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

In the Matter of the Accusation Against: **RAFAEL VELAZQUEZ dba MERCED DRUG** **35 E. 16th Street** **Merced, CA 95340** **Original Permit Number No. PHY 43562** **and** **RAFAEL VELAZQUEZ** **35 E. 16th Street** **Merced, CA 95340** **Original Pharmacist License No. RPH 40303** Respondents.	Case No. 5606 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about April 1, 1998, the Board of Pharmacy issued Original Permit Number PHY 43562 to Rafael Velazquez dba Merced Drug (Respondent Merced Drug). Rafael

Velazquez is and has been the Pharmacist-in-Charge at Respondent Merced Drug since April 1, 1998. The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed.

3. On or about August 28, 1986, the Board of Pharmacy issued Original Pharmacist License Number RPH 40303 to Rafael Velazquez (Respondent Velazquez). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2016, unless renewed.

JURISDICTION

4. This Accusation 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.

5. Code section 4300.1 states:

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

BUSINESS AND PROFESSIONS CODE

6. Code section 4081 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, 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. . . .

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7. Code section 4332 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

8. Health and Safety Code section 11165(d) states:

> For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
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> (1) Full name, address, and, if available, telephone number 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, and the gender, and date of birth of the ultimate user.
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> (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
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> (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
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> (4) National Drug Code (NDC) number of the controlled substance dispensed.
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> (5) Quantity of the controlled substance dispensed.
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> (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
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> (7) Number of refills ordered.
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> (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
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> (9) Date of origin of the prescription.
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> (10) Date of dispensing of the prescription.

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CODE OF FEDERAL REGULATIONS

9. Code of Federal Regulations, title 21, section 1304.11 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.

. . .

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. . . .

CALIFORNIA CODE OF REGULATIONS

10. California Code of Regulations, title 16, section 1707.5 states, in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

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

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

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COST RECOVERY

11. Code section 125.3 provides, in pertinent part, that a 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.

BACKGROUND

12. On or about December 15, 2014, Board Inspectors J. F. and A. H. conducted a routine inspection of Respondent Merced Drug.

13. During the December 15, 2014 inspection of Respondent Merced Drug, Board Inspector J. F. asked Respondent Velazquez to provide him with the pharmacy's most recent DEA Biennial Inventory. Velazquez provided J. F. with a DEA Biennial Inventory document dated June 22, 2009. Velazquez informed J. F. that he had not conducted a DEA Biennial Inventory since June 22, 2009.

14. During the December 15, 2014 inspection of Respondent Merced Drug, Board Inspector J. F. checked the most recent data table for Merced Drug's CURES transmission, however no data was found. Respondent Velazquez informed J. F. that Merced Drug was not transmitting data to CURES. Approximately two weeks later, on or about December 30, 2014, Velazquez informed J. F. that Merced Drug's last Controlled Substance Utilization Review and Evaluation System (CURES)[1] transmission occurred on July 28, 2009.

15. During the December 15, 2014 inspection of Respondent Merced Drug, Board Inspector A. H. conducted the Board of Pharmacy's "Survey of Pharmacies: Translation services Available in pharmacies." During the survey, A. H. asked Respondent Velazquez to provide the Board with example labels for the survey. A. H. requested two regular prescription labels (non-translated) and two translated prescription labels (translated into Spanish). After inspection of the

[1] CURES is a database containing information on Schedule II through IV controlled substances dispensed in California. It is a valuable investigative, preventive, and educational tool for the healthcare community, regulatory boards, and law enforcement.

prescription labels provided to A. H., it was discovered that Merced Drug's pharmacy prescription labels were not in compliance with Patient Centered Labeling regulations.

RESPONDENT MERCED DRUG

FIRST CAUSE FOR DISCIPLINE

(Biennial DEA Inventory Requirements)

16. Respondent Merced Drug is subject to disciplinary action under sections 4081(a) and 4332 of the Code, by and through section 1304.11(a) and (c) of title 21 of the Code of Federal Regulations, in that as of December 15, 2014, Merced Drug had not conducted a Biennial DEA Inventory since June 22, 2009. The circumstances are described with more particularity in paragraph 13.

SECOND CAUSE FOR DISCIPLINE

(Failure to Report to CURES)

17. Respondent Merced Drug is subject to disciplinary action under sections 4081(a) and 4332 of the Code, by and through section 11165(d) of the Health and Safety Code, in that as of December 15, 2014, Merced Drug had not reported the dispensing of controlled substance prescriptions to the Department of Justice through CURES since July 28, 2009. The circumstances are described with more particularity in paragraph 14.

THIRD CAUSE FOR DISCIPLINE

(Patient-Centered Labels for Prescription Drug Containers; Requirements)

18. Respondent Merced Drug is subject to disciplinary action under section 1707.5(a)(1) of Title 16 of the California Code of Regulations in that during a December 15, 2014 inspection of Merced Drug, the pharmacy's prescription labels failed to comply with Patient Centered Labeling regulations. The circumstances are described with more particularity in paragraph 15.

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RESPONDENT VELAZQUEZ

FOURTH CAUSE FOR DISCIPLINE

(Biennial DEA Inventory Requirements)

19. Respondent Velazquez is subject to disciplinary action under sections 4081(b) and 4332 of the Code, by and through section 1304.11(a) and (c) of title 21 of the Code of Federal Regulations, in that as of December 15, 2014, Velazquez, as the pharmacist-in-charge of Respondent Merced Drug, had not conducted a Biennial DEA Inventory for Merced Drug since June 22, 2009. The circumstances are described with more particularity in paragraph 13.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Report to CURES)

20. Respondent Velazquez is subject to disciplinary action under sections 4081(b) and 4332 of the Code, by and through section 11165(d) of the Health and Safety Code, in that as of December 15, 2014, Velazquez, as the pharmacist-in-charge of Respondent Merced Drug, had not reported the dispensing of controlled substance prescriptions to the Department of Justice through CURES since July 28, 2009. The circumstances are described with more particularity in paragraph 14.

SIXTH CAUSE FOR DISCIPLINE

(Patient-Centered Labels for Prescription Drug Containers; Requirements)

21. Respondent Velazquez is subject to disciplinary action under section 4081(b) of the Code, by and through section 1707.5(a)(1) of title 16 of the California Code of Regulations, in that on or about December 15, 2014, Velazquez, as the pharmacist-in-charge of Respondent Merced Drug, failed to ensure that the pharmacy's prescription labels complied with Patient Centered Labeling regulations. The circumstances are described with more particularity in paragraph 15.

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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. Revoking or suspending Original Permit Number PHY 43562, issued to Rafael Velazquez dba Merced Drug;

2. Revoking or suspending Original Pharmacist License Number RPH 40303, issued to Rafael Velazquez;

3. Ordering Rafael Velazquez dba Merced Drug, and Rafael Velazquez to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 2/20/16

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

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