

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
1515 Clay Street, 20th Floor
5 Post Office Box 70550
Oakland, California 94612-0550
6 Telephone: (510) 622-2143
Facsimile: (510) 622-2270
7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

Case No. 5605

12 **SAFeway PHARMACY INC.**
d.b.a. Safeway Pharmacy #4905
13 6100 Hellyer Avenue, Suite 100
San Jose, California 95138

ACCUSATION

14 **Original Permit No. PHY 52537**
15 **Original Permit No. PHY 53416,**

16 **SAFeway PHARMACY INC.**
d.b.a. Safeway Pharmacy #4526
17 255 Second Street
Los Altos, California 94022

18 **Original Permit No. PHY 51192,**

19 **JOHN VINCENT CASTALDO**
20 23750 Hutchinson Road
Los Gatos, California 95033

21 **Original Pharmacist License No. RPH 31324,**

22 **KAREN LYN MUIR**
23 156 Dunsmuir Way
Menlo Park, California 94025

24 **Original Pharmacist License No. RPH 39228,**

25 **and**
26
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28

1 **CHRISTINE MOHEB STEPHANOS**
2 **1845 Orangetree Lane**
3 **Mountain View, California 94040**

4 **Original Pharmacist License No. RPH 61981,**

5 Respondents.

6 Complainant Virginia Herold alleges:

7 **I. PARTIES**

8 1. Complainant brings this accusation solely in her official capacity as the Executive
9 Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

10 2. On December 3, 2014, the Board issued Original Permit No. PHY 52537 to
11 respondent Safeway Pharmacy Inc. (Safeway), d.b.a. Safeway Pharmacy #4905. Original Permit
12 No. PHY 52537 was cancelled on March 6, 2015. On February 27, 2015, the Board issued
13 Original Permit No. PHY 53416 to respondent Safeway Pharmacy #4905. Original Permit No.
14 PHY 53416 will expire on January 1, 2016, unless renewed.

15 3. On December 13, 2012, the Board issued Original Permit No. PHY 51192 to
16 respondent Safeway, d.b.a. Safeway Pharmacy #4526. Original Permit No. PHY 51192 was
17 cancelled on January 9, 2015.

18 4. On August 8, 1977, the Board issued Original Pharmacist License No. RPH 31324
19 to respondent John Vincent Castaldo. This original pharmacist license was in full force and effect
20 at all times relevant to the charges brought in this accusation and will expire on December 31,
21 2016, unless renewed.

22 5. On March 14, 1985, the Board issued Original Pharmacist License No.
23 RPH 39228 to respondent Karen Lyn Muir. This original pharmacist license was in full force and
24 effect at all times relevant to the charges brought in this accusation and will expire on April 30,
25 2016, unless renewed.

26 6. On November 20, 2008, the Board issued Original Pharmacist License No. RPH
27 61981 to respondent Christine Moheb Stephanos. This original pharmacist license was in full
28 force and effect at all times relevant to the charges brought in this accusation and will expire on

1 January 31, 2016, unless renewed.

2 **II. JURISDICTION**

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

5 8. Section 4300 states in part:

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

7 “(b) The board shall discipline the holder of any license issued by the board, whose
8 default has been entered or whose case has been heard by the board and found guilty, by any of
9 the following methods:

10 “(1) Suspending judgment.

11 “(2) Placing him or her upon probation.

12 “(3) Suspending his or her right to practice for a period not exceeding one year.

13 “(4) Revoking his or her license.

14 “(5) Taking any other action in relation to disciplining him or her as the board in its
15 discretion may deem proper.”

16 9. Section 4300.1 states:

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

22 10. Section 4304 states:

23 “The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for
24 any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of
25 Division 104 of the Health and Safety Code.”

26 **III. STATUTORY AND REGULATORY PROVISIONS**

27 11. Section 4169, subdivision (a), states in part:

28 “A person or entity shall not do any of the following:

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

12. Section 4301 states in part:

“The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

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

13. Section 4306.5 states in part:

“Unprofessional conduct for a pharmacist may include any of the following:

...

“(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.”

14. Health and Safety Code section 111335 states:

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

15. Health and Safety Code section 111397 subdivision (a), states:

“Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department

1 of Public Health is misbranded.”

2 16. Health and Safety Code section 111400 states:

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

5 17. Health and Safety Code section 111440 states:

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

8 18. California Code of Regulations, title 16, section 1735.3, subdivision (a), states in
9 part:

10 “For each compounded drug product, the pharmacy records shall include:

11 ...

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

13 IV. COST RECOVERY

14 19. Section 125.3, subdivision (a), states:

15 “Except as otherwise provided by law, in any order issued in resolution of a disciplinary
16 proceeding before any board within the department or before the Osteopathic Medical Board,
17 upon request of the entity bringing the proceedings, the administrative law judge may direct a
18 licentiate found to have committed a violation or violations of the licensing act to pay a sum not
19 to exceed the reasonable costs of the investigation and enforcement of the case.”

20 V. DRUGS

21 20. Domperidone is an anti-dopaminergic drug which acts as an antiemetic and
22 prokinetic agent. It is used relieve nausea and vomiting, and to increase lactation. It is a
23 dangerous drug under Business and Professions Code section 4022. Although the United States
24 Food and Drug Administration (FDA) may approve an application to use domperidone as an
25 investigational new drug in treating various gastrointestinal conditions, the use of domperidone is
26 not approved in the United States for any indication. The FDA has determined that any products
27 containing domperidone are unapproved new drugs and misbranded. Consequently, any product
28 containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et

1 seq.).

2 VI. FACTUAL BACKGROUND

3 21. On April 8, 2015, the Board inspected respondent Safeway at its present address of
4 record. The inspectors found a 500 gram bulk powder container of domperidone with an
5 expiration date of January 30, 2018. The container stated "NOT FOR HUMAN USE NOT FOR
6 US[E] IN FOOD[-]PRODUCING ANIMALS." Respondent Castaldo, the pharmacist-in-charge
7 at respondent Safeway, said that Safeway had been compounding domperidone. He said that the
8 domperidone manufacturer told him that the FDA told the manufacturer to put the warning on the
9 label but it is safe to use on humans. Respondent Castaldo told the inspectors that the
10 Professional Compounding Centers of America said to keep compounding with domperidone
11 until "somebody shuts you down." He said that nevertheless respondent Safeway had stopped
12 compounding domperidone about a month before the inspection. The inspectors embargoed the
13 domperidone.

14 22. Worksheets show the following instances of domperidone compounding at
15 respondent Safeway. All worksheets list respondent Castaldo as the pharmacist.

- | | | | |
|----|-------------|-------------------|---------------------------------|
| 16 | a) 7/21/14 | 600 10mg capsules | Checked by Muir |
| 17 | b) 10/8/14 | 300 30mg capsules | Checked by Muir |
| 18 | c) 10/27/14 | 300 10mg capsules | Checked by Castaldo |
| 19 | d) 11/13/14 | 300 10mg capsules | Checked by Muir |
| 20 | e) 12/11/14 | 300 10mg capsules | Checked by [unknown] |
| 21 | f) 1/12/15 | 300 10mg capsules | Checked by [blank] |
| 22 | g) 2/6/15 | 300 20mg capsules | Checked by [blank] |
| 23 | h) 2/18/15 | 300 10mg capsules | Checked by [blank] |
| 24 | i) 3/4/15 | 300 20mg capsules | Checked by [blank] ¹ |

25 23. Pharmacy records show respondent Safeway dispensed approximately 423
26 prescriptions for domperidone totaling approximately 45,898 capsules ranging from 5mg to

27 ¹ Instances a) through e) are attributable to respondent Safeway PHY 51192, f)
28 through h) to respondent Safeway PHY 52537, and i) to respondent Safeway PHY 53416.

1 40mg. Approximately 374 of these prescriptions totaling approximately 28,693 capsules were
2 dispensed by respondent Safeway PHY 51192, approximately 39 prescriptions totaling
3 approximately 16,263 capsules by respondent Safeway PHY 52537, and approximately 10
4 prescriptions totaling approximately 942 capsules by respondent Safeway PHY 53416.

5 24. Respondent Castaldo dispensed and verified approximately 190 prescriptions for
6 domperidone totaling approximately 21,360 capsules. Respondent Muir dispensed and verified
7 approximately 161 prescriptions totaling approximately 16,813 capsules. Respondent Stephanos
8 dispensed and verified 72 prescriptions totaling approximately 7,725 capsules.

9 **VII. CAUSES FOR DISCIPLINE**

10 **A. Safeway PHY 51192**

11 **First Cause for Discipline**
12 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
13 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
14 **Health and Safety Code section 111440**

15 25. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
16 if fully set forth.

17 26. Respondent Safeway has subjected its Original Permit No. PHY 51192 to
18 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
19 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 28,693
20 domperidone capsules were compounded at respondent Safeway PHY 51192.

21 **Second Cause for Discipline**
22 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
23 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
24 **Health and Safety Code section 111440**

25 27. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
26 if fully set forth.

27 28. Respondent Safeway has subjected its Original Permit No. PHY 51192 to
28 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
(Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
Respondent Safeway PHY 51192 dispensed approximately 374 prescriptions for domperidone

1 totaling approximately 28,693 capsules.

2 **B. Safeway PHY 52537**

3 **Third Cause for Discipline**
4 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
5 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
6 **Health and Safety Code section 111440**

7 29. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
8 if fully set forth.

9 30. Respondent Safeway has subjected its Original Permit No. PHY 52537 to
10 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
11 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 16,263
12 domperidone capsules were compounded at respondent Safeway PHY 52537.

13 **Fourth Cause for Discipline**
14 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
15 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
16 **Health and Safety Code section 111440**

17 31. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
18 if fully set forth.

19 32. Respondent Safeway has subjected its Original Permit No. PHY 52537 to
20 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
21 (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
22 Respondent Safeway PHY 52537 dispensed approximately 39 prescriptions for domperidone
23 totaling approximately 16,263 capsules.

24 **C. Safeway PHY 53416**

25 **Fifth Cause for Discipline**
26 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
27 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
28 **Health and Safety Code section 111440**

33. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
if fully set forth.

34. Respondent Safeway has subjected its Original Permit No. PHY 53416 to

1 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
2 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 942
3 domperidone capsules were compounded at respondent Safeway PHY 53416.

4 **Sixth Cause for Discipline**
5 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
6 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
7 **Health and Safety Code section 111440**

8 35. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
9 if fully set forth.

10 36. Respondent Safeway has subjected its Original Permit No. PHY 53416 to
11 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
12 (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
13 Respondent Safeway PHY 53416 dispensed approximately 10 prescriptions for domperidone
14 totaling approximately 942 capsules.

15 **D. Castaldo**

16 **Seventh Cause for Discipline**
17 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
18 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
19 **Health and Safety Code section 111440**

20 37. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
21 if fully set forth.

22 38. Respondent Castaldo has subjected his original pharmacist license to discipline for
23 the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301,
24 subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded
25 domperidone.

26 **Eighth Cause for Discipline**
27 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
28 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
Health and Safety Code section 111440

39. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
if fully set forth.

1 E. Muir

2 **Eleventh Cause for Discipline**
3 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
4 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
5 **Health and Safety Code section 111440**

6 45. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
7 if fully set forth.

8 46. Respondent Muir has subjected her original pharmacist license to discipline for the
9 unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301, subd.
10 (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded domperidone.

11 **Twelfth Cause for Discipline**
12 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
13 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
14 **Health and Safety Code section 111440**

15 47. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
16 if fully set forth.

17 48. Respondent Muir has subjected her original pharmacist license to discipline for the
18 unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. & Prof.
19 Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent Muir
20 dispensed and verified approximately 161 prescriptions for domperidone totaling approximately
21 16,813 capsules.

22 **Thirteenth Cause for Discipline**
23 **Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or**
24 **Corresponding Responsibility**
25 **Business and Professions Code sections 4301, 4306.5, subdivision (b)**

26 49. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
27 if fully set forth.

28 50. Respondent Muir has subjected her original pharmacist license to discipline for the
unprofessional conduct of failing to exercise or implement her best professional judgment or
corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs (Bus.
& Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent compounded, dispensed, and verified

1 prescriptions for domperidone.

2 **F. Stephanos**

3 **Fourteenth Cause for Discipline**
4 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
5 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
6 **Health and Safety Code section 111440**

7 51. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
8 if fully set forth.

9 52. Respondent Stephanos has subjected her original pharmacist license to discipline
10 for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. &
11 Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent
12 Stephanos dispensed and verified 72 prescriptions for domperidone totaling approximately 7,725
13 capsules.

14 **Thirteenth Cause for Discipline**
15 **Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or**
16 **Corresponding Responsibility**
17 **Business and Professions Code sections 4301, 4306.5, subdivision (b)**

18 53. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
19 if fully set forth.

20 54. Respondent Stephanos has subjected her original pharmacist license to discipline
21 for the unprofessional conduct of failing to exercise or implement her best professional judgment
22 or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs
23 (Bus. & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent dispensed and verified prescriptions
24 for domperidone.

25 **VIII. OTHER DISCIPLINARY CONSIDERATIONS**

26 55. To determine the degree of discipline, if any, to be imposed on Original Permit
27 No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626,
28 complainant alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60059
against Original Permit No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a.
Safeway Pharmacy #4626. The citation assessed a civil penalty of \$1,000 against respondent

1 Safeway for not maintaining its location so that drugs are properly maintained, secured, and
2 distributed (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subd. (b)). An
3 audit revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Safeway
4 appealed the citation. Respondent Safeway withdrew its request for appeal on August 19, 2015,
5 and paid the citation.

6 56. To determine the degree of discipline, if any, to be imposed on Original
7 Pharmacist License No. RPH 31324 issued to respondent John Vincent Castaldo, complainant
8 alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60060 against
9 respondent Castaldo's original pharmacist license. The citation assessed a civil penalty of \$1,000
10 for not effectively controlling against theft or diversion of dangerous drugs, and the records for
11 those drugs, as the pharmacist-in-charge (Cal. Code Regs., tit. 16, § 1714, subd. (d)). An audit
12 revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Castaldo
13 appealed the citation. Respondent Castaldo withdrew his request for appeal on August 14, 2015,
14 and paid the citation.

15 IX. PRAYER

16 WHEREFORE, complainant requests that a hearing be held on the matters alleged in this
17 accusation, and that following the hearing, the Board of Pharmacy issues a decision:

18 1. Revoking or suspending Original Permit No. PHY 52537 issued to respondent
19 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;

20 2. Revoking or suspending Original Permit No. PHY 53416 issued to respondent
21 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;

22 3. Revoking or suspending Original Permit No. PHY 51192 issued to respondent
23 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626;

24 4. Revoking or suspending Original Pharmacist License No. RPH 31324 issued to
25 respondent John Vincent Castaldo;

26 5. Revoking or suspending Original Pharmacist License No. RPH 39228 issued to
27 respondent Karen Lyn Muir;

28 6. Revoking or suspending Original Pharmacist License No. RPH 61981 issued to

1 respondent Christine Moheb Stephanos;

2 7. Ordering respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905,
3 under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable
4 costs of the investigation and enforcement of this case;

5 8. Ordering respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626,
6 under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable
7 costs of the investigation and enforcement of this case;

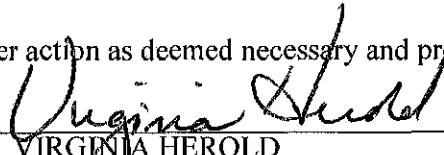
8 9. Ordering respondent John Vincent Castaldo under Business and Professions Code
9 section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and
10 enforcement of this case;

11 10. Ordering respondent Karen Lyn Muir under Business and Professions Code
12 section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and
13 enforcement of this case;

14 11. Ordering respondent Christine Moheb Stephanos under Business and Professions
15 Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and
16 enforcement of this case; and

17 12. Taking such other and further action as deemed necessary and proper.

18 DATED: 12/22/15


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

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