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

In the Matter of the Accusation Against: **Orlando's Fairmont Pharmacy dba Fairmont** **PIC Orlando Hernandez** 50 Belle Fontaine Street Pasadena, CA 91105 **Sterile Compounding Permit Number LSC 99057** and **Orlando Hernandez** 173 South Berkeley Avenue Pasadena, California 91107 **Pharmacist License Number RPH 37523** Respondents.	Case No. 5238 **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 May 6, 1986, the Board of Pharmacy issued Pharmacy Permit No. PHY 32744 to Orlando's Fairmont Pharmacy dba Fairmont (Respondent Pharmacy), located at 50 Belle Fontaine Street, Pasadena, California. Orlando Hernandez, RPH 37523 has been the President and the Pharmacist-in-Charge of Respondent Pharmacy since May 6, 1986. Maria Hernandez has been the Secretary of Respondent Pharmacy since May 6, 1986. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2015, unless renewed.

3. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99057 to Orlando's Fairmont Pharmacy dba Fairmont (Respondent Pharmacy), located at 50 Belle Fontaine Street, Pasadena, California. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2015, unless renewed.

4. On or about January 10, 1983, the Board of Pharmacy issued pharmacist license RPH 37523 to Orlando Hernandez (Respondent Hernandez). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 29, 2016, unless renewed. Respondent Hernandez has been the designated Pharmacist-in-Charge of Respondent Pharmacy since May 6, 1986.

JURISDICTION

5. 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.

6. 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."

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STATUTES

7. Section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

8. Section 4301 states:

"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."

9. Section 4342 states:

"(a) 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)."

"(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."

REGULATIONS

10. California Code of Regulations, title 16, section 1751.7, states:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be

examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, 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.

(c) Batch-produced sterile injectable drug products compounded from one or 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.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

11. California Code of Regulations, title 16, section 1735.3, states:

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

(1) The master formula record.

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

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

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

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

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

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

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."

COST RECOVERY

12. 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.

FIRST CAUSE FOR DISCIPLINE

(Violation of Compounding Requirements)

13. Respondents are subject to disciplinary action under sections 4300 and 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1751.7. The circumstances are that on or about on January 21, 2014, during an inspection of Respondent Pharmacy's facility, located at 50 Belle Fontaine Street, Pasadena, California, Board inspectors found that Respondents had batch produced Prostaglandin E1 500 mcg/ML injectable stock solution on October 30, 2013, and Papaverine 30 mg/ml injection stock solution on October 31, 2013, and December 23, 2013, and did not perform sterility and pyrogen tests prior to using the drugs to compound medications.

SECOND CAUSE FOR DISCIPLINE

(Nonconforming Compound Drugs)

14. Respondents are subject to disciplinary action under sections 4300, 4301, subdivision (o), and 4342, in that they had produced compound drugs that did not conform to the required standard and tests as to quality and strength. The circumstances are that on or about on January 21, 2014, during an inspection of Respondent Pharmacy's facility, located at 50 Belle Fontaine Street, Pasadena, California, Board inspectors found that Respondents had batch produced Prostaglandin E1 500 mcg/ML injectable stock solution on October 30, 2013, and Papaverine 30 mg/ml injection stock solution on October 31, 2013, and December 23, 2013, and did not perform sterility and pyrogen tests prior to using the drugs to compound medications. Respondents used these two drugs to compound the following products on the following days:

Date Compounded	Compounded Product
11/23/2013	PPP Trimix 16mg/.55mg/5.5mcg/ml injectable
11/19/2013	PPP 30-2-30mg/2mg/20mcg/ml injectable
11/19/2013	Prostaglandin 20mcg/ml injectable
11/18/2013	PPP Trimix 16mg/ .55mg/5.5mcg/ml injectable
11/15/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable
11/14/2013	PPP 30-1-10 30mg/1mg/1 Omcg/ml injectable
11/5/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable
10/31/2013	PPP Forte 27mg/.45mg/45mcg/ml injectable
10/30/2013	PPP Forte 27mg/.45mcg/ml Injectable

THIRD CAUSE FOR DISCIPLINE

(Violation of Compounding Recordkeeping Requirements)

15. Respondents are subject to disciplinary action under sections 4300 and 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1). The circumstances are that on or about on January 21, 2014, during an inspection of Respondent Pharmacy's facility, located at 50 Belle Fontaine Street, Pasadena, California, Board inspectors found that Respondents' compounding worksheets did not include all the required information for each compounded drug product, as follows:

Date Compounded	Compounded Product	Incomplete worksheet on one or more ingredients used to compound
1/9/2014	Progesterone 200mg Capsules	No Mfg, lot#, exp date
1/2/2014	Biestrogen3mg/0.5mg Cream	No Mfg, lot#, exp date
1/3/2014	Cyclosporin solution 150mg/ml	No Mfg, lot#, exp date
1/4/2014	Spironolactone 9mg/ml	No Mfg, lot#, exp date suspension
1/17/2014	Biestrogen/progesterone 2.5mg/50mg/gm cream	No Mfg, lot#, exp date
1/20/2014	Mupirocin Nasal Spray 0.01%	No Mfg, lot#, exp date. Mupirocin, Polysorbate, Base C polyglycol were expired according to worksheet
1/21/2014	Magic mouth wash (diphenhydramine, lidocaine, Maalox, nystatin)	No Mfg, lot#, exp date
1/10/2014	PPP 30-2-20-30mg/2mg/20mcg/ml injectable	No Mfg, lot#, exp date
1/20/2014	PPP Trimix 15mg/.55mcg/ml injectable	No Mfg, lot#, exp date
1/8/2014	PPP Trimix 16mg/.55mcg/ml intectable	No Mfg, lot#, exp date
1/3/2014	1/3/2014 Papaverine HCL fujection solution 30mg/ml injectable	No Mfg, lot#, exp date
1/17/2014	I/17/2014 PPP Trimix 16mg/.55mcg/ml intectable	No Mfg, lot#, exp date
1/7/2014	Cocaine 4% ophthalmic	No Mfg, lot#, exp date

10/1/2013	PPP 30-2-80 30mg/2mg/80mcg/ml injectable	No Mfg, lot#, exp date
10/1/2013	PPP 30-1.5-50 Super 30/1.5mg/50mcg/ml injectable	No Mfg, lot#, exp date
11/23/2013	PPP Trimix 16mg/.55mg/5.5mcg/ml injectable	No Mfg, lot#, exp date
11/19/2013	PPP 30-2-30mg/2mg/20mcg/ml injectable	No Mfg, lot#, exp date
11/19/2013	Prostaglandin 20mcg/ml injectable	No Mfg, lot#, exp date
11/18/2013	PPP Trimix 16mg/ .5 5mg/5 .5mcg/ml injectable	No Mfg, lot#, exp date
11/15/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable	No Mfg, lot#, exp date
11/14/2013	PPP 30-1-10 30mg/1mg/1 Omcg/ml injectable	No Mfg, lot#, exp date
11/5/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable	No Mfg, lot#, exp date
10/31/2013	PPP Forte 27mg/.45mg/45mcg/ml injectable	No Mfg, lot#, exp date
10/30/2013	PPP Forte 27mg/.45mcg/ml Injectable	No Mfg, lot#, exp date

*mfg=manufacturer name; exp=expiration

DISCIPLINE CONSIDERATIONS

16. To determine the degree of discipline, Complainant alleges that:

a. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and issued to Respondent Pharmacy LSC 99057 administrative Citation No. CI 2008 38908 with $1,000 fine for violating California Code of Regulations, title 16, sections

1716.2(a)(3) (Compounding for Future Use) and 1751.7(c) (Failure to Comply with Sterile Injectable Compounding Quality Assurance and Process Validation). The Citation is final.

b. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and issued to Respondent Pharmacy PHY 32744 administrative Citation No. CI 2009 42712 with $1000 fine for violating Section 4342 and California Code of Regulations, title 16, section 1716 (Variation from Prescriptions). The Citation is final.

c. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and issued to Respondent Hernandez, Pharmacist License Number RPH 37523 administrative Citation No. CI 2009 42713 with $2000 fine for violating Business and Professions Code section 4342 and California Code of Regulations, title 16, sections 1716.2(a)(3) (Compounding for Future Use) and 1751.7(c) (Failure to Comply with Sterile Injectable Compounding Quality Assurance and Process Validation Requirements). The Citation is final.

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 Sterile Compounding Permit Number LSC 99057, issued to Orlando's Fairmont Pharmacy dba Fairmont;

2. Revoking or suspending Pharmacist License RPH 37523 to Orlando Hernandez;

3. Ordering Respondents 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;

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

DATED: 2/26/15

VIRGINIA K. HEROLD
Executive Officer
California State Board of Pharmacy
State of California
Complainant

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