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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 Statement of Issues
12 Against:

Case No. 5266

13 **COMMUNITY INFUSION SERVICES**
14 **INC., DBA CDM DRUGS**

STATEMENT OF ISSUES

15 **CHAD TRENOR KEARNS, President and**
16 **Owner**

17 **Licensed Sterile Compounding License**
18 **Applicant**

Respondent.

19
20 Complainant alleges:

21 **PARTIES**

22 1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official
23 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

24 2. On or about July 3, 2002, the Board issued Pharmacy Permit Number PHY 46007 to
25 Community Infusion Services, Inc., doing business as CDM Drugs (Respondent) with Chad
26 Trenor Kearns designated as the Pharmacist-in-Charge, Owner and President. The Pharmacy
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28

1 Permit was in full force and effect at all times relevant to the charges brought herein and will
2 expire on July 1, 2015, unless renewed.

3 3. On or about June 11, 2014, the Board of Pharmacy, Department of Consumer Affairs
4 received an application for a Licensed Sterile Compounding License from Respondent. On or
5 about June 2, 2014, the President and Pharmacist-in-Charge of Respondent, Chad Trenor Kearns,
6 certified under penalty of perjury to the truthfulness of all statements, answers, and
7 representations in the application. The Board denied the application on June 24, 2014.

8 JURISDICTION

9 4. This Statement of Issues is brought before the Board of Pharmacy (Board),
10 Department of Consumer Affairs, under the authority of the following laws. All section
11 references are to the Business and Professions Code unless otherwise indicated.

12 5. Section 4300 (c), of the Code states:

13 The board may refuse a license to any applicant guilty of unprofessional
14 conduct. The board may, in its sole discretion, issue a probationary license to any
15 applicant for a license who is guilty of unprofessional conduct and who has met all
16 other requirements for licensure. . . .

17 STATUTORY PROVISIONS

18 6. Section 480 of the Code states, in pertinent part:

19 (a) A board may deny a license regulated by this code on the grounds that the
20 applicant has one of the following:

21 ...

22 (3) Done any act which if done by a licentiate of the business or profession in
23 question, would be grounds for suspension or revocation of license.

24 7. Section 4022 of the Code states:

25 Dangerous drug" or "dangerous device" means any drug or device unsafe for
26 self-use in humans or animals, and includes the following:

27 (a) Any drug that bears the legend: "Caution: federal law prohibits
28 dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this
device to sale by or on the order of a _____," "Rx only," or words of similar import,
the blank to be filled in with the designation of the practitioner licensed to use or
order use of the device.

1 (c) Any other drug or device that by federal or state law can be lawfully
dispensed only on prescription or furnished pursuant to Section 4006.

2 8. Section 4076(a)(7) of the Code states:

3 A pharmacist shall not dispense any prescription except in a container that
4 meets the requirements of state and federal law and is correctly labeled with all of the
following:

5

6 The strength of the drug or drugs dispensed.

7 9. Section 4113, subdivision (c) of the Code states:

8 The pharmacist-in-charge shall be responsible for a pharmacy's compliance with
9 all state and federal laws and regulations pertaining to the practice of pharmacy.

10 10. Section 4127.7 of the Code states:

11 On or after July 1, 2005, a pharmacy shall compound sterile injectable products
12 from one or more nonsterile ingredients in one of the following environments:

13 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The
cleanroom must have a positive air pressure differential relative to adjacent areas.

14 (b) An ISO class 5 cleanroom.

15 (c) A barrier isolator that provides an ISO class 5 environment for
16 compounding.

17 11. Section 4301 of the Code states in pertinent part:

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

21

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

24

25 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
26 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
27 pharmacy, including regulations established by the board or by any other state or
federal regulatory agency.
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12. Section 4302 of the Code states:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

13. Section 4306.5 of the Code states, in pertinent part:

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

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

....

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

14. Section 4342(a) of the Code states:

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

REGULATORY PROVISIONS

15. Title 16, California Code of Regulations, section 1735 (a) states in pertinent part:

“Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
-

1 16. Title 16, California Code of Regulations, section 1735.2 (d), (e) and (h) states:

2 (d) A drug product shall not be compounded until the pharmacy has first
3 prepared a written master formula record that includes at least the following elements:

- 4 (1) Active ingredients to be used.
5 (2) Equipment to be used.
6 (3) Expiration dating requirements.
7 (4) Inactive ingredients to be used.
8 (5) Process and/or procedure used to prepare the drug.
9 (6) Quality reviews required at each step in preparation of the drug.
10 (7) Post-compounding process or procedures required, if any.

11 (e) Where a pharmacy does not routinely compound a particular drug product,
12 the master formula record for that product may be recorded on the prescription
13 document itself.

14 ...

15 (h) Every compounded drug product shall be given an expiration date
16 representing the date beyond which, in the professional judgment of the pharmacist
17 performing or supervising the compounding, it should not be used. This "beyond use
18 date" of the compounded drug product shall not exceed 180 days from preparation or
19 the shortest expiration date of any component in the compounded drug product,
20 unless a longer date is supported by stability studies of finished drugs or compounded
21 drug products using the same components and packaging. Shorter dating than set forth
22 in this subsection may be used if it is deemed appropriate in the professional
23 judgment of the responsible pharmacist.

24

25 17. Title 16, California Code of Regulations, section 1735.3 (a), (b) and (c), states:

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

- 27 (1) The master formula record.
28 (2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer, expiration date and lot number of each component. If the
manufacturer name is demonstrably unavailable, the name of the supplier may be

1 substituted. Exempt from the requirements in this paragraph are sterile products
2 compounded on a one-time basis for administration within seventy-two (72) hours
3 and stored in accordance with standards for "Redispensed CSPS" found in Chapter
4 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th
5 Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in
6 a health care facility licensed under section 1250 of the Health and Safety Code.

7 (7) A pharmacy assigned reference or lot number for the compounded drug
8 product.

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

10 (9) The quantity or amount of drug product compounded.

11 (b) Pharmacies shall maintain records of the proper acquisition, storage, and
12 destruction of chemicals, bulk drug substances, drug products, and components used
13 in compounding.

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

20 ...

21 18. Title 16, California Code of Regulations, section 1735.4 (b) states:

22 A statement that the drug has been compounded by the pharmacy shall be
23 included on the container or on the receipt provided to the patient.

24 19. Title 16, California Code of Regulations, section 1735.5 states:

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

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

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any
changes in processes or to the policy and procedures manual

(2) Documentation of a plan for recall of a dispensed compounded drug product
where subsequent verification demonstrates the potential for adverse effects with
continued use of a compounded drug product;

(3) The procedures for maintaining, storing, calibrating, cleaning, and
disinfecting equipment used in compounding, and for training on those procedures as
part of the staff training and competency evaluation process.

1 (4) Documentation of the methodology used to test integrity, potency, quality,
and labeled strength of compounded drug products.

2 (5) Documentation of the methodology used to determine appropriate
3 expiration dates for compounded drug products.

4 20. Title 16, California Code of Regulations, section 1735.6 (a) states:

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

9 21. Title 16, California Code of Regulations, section 1735.7 (a) states:

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

14 22. Title 16, California Code of Regulations, section 1735.8 (a) states:

15 Any pharmacy engaged in compounding shall maintain, as part of its written
16 policies and procedures, a written quality assurance plan designed to monitor and
17 ensure the integrity, potency, quality, and labeled strength of compounded drug
18 products.

19 23. Title 16, California Code of Regulations, section 1751 (b)(4) states:

20 (b) Any pharmacy compounding sterile injectable drug products shall have a
21 designated area for the preparation of sterile injectable products which shall meet the
22 following standards:

23

24 (4) Be certified annually by a qualified technician who is familiar with the
25 methods and procedures for certifying laminar air flow hoods and clean room
26 requirements, in accordance with standards adopted by the United States General
27 Services Administration. Certification records must be retained for at least 3 years.

28 24. Title 16, California Code of Regulations, section 1751.4 (d) states:

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

25 25. Title 16, California Code of Regulations, section 1751.6 (e)(1) states:

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

28 (1) The pharmacy must establish and follow a written program of training and
performance evaluation designed to ensure that each person working in the designated
area has the knowledge and skills necessary to perform their assigned tasks properly.

1 This program of training and performance evaluation must address at least the following:

- 2 (A) Aseptic technique.
- 3 (B) Pharmaceutical calculations and terminology.
- 4 (C) Sterile product compounding documentation.
- 5 (D) Quality assurance procedures.
- 6 (E) Aseptic preparation procedures.
- 7 (F) Proper gowning and gloving technique.
- 8 (G) General conduct in the controlled area.
- 9 (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- 10 (I) Sterilization techniques.
- 11 (J) Container, equipment, and closure system selection.

12 26. Title 16, California Code of Regulations, section 1751.7 (b) and (c) states:

13 (b) Each individual involved in the preparation of sterile injectable products
14 must first successfully complete a validation process on technique before being
15 allowed to prepare sterile injectable products. The validation process shall be carried
16 out in the same manner as normal production, except that an appropriate
17 microbiological growth medium is used in place of the actual product used during
18 sterile preparation. The validation process shall be representative of all types of
19 manipulation, products and batch sizes the individual is expected to prepare. The
20 same personnel, procedures, equipment, and materials must be involved. Completed
21 medium samples must be incubated. If microbial growth is detected, then the sterile
preparation process must be evaluation, corrective action taken, and the validation
process repeated. Personnel competency must be revalidated at least every twelve
months, whenever the quality assurance program yields an unacceptable result, when
the compounding process changes, equipment used in the compounding of sterile
injectable drug products is repaired or replaced, the facility is modified in a manner
that affects airflow or traffic patterns, or whenever improper aseptic techniques are
observed. Revalidation must be documented.

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

24 DRUGS

25 27. Sodium Phosphorous is a dangerous drug pursuant to Business and Professions Code
26 section 4022.

1 28. Potassium Phosphorous is a dangerous drugs pursuant to Business and Professions
2 Code section 4022.

3 29. Calcium Gluconate is a dangerous drugs pursuant to Business and Professions Code
4 section 4022.

5 30. Sodium Chloride is a dangerous drugs pursuant to Business and Professions Code
6 section 4022.

7 **FACTUAL ALLEGATIONS**

8 31. Since July 3, 2002, Chad Kearns has been the owner, officer and Pharmacist-in-
9 Charge of Respondent.

10 32. On April 20, 2012, the Board notified Respondent that it needed to maintain records
11 of: (1) training and ongoing competence for the staff who were compounding drugs and (2)
12 cleaning logs for the sterile compounding area. The Board issued a notice of correction to
13 Respondent for its failure to identify drug products as compounded on their labels.

14 33. In 2013 and 2014, Respondent compounded and sold Total Parenteral Nutrition
15 (TPN) sterile injectable drug products which contained the following dangerous drug components
16 or ingredients, sodium phosphorous, potassium phosphorous, ascorbic folic acid, calcium
17 gluconate or sodium chloride.

18 34. From June 24, 2013 through April 22, 2014, Respondent compounded sterile
19 injectable batch products of sodium phosphate, potassium phosphate, calcium gluconate and
20 concentrated sodium chloride from non-sterile sources and added them to the TPN sterile
21 injectable drug products without compounding those dangerous drug products in either: (a) an
22 ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure
23 differential relative to the adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that
24 provides an ISO class 5 environment for compounding.

25 35. From June 24, 2013 through March 4, 2014, Respondent utilized a horizontal laminar
26 flow hood to compound TPN sterile injectable drug products. However, the horizontal laminar
27 flow hood used to compound those sterile injectable drug products had not been certified since
28 March 29, 2012, by a qualified technician who was familiar with the methods and procedures for

1 certifying laminar air flow hoods and clean room requirements in accordance with standards
2 adopted by the United States General Services Administration.

3 36. Respondent did not disinfect hard surfaces in the designated compounding area
4 weekly and after any unanticipated event that could increase risk of contamination.

5 37. Respondent did not possess records showing that it had conducted documented end
6 product testing to confirm sterility and acceptable levels of pyrogens for the components
7 compounded from non-sterile ingredients which were used to compound TPN sterile injectable
8 drug products. Respondent did not conduct that testing or quarantine the ingredients until the end
9 product testing confirmed sterility and acceptable levels of pyrogens. Respondent also failed to
10 produce and maintain documentation of the methodology used to test integrity, potency, quality
11 and strength of compounded drug products.

12 38. Respondent did not possess training records, performance evaluations or records
13 showing each individual involved in the preparation of sterile injectable drug products
14 successfully completed a validation process on technique before being allowed to prepare sterile
15 injectable drug products. Individuals involved in the preparation of sterile injectable drug
16 products did not successfully complete a validation process on technique before being allowed to
17 prepare sterile injectable drug products.

18 39. Similarly, Respondent did not possess updated compounding policies and procedures,
19 a compounding quality assurance plan or documentation of facilities and equipment for
20 compounding. The policy and procedure manual was not reviewed on an annual basis by the
21 pharmacist-in-charge and not updated whenever changes in processes were implemented.

22 40. Respondent did not possess complete compounding records identifying all individuals
23 who compounded the TPN sterile injectable drug products and the dates that those drug products
24 were compound by them. Additionally, Respondent did not record the lot numbers and expiration
25 dates for the dangerous drug components which were made from non-sterile sources. Also, there
26 was a variance between the compounding records for TPN sterile injectable drug products in that
27 the compounding record stated RX number 1144 contained 15 ml of potassium phosphate while
28 the worksheets stated that they contained 4 ml of sodium phosphate and RX number 711

1 contained 4 ml of potassium phosphate while the worksheet stated that it contained 25 ml of
2 sodium phosphate. Moreover, Respondent did not possess and produce the prescriptions with the
3 master formulas recorded on them for TPN sterile injectable drug products compounded by them.

4 41. Respondent did not accurately label certain TPN sterile injectable drug products in
5 that they were labeled as containing 15 ml of potassium phosphate, but actually contained 4ml of
6 sodium phosphate.

7 42. In or about March 2014, Respondent maintained numerous expired dangerous drugs
8 on the shelves of the pharmacy, including bulk quantities of the dangerous drug components used
9 to compound drugs.

10 43. Respondent assigned a beyond use date of 365 days for a topical gel compounded by
11 them (Rx number 132517) without adequate testing to support that beyond use date.
12 Additionally, calcium gluconate compounded from a non sterile source and used in the TPN
13 sterile injectable drug products was assigned beyond use dates of 365 days without adequate
14 testing to support those beyond use dates.

15 44. Respondent did not record that a topical gel (Rx number 132517) was compounded on
16 the label of the container when it had been compounded by Respondents.

17 45. On March 4, 2014, Chad Kearns informed the Board that he did not compound any
18 sterile injectable drug products from non-sterile components when he had done so. On May 2,
19 2014, Chad Kearns informed the Board that he had purchased sterile dangerous drug components
20 to compound the TPN sterile injectable drug products when he had in fact compounded those
21 components from non-sterile sources. Chad Kearns also informed the Board that he had
22 purchased an injectable ascorbic acid product from two manufacturers when he had not purchased
23 that product from them.

24 **FIRST CAUSE FOR DENIAL**

25 **(Inadequate Record-Keeping)**

26 46. Respondent's application is subject to denial under Code sections 480(a)(3) and
27 4301(o), for violating Pharmacy Law and regulations, as set forth in paragraphs 31 through 45,
28 which are incorporated herein by reference and as described below:

- 1 a. California Code of Regulations, title 16, sections 1735.7(a) and 1751.6(e)(1):
2 Failure to maintain training records for compounding staff.
- 3 b. California Code of Regulations, title 16, section 1735.5(a): Failure to
4 maintain current written policies and procedures for compounding.
- 5 c. California Code of Regulations, title 16, section 1735.5(b): Failure to
6 review policy and procedures manual on an annual basis and update it.
- 7 d. California Code of Regulations, title 16, section 1735.6(a): Failure to
8 maintain written documentation of facilities and equipment for compounding.
- 9 e. California Code of Regulations, title 16, section 1735.8(a): Failure to
10 maintain a compounding quality assurance plan.
- 11 f. California Code of Regulations, title 16, section 1735.5(c)(4): Failure to
12 produce and maintain documentation of the methodology used to test integrity, potency, quality,
13 and labeled strength of compounded drug products.
- 14 g. California Code of Regulations, title 16, section 1735.3: Failure to produce
15 and maintain complete records or any records of compounded drugs, including failing to record
16 the lot number, the expiration date of all components, the pharmacist who verified the
17 compounded drugs and the identity of the pharmacy staff who compounded the drug product.
- 18 h. California Code of Regulations, title 16, section 1735.2(d) and (e): Failure
19 to produce and maintain current prescriptions with the master formulas recorded on them for TPN
20 sterile injectable drug products.
- 21 i. California Code of Regulations, title 16, section 1751.7(b) and (c): Failure
22 to produce and maintain records for each individual involved in the preparation of sterile
23 injectable drug products having completed a validation process on technique before being allowed
24 to compound sterile injectable drug products. Failure to produce and maintain records of end
25 product testing of batch-produced sterile injectable drug products compounded from one or more
26 non-sterile ingredients.

1 **SIXTH CAUSE FOR DENIAL**

2 **(Compounded Sterile Injectable Drugs in Uncertified Hood)**

3 51. Respondent's application is subject to denial under Code sections 480(a)(3) and
4 4301(o), for violating California Code of Regulations, title 16, section 1751(b)(4), in that in or
5 about June 2013 through March 2014, Respondent compounded sterile injectable drugs from non-
6 sterile ingredients, in a horizontal laminar flow hood that had not been certified since March
7 2012, as set forth in paragraphs 31 through 45, which are incorporated herein by reference.

8 **SEVENTH CAUSE FOR DENIAL**

9 **(Failure to Conduct End Product Testing for Sterile Injectable Drug Products)**

10 52. Respondent's application is subject to denial under Code sections 480(a)(3) and
11 4301(o), for violating title 16, California Code of Regulations, section 1751.7(c), in that it failed
12 to properly test sterile injectable drug products, as set forth in paragraphs 31 through 45, which
13 are incorporated herein by reference.

14 **EIGHTH CAUSE FOR DENIAL**

15 **(Failure to Properly Label Strength of Compounded Sterile Injectable Drugs)**

16 53. Respondent's application is subject to denial under Code sections 480(a)(3) and
17 4301(o), for violating Code section 4076(a)(7), in that it labeled TPN sterile injectable drug
18 product RX number 1144 as containing 15 ml of potassium phosphate when it actually contained
19 4 ml of sodium phosphate and TPN sterile injectable product RX number 711 as containing 4 ml
20 of potassium phosphate when it actually contained 25 ml of sodium phosphate, as set forth in
21 paragraphs 31 through 45, which are incorporated herein by reference.

22 **NINTH CAUSE FOR DENIAL**

23 **(Maintained Expired Dangerous Drugs on Shelves)**

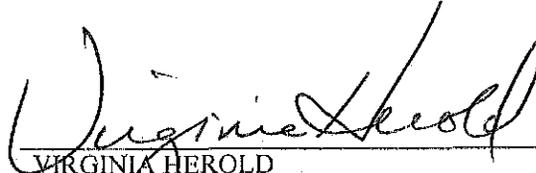
24 54. Respondent's application is subject to denial under Code sections 480(a)(3) and
25 4301(o), for violating Code section 4342(a), in that Respondent maintained expired dangerous
26 drugs on the shelves of the pharmacy, as set forth in paragraphs 31 through 45, which are
27 incorporated herein by reference.

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1. Denying the application of Community Infusion Services Inc., doing business as CDM Drugs for a Licensed Sterile Compounding License;
2. Taking such other and further action as deemed necessary and proper.

DATED: _____

1/7/15



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

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