMA**
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21 **Pharmacist License No. RPH 46446**

22 Respondents.

23
24 Complainant alleges:

25 **PARTIES**

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

28 ///

1 11. Section 4113, subdivision (c) of the Code states: “The pharmacist-in-charge shall be
2 responsible for a pharmacy’s compliance with all state and federal laws and regulations pertaining
3 to the practice of pharmacy.”

4 12. California Code of Regulations, title 16, section 1714, subdivision (b) states: “Each
5 pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that
6 drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall
7 be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.”

8 13. California Code of Regulations, title 16, section 1735.7 provides, in pertinent part:

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

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

15 14. California Code of Regulations, title 16, section 1751.4, subdivision (d) states:
16 “Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors,
17 ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event
18 that could increase the risk of contamination.”

19 15. California Code of Regulations, title 16, section 1751.5 provides, in pertinent part:

20 “(a) When preparing cytotoxic agents, gowns and gloves shall be worn.

21 “(b) When compounding sterile products from one or more non-sterile ingredients the
22 following standards must be met:

23 “(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and
24 shoe covers must be worn inside the designated area at all times.”

25 16. California Code of Regulations, title 16, section 1751.6 provides, in pertinent part:

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

1 cytotoxic agents if the pharmacy compounds products with cytotoxic agents.

2 “(c) Records of training and demonstrated competence shall be available for each individual
3 and shall be retained for three years beyond the period of employment.

4 “(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of
5 pharmacy personnel engaged in compounding sterile injectable products.

6 “(e) Pharmacies that compound sterile products from one or more non-sterile ingredients
7 must comply with the following training requirements:

8 “(1) The pharmacy must establish and follow a written program of training and
9 performance evaluation designed to ensure that each person working in the designated area has
10 the knowledge and skills necessary to perform their assigned tasks properly. This program of
11 training and performance evaluation must address at least the following:

12 “(A) Aseptic technique.

13 “(B) Pharmaceutical calculations and terminology.

14 “(C) Sterile product compounding documentation.

15 “(D) Quality assurance procedures.

16 “(E) Aseptic preparation procedures.

17 “(F) Proper gowning and gloving technique.

18 “(G) General conduct in the controlled area.

19 “(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

20 “(I) Sterilization techniques.

21 “(J) Container, equipment, and closure system selection.

22 “(2) Each person assigned to the controlled area must successfully complete practical skills
23 training in aseptic technique and aseptic area practices. Evaluation must include written testing
24 and a written protocol of periodic routine performance checks involving adherence to aseptic area
25 policies and procedures. Each person’s proficiency and continuing training needs must be
26 reassessed every 12 months. Results of these assessments must be documented and retained in
27 the pharmacy for three years.”

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1 17. California Code of Regulations, title 16, section 1751.7 provides, in pertinent part:
2 “(b) Each individual involved in the preparation of sterile injectable products must first
3 successfully complete a validation process on technique before being allowed to prepare sterile
4 injectable products. The validation process shall be carried out in the same manner as normal
5 production, except that an appropriate microbiological growth medium is used in place of the
6 actual product used during sterile preparation. The validation process shall be representative of
7 all types of manipulations, products and batch sizes the individual is expected to prepare. The
8 same personnel, procedures, equipment, and materials must be involved. Completed medium
9 samples must be incubated. If microbial growth is detected, then the sterile preparation process
10 must be evaluated, corrective action taken, and the validation process repeated. Personnel
11 competency must be revalidated at least every twelve months, whenever the quality assurance
12 program yields an unacceptable result, when the compounding process changes, equipment used
13 in the compounding of sterile injectable drug products is repaired or replaced, the facility is
14 modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic
15 techniques are observed. Revalidation must be documented.

16 “(c) Batch-produced sterile injectable drug products compounded from one or more non-
17 sterile ingredients shall be subject to documented end product testing for sterility and pyrogens
18 and shall be quarantined until the end product testing confirms sterility and acceptable levels of
19 pyrogens.”

20 **COSTS**

21 18. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
22 administrative law judge to direct a licentiate found to have committed a violation or violations of
23 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
24 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
25 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
26 included in a stipulated settlement.

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28 ///

1 **FACTUAL BACKGROUND**

2 19. On or about November 10, 2016, two Board inspectors conducted an annual sterile
3 compounding license inspection at Respondent Pharmacy. During the inspection, the inspectors
4 discovered at least five (5) expired products on the pharmacy's shelves.

5 20. At one point during the inspection, the inspectors were led to Respondent Pharmacy's
6 compounding area by William Wong (Wong), a registered pharmacist and employee of
7 Respondent Pharmacy. Before entering the compounding area, Wong instructed the inspectors to
8 don a gown, wash their hands, put on hair nets, put on masks, and don non-sterile gloves. This
9 procedure was incorrect, in that washing must be completed prior to gowning. Wong gave the
10 inspectors plastic clogs with furry cloth lining to put on for entering the compounding area.
11 Wong did not provide the inspectors with shoe covers prior to entering the compounding area.

12 21. Once inside the pharmacy's compounding area, the inspectors noticed an exposed
13 wood panel on one of the walls that did not show signs of having been cleaned or disinfected.

14 22. The inspectors reviewed temperature logs for the pharmacy's refrigerator and freezer
15 for the months of September and October 2016. According to the refrigerator log, the refrigerator
16 temperature was not in the required range for those two months.

17 23. One of the inspectors reviewed compounding logs and labels for vancomycin eye
18 drops and tobramycin eye drops, both of which are batch-produced sterile drug preparations and
19 batch-produced non-sterile to sterile drug preparations. Respondent Pharmacy released those
20 products after only three (3) days of the fourteen (14) day period for sterility testing.

21 24. Respondent Pharmacy did not maintain the required documentation of annual training
22 and performance evaluation relating to compounding for any of the pharmacists or pharmacy
23 technicians employed at Respondent Pharmacy. Also, with the exception of one pharmacy
24 technician, Respondent Pharmacy did not maintain the required documentation showing that the
25 pharmacists and pharmacy technicians employed at Respondent Pharmacy had successfully
26 completed the annual validation process relating to the preparation of sterile injectable products.

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1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Failure to Disinfect Surfaces in the Compounding Area)**

3 25. Respondents' licenses and permits are subject to disciplinary action under section
4 4301, subdivision (o) of the Code and California Code of Regulations, title 16, section 1751.4,
5 subdivision (d), in that Respondents did not properly disinfect Respondent Pharmacy's
6 compounding area. The circumstances of Respondents' conduct are set forth above in paragraphs
7 19-24.

8 **SECOND CAUSE FOR DISCIPLINE**

9 **(Failure to Wear Required Personal Protective Equipment)**

10 26. Respondents' licenses and permits are subject to disciplinary action under section
11 4301, subdivision (o) of the Code and California Code of Regulations, title 16, section 1751.5,
12 subdivision (b)(1), in that Respondents did not comply with cleanroom garb requirements
13 applicable to compounding sterile products. The circumstances of Respondents' conduct are set
14 forth above in paragraphs 19-24.

15 **THIRD CAUSE FOR DISCIPLINE**

16 **(Failure to Ensure that Compounding Staff Has Necessary Knowledge and Skills)**

17 27. Respondents' licenses and permits are subject to disciplinary action under section
18 4301, subdivision (o) of the Code and California Code of Regulations, title 16, section 1751.6,
19 subdivision (e)(1)(F), in that Respondents failed to establish and/or follow a written program of
20 training and performance evaluation designed to ensure that compounding staff had the
21 knowledge and skills necessary to perform proper gowning technique. The circumstances of
22 Respondents' conduct are set forth above in paragraphs 19-24.

23 **FOURTH CAUSE FOR DISCIPLINE**

24 **(Failure to Quarantine Batch-Produced Sterile Drug Preparations)**

25 28. Respondents' licenses and permits are subject to disciplinary action under section
26 4301, subdivision (o) of the Code and California Code of Regulations, title 16, section 1751.7,
27 subdivision (c), in that Respondents failed to quarantine two (2) batch-produced sterile drug
28 preparations until Respondents obtained the results of end product testing confirming sterility and

1 acceptable levels of pyrogens. The circumstances of Respondents' conduct are set forth above in
2 paragraphs 19-24.

3 **FIFTH CAUSE FOR DISCIPLINE**

4 **(Failure to Maintain Facilities, Fixtures, and Equipment)**

5 29. Respondents' licenses and permits are subject to disciplinary action under section
6 4301, subdivision (o) of the Code and California Code of Regulations, title 16, section 1714,
7 subdivision (b), in that in September and October 2016, Respondents did not adequately maintain
8 Respondent Pharmacy's facilities, space, fixtures, and/or equipment so that drugs were safely and
9 properly maintained and/or secured. The circumstances of Respondents' conduct are set forth
10 above in paragraphs 19-24.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Failure to Maintain Training Documentation)**

13 30. Respondents' licenses and permits are subject to disciplinary action under section
14 4301, subdivision (o) of the Code in that Respondents did not maintain adequate training
15 documentation related to compounding, as required by California Code of Regulations, title 16,
16 sections 1735.7, subdivisions (a) and (b), 1751.6, subdivisions (b), (c), (e)(1), and (e)(2), and
17 1751.7, subdivision (b). The circumstances of Respondents' conduct are set forth above in
18 paragraphs 19-24.

19 **OTHER MATTERS**

20 31. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number
21 PHY 43124 issued to Respondent Pharmacy while Robert Brede Lima was an officer or owner of
22 Respondent Pharmacy and had knowledge of or knowingly participated in any conduct for which
23 Original Permit Number PHY 43124 was disciplined, Robert Brede Lima shall be prohibited
24 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
25 of a licensee for five years if Original Permit Number PHY 43124 is placed on probation or until
26 Original Permit Number PHY 43124 is reinstated if it is revoked.

27 32. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number
28 PHY 43124 issued to Respondent Pharmacy while Ramona Lima was an officer or owner of

1 Respondent Pharmacy and had knowledge of or knowingly participated in any conduct for which
2 Original Permit Number PHY 43124 was disciplined, Ramona Lima shall be prohibited from
3 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
4 licensee for five years if Ramona Lima is denied a license, if Pharmacist License Number RPH
5 46446 issued to Ramona Lima is revoked or under suspension, or if Original Permit Number
6 PHY 43124 is placed on probation, or until Original Permit Number PHY 43124 or Pharmacist
7 License Number RPH 46446 are reinstated if they are revoked.

8 **PRAYER**

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

- 11 1. Revoking or suspending Original Permit Number PHY 43124 issued to Limas
12 Professional Pharmacy 1, Robert Brede Lima, Owner and Chief Executive Officer, and Ramona
13 Lima, Owner and Secretary;
- 14 2. Revoking or suspending Original Sterile Compounding Permit Number LSC 100544
15 issued to Limas Professional Pharmacy 1, Robert Brede Lima, Owner and Chief Executive
16 Officer, and Ramona Lima, Owner and Secretary;
- 17 3. Revoking or suspending Pharmacist License Number RPH 46446 issued to Ramona
18 Lima;
- 19 4. Prohibiting Robert Brede Lima from serving as a manager, administrator, owner,
20 member, officer, director, associate, or partner of a licensee for five years if Original Permit
21 Number PHY 43124 is placed on probation or until Original Permit Number PHY 43124 is
22 reinstated if it is revoked;
- 23 5. Prohibiting Ramona Lima from serving as a manager, administrator, owner, member,
24 officer, director, associate, or partner of a licensee for five years if Ramona Lima is denied a
25 license, if Pharmacist License Number RPH 46446 issued to Ramona Lima is revoked or under
26 suspension, or if Original Permit Number PHY 43124 is placed on probation, or until Original
27 Permit Number PHY 43124 or Pharmacist License Number RPH 46446 are reinstated if they are
28 revoked;

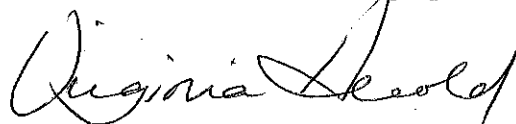
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6. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case pursuant to Business and Professions Code section 125.3; and

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

DATED:

12/13/17



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

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