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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: **CALMEX SPECIAL SERVICES, INC., DBA CAL-MEX PHARMACY,** Respondent.	Case No. 4009 **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.

2. On or about June 25, 2010, the Board of Pharmacy, Department of Consumer Affairs received an application for a pharmacy permit from Calmex Special Services, Inc., dba Cal-Mex Pharmacy (Respondent). On or about June 15, 2010, Olugbenga S. Oduyale, President of Cal-Mex Special Services, Inc. (Cal-Mex); Anna Murillo, Secretary of Cal-Mex; and Oluwatoyin Oduyale, Cal-Mex Board Member; each certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. Olugbenga S. Oduyale indicated on the application that he will be the Pharmacist-in-Charge of Cal-Mex Pharmacy. The Board denied the application on November 22, 2010.

JURISDICTION

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

4. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, section 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, section 11000 et seq.].

5. Section 4300 of the Code states, in pertinent part:

. . .

> (c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:
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> (1) Medical or psychiatric evaluation.
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> (2) Continuing medical or psychiatric treatment.
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> (3) Restriction of type or circumstances of practice.
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> (4) Continuing participation in a board-approved rehabilitation program.
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> (5) Abstention from the use of alcohol or drugs.
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> (6) Random fluid testing for alcohol or drugs.
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> (7) Compliance with laws and regulations governing the practice of pharmacy.

STATUTORY PROVISIONS

6. Section 475 of the Code states, in pertinent part:

> (a) Notwithstanding any other provisions of this code, the provisions of this division shall govern the denial of licenses on the grounds of:
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> (1) Knowingly making a false statement of material fact, or knowingly omitting to state a material fact, in an application for a license.
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> (2) Conviction of a crime.
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> (3) Commission of any act involving dishonesty, fraud or deceit with the intent to substantially benefit himself or another, or substantially injure another.

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

7. Section 480 of the Code states, 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:

. . . .

(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.

8. Section 4022 states:

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

(a) Any drug that bears the legend: "Caution: federal law prohibits 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.

(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.

9. Section 4059.5 states, in pertinent part:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.

. . . .

10. Section 4076 states, in pertinent part:

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

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the

principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

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11. Section 4081 states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food animal drug retailer, 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.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food animal drug retailer shall be jointly responsible, with the pharmacist in charge or representative-in-charge, for maintaining the records and inventory described in this section. . . .

12. Section 4125 states:

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

13. Section 4169 provides in pertinent part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

. . . .

(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.

. . . .

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

14. 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 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.

15. 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.

REGULATIONS

16. Section 1711 of the California Code of Regulations, Title 16, (CCR) states, in pertinent part:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

. . . .

17. Section 1718 of the California Code of Regulations, Title 16, (CCR) states:

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.

18. Section 1769 of the California Code of Regulations, Title 16, (CCR) states, in pertinent part:

(a) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

19. Section 1304.04 of the Code of Federal Regulations, Title 21, (CFR) sets forth the DEA requirements for the maintenance and inventories of controlled substances and states, in pertinent part:

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

20. Section 1304.11 of the Code of Federal Regulations, Title 21, (CFR) sets forth the DEA inventory requirements for controlled substances and states, in pertinent part:

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

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COST RECOVERY

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

DRUGS

22. Floxin is a dangerous drug pursuant to Business and Professions Code section 4022.

23. Levaquin is a dangerous drug pursuant to Business and Professions Code section 4022.

24. Naproxen is a dangerous drug pursuant to Business and Professions Code section 4022.

25. Viagra is a dangerous drug pursuant to Business and Professions Code section 4022.

26. Vicodin, a brand name for hydrocodone, is a Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(4), and is a dangerous drug pursuant to Business and Professions Code section 4022.

27. Xanax, a brand name for alprazolam, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(1), and is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTS

28. The President of Respondent Cal-Mex, Olugbenga Solomon Oduyale, is a licensed pharmacist. On or about August 8, 1989, the Board of Pharmacy issued original pharmacist license number RPH 42719 to Olugbenga Solomon Oduyale. The license will expire on October 31, 2012, unless renewed.

29. From approximately March of 1997 until approximately January of 2003, Olugbenga Solomon Oduyale worked as the Pharmacist-in-Charge at Rite-Aid Pharmacy in Calexico, California (Calexico Rite-Aid.)

30. On or about December 31, 2002, just after midnight, Olugbenga Solomon Oduyale was observed by a California Highway Patrol (CHP) Officer driving erratically, drifting across

lanes of traffic. The Officer pulled Olugbenga Solomon Oduyale over and observed a wooden billyclub and two brown prescription bottles without prescription labels on them in his car. Olugbenga Solomon Oduyale was in possession of the controlled substances Vicodin and Xanax illegally without a valid prescription and the controlled substances were in containers without proper labeling. Olugbenga Solomon Oduyale was arrested for possession of controlled substances and a dangerous weapon.

31. Once Olugbenga Solomon Oduyale was arrested, the officer searched Olugbenga Solomon Oduyale and found more prescription medicines which were identified as Viagra, Floxin, Naproxen, and Levaquin. Olugbenga Solomon Oduyale also had $968.00 in cash in his pocket and $3,734.00 in cash in the trunk of his car.

32. From approximately January of 2003 until approximately March of 2005, Olugbenga Solomon Oduyale worked as the Pharmacist-in-Charge at Palo Verde Hospital Pharmacy (PVH Pharmacy) in Blythe, California.

33. On or about March 11, 2004, the Board conducted an inspection of PVH Pharmacy. The inspection revealed that Olugbenga Solomon Oduyale failed to keep accurate and complete records of the acquisition and disposition of controlled substances at PVH Pharmacy. Olugbenga Solomon Oduyale did not have a written quality assurance program at PVH Pharmacy. Olugbenga Solomon Oduyale did not have a Drug Enforcement Agency (DEA) Inventory at the PVH Pharmacy. Most drug deliveries at PVH Pharmacy were received and signed for by non-pharmacists. As Pharmacist-in-Charge, Olugbenga Solomon Oduyale should not have permitted non-pharmacists to accept drug deliveries.

34. On or about April 29, 2005, Accusation Case No. 2733 was filed before the Board against Olugbenga Solomon Oduyale. A copy of Accusation Case No. 2733 is attached hereto as Exhibit 1 and is incorporated by reference.

35. Following a hearing on February 6, 7, and 8, 2006, in Accusation Case No. 2733, a decision was rendered against Olugbenga Solomon Oduyale revoking his pharmacist's license, with the revocation stayed and probation imposed for three years on terms and conditions. The decision was to become effective on August 31, 2006, but Olugbenga Solomon Oduyale filed a

Petition for Reconsideration. The Board granted reconsideration solely on a condition of probation concerning supervision. The Board rendered a decision after reconsideration allowing Olugbenga Solomon Oduyale to supervise ancillary personnel, including registered pharmacy technicians. The decision became effective on December 21, 2006. The three year probationary term was completed on December 20, 2009. The decision was rendered imposing discipline for the following violations based upon the facts set forth in paragraphs 29 through 33 above:

a. Dispensing prescription drugs in containers not labeled as legally required;

b. Failure to provide records of filled prescriptions at PVH Pharmacy and all records required for inspection by the Board's inspector;

c. Failure to have all records of sale, acquisition, or disposition of dangerous drugs open to inspection by the Board inspector at all times during business hours;

d. Failure to have a quality assurance program in place at PVH Pharmacy when inspected on March 11, 2004;

e. Failure to have an accurate and complete written DEA inventory at PVH when inspected on March 11, 2004; and

f. As Pharmacist-in-Charge, regularly allowing non-pharmacists to receive and sign for drug delivers made to PVH Pharmacy.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Dispensing Dangerous Drugs Without Labeling)

36. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of section 4076 (a) in that Olugbenga Solomon Oduyale dispensed prescription drugs (dangerous drugs) in containers not labeled as legally required, as set forth above in paragraphs 28 to 35.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Failure to Provide Records)

37. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of sections 4081 and 4332 in that Olugbenga Solomon Oduyale failed to provide to the Board's inspector records of all filled prescriptions at the PVH Pharmacy and all required

records during the inspection on or about March 11, 2004 and for a reasonable time thereafter when requested by the Board inspector, as set forth above in paragraphs 28 to 35.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Failure to Maintain Accurate Records and Complete Accountability of Inventory)

38. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of section 4081 as well as CCR section 1718 in that Olugbenga Solomon Oduyale failed to have all records of sale, acquisition, or disposition of dangerous drugs open to inspection by the Board inspector at all times during business hours at PVH Pharmacy, including complete accountability for all inventory, as set forth above in paragraphs 28 to 35.

FOURTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Failure to Implement Quality Assurance Program)

39. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of section 4125 as well as CCR section 1711 in that Olugbenga Solomon Oduyale failed to have a quality assurance program in place at PVH Pharmacy when inspected on or about March 11, 2004, as set forth above in paragraphs 28 to 35.

FIFTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Failure to Maintain DEA Inventory)

40. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of CCR section 1718 and CFR sections 1304.04 and 1304.11 in that Olugbenga Solomon Oduyale failed to have an accurate and complete written or printed DEA Inventory at PVH Pharmacy when inspected on or about March 11, 2004, as set forth above in paragraphs 28 to 35.

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SIXTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Allowing Non-Pharmacists to Receive Drug Purchases)

41. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of section 4059.5(a) in that as Pharmacist-in-Charge at PVH Pharmacy, Olugbenga Solomon Oduyale regularly allowed non-pharmacists to receive and sign for drug deliveries made to PVH Pharmacy, as set forth above in paragraphs 28 to 35.

SEVENTH CAUSE FOR DENIAL OF APPLICATION

(Acts if Done by Licentiate are Grounds for Discipline)

42. Respondent's application is subject to denial under Code sections 480(a)(3)(A) in that Olugbenga Solomon Oduyale has done acts that if done by a licentiate would be grounds for suspension or revocation of his license, when Olugbenga Solomon Oduyale dispensed prescription drugs (dangerous drugs) in containers not labeled as legally required in violation of section 4076(a); failed to provide to the Board's inspector records of all filled prescriptions at the PVH Pharmacy and all required records during the inspection on or about March 11, 2004 and for a reasonable time thereafter when requested by the Board inspector in violation of sections 4081 and 4332; failed to have all records of sale, acquisition, or disposition of dangerous drugs open to inspection by the Board inspector at all times during business hours at PVH Pharmacy, including complete accountability for all inventory, in violation of section 4081 as well as CCR section 1718; failed to have a quality assurance program in place at PVH Pharmacy when inspected on or about March 11, 2004 in violation of section 4125 as well as CCR section 1711; failed to have an accurate and complete written or printed DEA Inventory at PVH Pharmacy when inspected on or about March 11, 2004 in violation of CCR section 1718 and CRF sections 1304.04 and 1304.11; and regularly allowed non-pharmacists to receive and sign for drug deliveries made to PVH Pharmacy in violation of Code section 4059.5(a), as set forth above in paragraphs 28 to 35.

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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 Calmex Special Services, Inc. dba Cal-Mex Pharmacy for a pharmacy permit.

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

DATED: 5/10/11

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

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EXHIBIT 1

ACCUSATION CASE NO. 2733