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

In the Matter of the Statement of Issues Against: **EMERALD PHARMACY, LLC** **dba EMERALD PHARMACY** **JON PAUL LETKO, PRESIDENT** **Nonresident Pharmacy Permit Applicant** Respondent.	Case No. 6250 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

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

2. On or about June 7, 2016, the Board received an application for a Nonresident Pharmacy Permit from Emerald Pharmacy, LLC dba Emerald Pharmacy, Jon Paul Letko, President (Respondent). On or about June 1, 2016, Respondent's sole owner, Jon Paul Letko, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on August 25, 2017.

JURISDICTION

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

STATUTORY PROVISIONS

4. Section 480 of the Business and Professions Code ("Code") provides, in pertinent part:

> (a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:
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> . . .
>
> (3)(A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.
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> (B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made. . . .

5. Section 4081 of the Code states, in pertinent part:

> (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
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> (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section. . . .

6. Section 4300 of the Code states, in pertinent part that the board may refuse a license to any applicant guilty of unprofessional conduct.

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7. Section 4301 of the Code states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
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> . . .
>
> (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 licensee or otherwise, and whether the act is a felony or misdemeanor or not.
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> . . .
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> (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. . . .

8. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

HEALTH AND SAFETY CODE

9. Health and Safety Code section 11164 states, in pertinent part:

> Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
>
> (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
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> (1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
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> (2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the

prescription or maintain this information in a readily retrievable form in the pharmacy. . . .

REGULATORY PROVISIONS

10. Code of Federal Regulations, title 16, section 1701.1 states, in pertinent part:

(a) In order to assist manufacturers of prescription drugs in discharging their responsibilities under the act concerning such drugs that are distributed to pharmacies, the Consumer Product Safety Commission has codified this statement of its policy concerning which prescription drug packages supplied by manufacturers to pharmacies must comply with the "special" (child-resistant) packaging requirements contained in 16 CFR 1700.15.

. . .

(c) Manufacturers should also note that section 4(a) of the act (which allows a product to be marketed in noncomplying packaging of a single size under certain circumstances) does not apply to prescription drugs subject to section 4(b) of the act. Thus, since the section 4(a) single-size exemption for over-the-counter drugs and other household substances does not apply to prescription drugs, every unit of a prescription drug subject to a special packaging standard which is distributed to a pharmacy in a package intended by the manufacturer to be dispensed to a consumer shall be in special packaging. . . .

11. California Code of Regulations, title 16, section 1707.2 states:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)

(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

12. California Code of Regulations, title 16, section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

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13. California Code of Regulations, title 16, section 1761(a) states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription. . . ."

14. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

DANGEROUS DRUGS AND CONTROLLED SUBSTANCES

15. Lidocaine is a combination medication used to treat irritation, soreness, and itchiness from certain skin conditions (e.g., scrapes, minor burns, eczema, and insect bites). It is a dangerous drug under Code section 4022.

16. Diclofenac is a nonsteroidal anti-inflammatory drug. It is a dangerous drug under Code section 4022.

17. Omega-3 is a fish oil supplement that is issued by prescription. It is a dangerous drug under Code section 4022.

18. Oxycodone is an opioid pain medication. It is a Schedule II controlled substance under Code of Federal Regulations, title 21, section 1308.12(b)(1)(xiii), and California Health and Safety Code section 11055(b)(1)(M).

19. Norco is a brand name for the combination prescription drug acetaminophen/hydrocodone. It is used to treat moderate to severe pain. It is a Schedule II controlled substance under Code of Federal Regulations, title 21, section 1308.12(b)(vi), and California Health and Safety Code section 11055(b)(2).

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20. Ambien (zolpidem) is a sedative, also called a hypnotic. It is a Schedule IV controlled substance under Code of Federal Regulations, title 21, section 1308.14(c)(54), and California Health and Safety Code section 11057(d)(32).

21. Alprazolam is a benzodiazepine. It is used to treat anxiety disorders, panic disorders, and anxiety caused by depression. It is a Schedule IV controlled substance under Code of Federal Regulations, title 21, section 1308.14(c)(2), and California Health and Safety Code section 11057(d)(1).

FACTUAL BACKGROUND

22. Jon Paul Letko is CEO/President of the following businesses:

a. Global Healthcare Management, LLC, located in Milford, NJ

b. Keystone Choice Pharmacy, LLC, located in Easton, PA

c. Loyalton Pharmacy, located in Loyalton, CA

23. On or about September 16, 2016, the Board issued Original Permit No. PHY 54562 to Complete Pharmacy Services LLC, Sierra Nevada Pharmacy Holdings LLC, Melchor Wealth Management, Inc., Letko Asset Management LLC, and Loyalton Holding LLC to do business as Loyalton Pharmacy, with Jon Letko as president.

24. On or about June 1, 2017, the Board received an online complaint from S.E., a physician assistant with LifeLong Medical Care (LifeLong), a non-profit organization with health centers that provide primary health and dental care, pediatric, adult, and geriatric care, and chronic disease and HIV/AIDS treatment, located in Berkeley, California. According to the complaint, since late 2016, LifeLong staff received faxes and calls from various clinics and call centers requesting approval for fraudulent prescriptions, usually Lidocaine ointment. In every instance, the patient was a LifeLong patient and the prescribers had not prescribed Lidocaine ointment. The faxes were from Loyalton Pharmacy, USA Health Initiatives, Curexa, and Woods Pharmacy.

25. On or about June 26, 2017, Board Inspector P.P. spoke with physician assistant S.E. S.E. stated that the callers said they were from Loyalton Pharmacy and requested prescriptions for

Lidocaine ointment, sometimes patches. A couple of the callers said they were from Global Healthcare. LifeLong rarely prescribes Lidocaine.

26. On or about July 6, 2017, Board Inspector P.P. conducted an inspection of Loyalton Pharmacy.

27. Loyalton Pharmacy's Pharmacist-in-Charge E.P. said that Global Healthcare advertised diabetic supplies on television and the internet. When asked how Loyalton Pharmacy received the prescriptions, E.P. first said Global Healthcare called the patients to approve Lidocaine prescriptions, then changed her answer to Loyalton Pharmacy calling the patients to approve Lidocaine prescriptions. E.P. said she did not know whether the patients had Lidocaine products prior to the calls, however she had no record of previous prescriptions having been issued at Loyalton Pharmacy.

28. Board Inspector P.P. investigated whether Loyalton Pharmacy maintained allergy information and physical addresses for its patients. From a patient list P.P. was using throughout her inspection, she discovered seven patients with no allergy information on file, and eight patients with no physical address on file. For this group of patients, P.P. discovered that Loyalton Pharmacy had dispensed the following controlled substances: Oxycodone 10mg, Norco 10/325mg, Norco 5/325mg, Ambien 10mg, Oxycodone ER 10mg, and Alprazolam 1mg. P.P. asked Pharmacist-in-Charge E.P. how she would know if these patients lived in the area, and E.P. stated she would not know, she just assumed the patients lived in or around Loyalton. When P.P. showed E.P. one of the prescriptions Norco 10 for a patient whose doctor was in Grass Valley, hours away from Loyalton Pharmacy, E.P. admitted she had not verified the prescription with the doctor.

29. During the inspection, Pharmacist-in-Charge E.P. provided Board Inspector P.P. with a list which described the process for dispensing prescription-only medication by Loyalton Pharmacy. According to this process, Keystone Choice Pharmacy, rather than Loyalton Pharmacy, would engage in prospective drug review, interventions, and patient counseling, and then create labels for prescriptions which would be overnight-mailed to Loyalton Pharmacy.

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30. Board Inspector P.P. conducted an audit of some of Loyalton Pharmacy's dangerous drugs which revealed the following:

Dangerous Drug	Beginning Inventory	Total Acquisitions	Ending Inventory	Total Disposition	Variance
Omega 3 1gm	19	96,169	0	75,870	20,299
Lidocaine 5% Ointment	0	1,894,550	88,270	1,817,029	77,521
Lido/ prolocaine 2.5%	0	327,600	510	301,650	25,950
Diclofenac 1.5 ml	0	64,800	11,250	61,800	3,000

31. After auditing Loyalton Pharmacy's inventory, Board Inspector P.P. spoke with Pharmacist-in-Charge E.P. regarding invoices for the dangerous drugs that P.P. audited. E.P. said she did not have invoices because they were sent "back east" so they would pay the invoices. E.P. acknowledged to P.P. that the invoices were to be kept in the pharmacy and stored for seven years.

32. Loyalton Pharmacy was unable to account for any of the variances (losses) identified by Board Inspector P.P.'s audit for Omega 3, Lidocaine 5% ointment, Lido/prolocaine 2.5%, and diclofenac.

33. On or about August 18, 2017, Pharmacist-in-Charge E.P. provided Board Inspector P.P. with audio records of Patient H.G. regarding how this patient obtained Lidocaine from Loyalton Pharmacy. In the first recording, H.G. called into a website to order a knee and back brace. In the second recording, H.G. spoke with a representative from Global Healthcare, where H.G. again indicated an interest in knee and back braces. The Global Healthcare representative solicited H.G. to obtain Lidocaine and diclofenac topicals for pain. H.G. told the Global

Healthcare representative that she was taking Ibuprofen. The Global Healthcare representative told H.G. there was no problem using Lidocaine and diclofenac with the medications H.G. was on. The Global Healthcare representative told H.G. that Loyalton Pharmacy would be giving H.G. the prescriptions and gave H.G. Loyalton Pharmacy's customer service number.

34. Diclofenac external and Ibuprofen oral are in the steroidal anti-inflammatory agents class and may represent a therapeutic duplication. They have potentially severe life-threatening reaction/interaction which may cause deterioration in the patient's clinical status. Administration of diclofenac sodium external should be used with extreme caution in geriatric patients.

35. After receiving the audio recordings, Board Inspector P.P. spoke with Pharmacist-in-Charge E.P. E.P admitted that she never called and consulted with Patient H.G. on the use of Lidocaine or diclofenac. E.P. admitted that no one from Loyalton Pharmacy called H.G. to obtain a medication history. E.P. admitted that she did not check H.G.'s medication history for drug interactions or use in the elderly.

36. At the conclusion of her investigation, Board Inspector P.P. determined that Global Healthcare used a call-in request for knee and back braces to obtain the callers' medical information and to solicit prescriptions from the callers' prescribers. Loyalton Pharmacy then used the information Global Healthcare obtained to solicit prescriptions from the callers' prescribers when the callers had not been issued the prescriptions previously.

Patient H.G.

37. On or about February 21, 2017, Board Inspector P.P. received a complaint from Patient H.G. H.G. alleged that she had received Lidocaine from Loyalton Pharmacy without any notification from her doctor that such a prescription was issued. The prescription was issued on or about December 7, 2016.

38. During Board Inspector P.P.'s July 6, 2017 inspection of Loyalton Pharmacy, she conducted an investigation regarding Loyalton Pharmacy's issuance of Lidocaine to Patient H.G.

39. Pharmacist-in-Charge E.P. stated that she could not find the prescription for Lidocaine for Patient H.G. Loyalton Pharmacy never provided this prescription to Board Inspector P.P., after being requested to do so.

Patient P.G.

40. On or about February 23, 2017, the Board received a complaint regarding Patient P.G.'s receipt of prescription medications from Loyalton Pharmacy which P.G. contended were not authorized by his doctor. P.G. lived in Claremont, CA, approximately 500 miles away from Loyalton Pharmacy.

41. During Board Inspector P.P.'s July 6, 2017 inspection of Loyalton Pharmacy, she conducted an investigation regarding Loyalton Pharmacy's issuance of prescription medication to Patient P.G.

42. While reviewing Patient P.G.'s profile with Pharmacist G.S., it was determined that on or about January 16, 2017, Loyalton Pharmacy issued Patient P.G. Lidocaine 5% ointment. Pharmacist G.S. was unable to retrieve any prescription for P.G.

43. On or about August 18, 2017, Board Inspector P.P. spoke with Pharmacist-in-Charge E.P. regarding the Lidocaine prescription that was issued to Patient P.G. Pharmacist-in-Charge E.P. admitted that she did not consult with P.G. on the use of Lidocaine or diclofenac, that no one from Loyalton Pharmacy called P.G. to obtain a medication history, and that E.P. did not check P.G.'s medication history for drug interactions or use in the elderly.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Commission of Acts of Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

44. Respondent's application is subject to denial under section 480, subdivision (a)(3) of the Code as follows:

45. Loyalton Pharmacy, for which Respondent's president, Jon Paul Letko, is also president and CEO, violated Code section 4301, subdivision (f), in that between September 16, 2016 and July 6, 2017, Loyalton Pharmacy committed acts of unprofessional conduct as follows:

a. Could not account for the losses of Omega-3, Lidocaine 5% ointment, diclofenac 1.5% solution, and Lidocaine/prilocaine 2.5% cream.

b. Pharmacist-in-Charge E.P. had no relationship with most of the patients who received Omega-3, Lidocaine 5% ointment, Lidocaine/prilocaine 2.5% cream, and diclofenac 1.5% solution. E.P. did not know how the prescriptions were obtained nor was she aware that Loyalton

Pharmacy obtained the prescriptions by solicitation of prescribers when patients were not on the prescriptions previously.

c. Failed to keep, store, and provide invoices to show purchases of Omega-3, Lidocaine 5% ointment, Lidocaine/prilocaine 2.5% cream, and diclofenac 1.5% solution.

d. Failed to obtain addresses of patients who received Schedule II through IV controlled substances, thereby increasing the risk of drug diversion.

e. The facts and circumstances are described with more particularity in paragraphs 27-28 and 30-36, above.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Violation of Federal and State Laws and Regulations Governing Pharmacy)

46. Respondent's application is subject to denial under section 480, subdivision (a)(3) of the Code as follows.

47. Loyalton Pharmacy, for which Respondent's president, Jon Paul Letko, is also president and CEO, violated Code section 4301, subdivision (o), as follows:

a. Failed to obtain physical addresses on prescriptions written for controlled substances, in violation of Health and Safety Code section 11164, subdivision (a)(2).

b. Failed to obtain allergy information for up to fifty percent of its patients prior to dispensing dangerous drugs, which could result in serious adverse reactions to patients, in violation of Code of Federal Regulations, title 16, section 1701.1, subdivision (a).

c. Loyalton Pharmacy entered into an agreement with Keystone Choice Pharmacy, located in Easton, PA, and for which Jon Paul Letko is also president and CEO, to conduct drug review, interventions, and patient counseling for prescriptions obtained for Loyalton Pharmacy, in violation of California Code of Regulations, title 16, section 1707.2.

d. Loyalton Pharmacy dispensed a prescription for Lidocaine 5% ointment without first verifying the legitimacy of the prescription, which was sent to Loyalton Pharmacy from Global Healthcare, in violation of California Code of Regulations, title 16, section 1761, subdivision (a).

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e. Loyalton Pharmacy dispensed a prescription for Lidocaine 5% ointment without first verifying the legitimacy of the prescription, which was sent to Loyalton Pharmacy from Global Healthcare, in violation of California Code of Regulations, title 16, section 1761, subdivision (a).

f. The facts and circumstances are described with more particularity in paragraphs 22-43, above.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Failure to Maintain Records and Inventory)

48. Respondent's application is subject to denial under section 480, subdivision (a)(3) of the Code as follows.

49. Loyalton Pharmacy, for which Respondent's president, Jon Paul Letko, is also president and CEO, violated Code section 4081, subdivisions (a) and (b) as follows:

a. Failed to maintain invoices for dangerous drugs, in violation of California Code of Regulations, title 16, section 1718.

b. Failed to have complete accountability for all dangerous drugs, in violation of Code section 4332 and California Code of Regulations, title 16, section 1718.

c. The facts and circumstances are described with more particularity in paragraphs 30-32, above.

FOURTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

50. Respondent's application is subject to denial under section 4300 of the Code in that Respondent's sole owner and president, Jon Paul Letko, committed unprofessional conduct. The facts and circumstances are described with more particularity in paragraphs 22-43, above.

PRAYER

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

1. Denying the application of Emerald Pharmacy, LLC dba Emerald Pharmacy for a Nonresident Pharmacy Permit; and,

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

DATED: 1/16/18

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

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