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8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA
10

11 In the Matter of the Accusation Against:

Case No. 5743

12 **Orlando's Fairmont Pharmacy, Inc.**
dba Fairmont Pharmacy
13 **PIC Orlando Hernandez, Owner/Pres.**
Maria A. Hernandez, Owner/Vice Pres.
14 50 Belle Fontaine Street
Pasadena, CA 91105
15 **Original Permit Number PHY 32744**

ACCUSATION

16 and

17 **Orlando Hernandez**
173 South Berkeley Avenue
18 Pasadena, California 91107
19 **Pharmacist License Number RPH 37523**

20 and

21 **Cindy P. Cheng**
50 Belle Fontaine Street
22 Pasadena, CA 91105
23 **Pharmacist License Number RPH 50473**

24 Respondents.
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1 Complainant alleges:

2 PARTIES

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

5 2. On or about May 6, 1986, the Board of Pharmacy issued Pharmacy Permit No. PHY
6 32744 to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy (Respondent Pharmacy),
7 located at 50 Belle Fontaine Street, Pasadena, California. Orlando Hernandez, RPH 37523 has
8 been the President and a 50% owner of Respondent Pharmacy since May 6, 1986. Maria
9 Hernandez has been a 50% owner and Vice President of Respondent Pharmacy since May 6,
10 1986. The Pharmacy Permit was in full force and effect at all times relevant to the charges
11 brought herein and will expire on May 1, 2017, unless renewed.

12 3. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding Permit
13 Number LSC 99057 to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy, located at 50
14 Belle Fontaine Street, Pasadena, California. The Sterile Compounding Permit was in full force
15 and effect at all times relevant to the charges brought herein and will expire on May 1, 2017,
16 unless renewed.

17 4. On or about January 10, 1983, the Board of Pharmacy issued pharmacist license RPH
18 37523 to Orlando Hernandez (Respondent Hernandez). The pharmacist license was in full force
19 and effect at all times relevant to the charges brought herein and will expire on February 28, 2018,
20 unless renewed. Respondent Hernandez has been the designated Pharmacist-in-Charge of
21 Respondent Pharmacy since May 6, 1986.

22 5. In a prior disciplinary action entitled *In the Matter of the Accusation Against*
23 *Orlando's Fairmont Pharmacy dba Fairmont Pharmacy and Orlando Hernandez*, Case Number
24 5238, the Board issued a decision, effective December 4, 2015, in which Sterile Compounding
25 Permit Number LSC 99057 issued to Respondent Pharmacy and Pharmacist License Number
26 RPH 37523 issued to Respondent Hernandez were revoked, the revocations were stayed, and the
27 sterile compounding permit and the pharmacist license were placed on probation for five years.
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1 any partnership, corporation, firm, or association whose application for a license has been denied
2 or revoked, is under suspension or has been placed on probation, and while acting as the manager,
3 administrator, owner, member, officer, director, associate, or partner had knowledge of or
4 knowingly participated in any conduct for which the license was denied, revoked, suspended, or
5 placed on probation, shall be prohibited from serving as a manager, administrator, owner,
6 member, officer, director, associate, or partner of a licensee as follows:

7 (1) Where a probationary license is issued or where an existing license is placed on
8 probation, this prohibition shall remain in effect for a period not to exceed five years.

9 (2) Where the license is denied or revoked, the prohibition shall continue until the
10 license is issued or reinstated.”

11 STATUTORY PROVISIONS

12 13. Section 4301 states:

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

16 ...

17 “(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
18 violation of or conspiring to violate any provision or term of this chapter or of the applicable
19 federal and state laws and regulations governing pharmacy, including regulations established by
20 the board or by any other state or federal regulatory agency.”

21 14. Section 4342 states:

22 “(a) The board may institute any action or actions as may be provided by law and that, in its
23 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not
24 conform to the standard and tests as to quality and strength, provided in the latest edition of the
25 United States Pharmacopoeia or the National Formulary, or that violate any provision of the
26 Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division
27 104 of the Health and Safety Code).”
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19. **DRUG CLASSIFICATION**

Brand Name(s)	Generic Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications For Use
Motilium	Domperidone	Not FDA Approved	No	Domperidone is available via an Investigational New Drug Application (IND) with the FDA for severe gastrointestinal disorders

20. The United States Food and Drug Administration (FDA) does not approve the drug domperidone for human use because of the potential of serious health risks associated with its use, which include cardiac arrhythmias, cardiac arrest, and sudden death. The higher the blood levels of domperidone, the higher the risk. The FDA does not permit the compounding of domperidone in the United States, with the exception of an investigational new drug (IND) application filing with the FDA. Currently, only Dougherty's Pharmacy located in Dallas, Texas, is approved by the FDA to compound domperidone.

21. On April 14, 2015, the Board issued a subscriber alert that stated that "Domperidone is not FDA-approved for any use in humans in the United States". It provided that the FDA permits patients with certain gastrointestinal conditions to be treated with domperidone through an Expanded Access Program, and physicians must file an IND application to the FDA to obtain expanded access for domperidone. The alert also noted that "[c]urrently, no pharmacies are authorized to compound domperidone under the Expanded Access program."

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1 **CAUSE FOR DISCIPLINE**

2 **(Unlawful manufacturing and sales of misbranded drugs)**

3 22. Respondents are subject to disciplinary action under sections 4300 and 4301,
4 subdivision (o), in that they violated section 4169, subdivision (a)(3) and Health and Safety Code
5 section 111375, subdivision (c). The circumstances are that between on or about May 27, 2015,
6 and on or about July 21, 2015, while working as a pharmacist at Respondent Pharmacy's facility,
7 located at 50 Belle Fontaine Street, Pasadena, California, Respondent Cheng compounded
8 domperidone 10mg capsules and dispensed to patient D.F. four (4) domperidone prescriptions
9 (800 capsules in total), which were compounded from the unapproved drug, domperidone.
10 Respondents failed to warn patient D.F. of the unapproved and possible unsafe dosage status with
11 the FDA. Respondents continued to dispense domperidone even after the Board's warning on
12 April 14, 2015.

13 **DISCIPLINE CONSIDERATIONS**

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

15 a. In a prior disciplinary action entitled *In the Matter of the Accusation Against*
16 *Orlando's Fairmont Pharmacy dba Fairmont Pharmacy and Orlando Hernandez*, Case Number
17 5238, the Board issued a decision, effective December 4, 2015, in which Sterile Compounding
18 Permit Number LSC 99057 issued to Respondent Pharmacy and Pharmacist License Number
19 RPH 37523 issued to Respondent Hernandez were revoked, the revocations were stayed, and the
20 sterile compounding permit and the pharmacist license were placed on probation for five years.
21 The discipline was imposed for violating California Code of Regulations, title 16, section 1751.7
22 (Violation of Compounding Requirements), Section 4342 (Production of Nonconforming
23 Compound Drugs), and California Code of Regulations, title 16, section 1735.3, subdivision
24 (a)(1) (Violation of Compounding Recordkeeping Requirements). That decision is now final and
25 is incorporated by reference as if fully set forth.

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

1 1716.2, subdivision (a)(3) (Compounding for Future Use) and 1751.7, subdivision (c) (Failure to
2 Comply with Sterile Injectable Compounding Quality Assurance and Process Validation). The
3 Citation is final.

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

8 d. On or about January 21, 2010, a representative of the Board inspected Respondent
9 Pharmacy's facility and issued to Respondent Hernandez, Pharmacist License Number RPH
10 37523 administrative Citation No. CI 2009 42713 with \$2000 fine for violating Business and
11 Professions Code section 4342 and California Code of Regulations, title 16, sections 1716.2,
12 subdivision (a)(3) (Compounding for Future Use) and 1751.7, subdivision (c) (Failure to Comply
13 with Sterile Injectable Compounding Quality Assurance and Process Validation Requirements).
14 The Citation is final.

15 OTHER MATTERS

16 24. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
17 Number PHY 32744 issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy
18 (Respondent Pharmacy), Respondent Pharmacy shall be prohibited from serving as a manager,
19 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
20 Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number
21 PHY 32744 is reinstated if it is revoked.

22 25. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
23 Number PHY 32744 issued to Respondent Pharmacy while Orlando Hernandez has been an
24 officer and owner and had knowledge of or knowingly participated in any conduct for which the
25 licensee was disciplined, Orlando Hernandez shall be prohibited from serving as a manager,
26 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
27 Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number
28 PHY 32744 is reinstated if it is revoked.

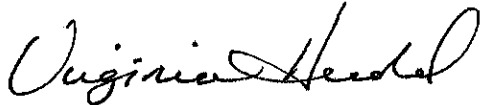
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reinstated, as applicable, if Pharmacy Permit Number PHY 32744 issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy is revoked;

7. Ordering Respondents, jointly and severally, 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;

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

DATED: 10/10/16



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

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