



**California State Board of Pharmacy**  
 1625 N. Market Blvd., N219, Sacramento, CA 95834  
 Phone: (916) 574-7800  
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 www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
 DEPARTMENT OF CONSUMER AFFAIRS  
 GOVERNOR EDMUND G. BROWN JR.

**APPLICATION FOR VOLUNTARY SURRENDER OF PREMISES LICENSE**

PLEASE PRINT IN BLACK OR BLUE INK OR TYPE YOUR RESPONSES

Name: <u>FAIRMONT PHARMACY</u>	Case No. <u>5238</u>
Address of Record: <u>50 BELLEFONTAINE ST #103</u> <u>PASADENA, CA 91105</u>	

Pursuant to the terms and conditions of probation against my ~~premises~~<sup>LSC</sup> license with the California State Board of Pharmacy (Board) in Case No. 5238, I hereby request to surrender my ~~premises~~<sup>LSC</sup> license, License No. 99057 LSC. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, the premises will no longer be subject to the terms and conditions of probation. <sup>RELATED TO THE LSC LICENSE.</sup> I understand that this surrender constitutes a record of discipline and shall become a part of the premises license history with the Board.

Upon the acceptance of the surrender, I shall relinquish my ~~premises~~<sup>LSC</sup> license to the Board within ten (10) days of notification by the Board that the surrender is accepted. ~~I understand that I shall, among other things, submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.~~ I may not reapply for any new ~~premises~~<sup>LSC</sup> license from the board for three (3) years from the effective date of the surrender. I further understand that I shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

PLEASE BE ADVISED THAT YOU ARE NOT RELIEVED OF THE REQUIREMENTS OF YOUR PROBATION UNLESS THE BOARD NOTIFIES YOU THAT YOUR REQUEST TO SURRENDER YOUR LICENSE HAS BEEN ACCEPTED.

[Signature]  
 Applicant's Signature

[Signature]  
 Executive Officer's Approval

3-6-2017  
 Date

3-13-17  
 Date

All items on this application are mandatory in accordance with your probationary order and the Board's Disciplinary Guidelines as authorized by Title 16, California Code of Regulations section 1760. Failure to provide any of the requested information or providing unreadable information will result in the application being rejected as incomplete. The information provided on this form will be used to determine eligibility for surrender. The official responsible for information maintenance is the Executive Officer, telephone (916) 574-7900, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. The information you provide may also be disclosed in the following circumstances: (1) in response to a Public Records Act request; (2) to another government agency as required by state or federal law; or, (3) in response to a court or administrative order, a subpoena, or a search warrant. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

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

In the Matter of the Accusation Against:

Case No. 5238

**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, CA 91107  
Pharmacist License Number RPH 37523**

Respondent.

**DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on December 4, 2015.

It is so ORDERED on November 4, 2015.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

\_\_\_\_\_  
Amy Gutierrez, Pharm.D.  
Board President

1 KAMALA D. HARRIS  
Attorney General of California  
2 ARMANDO ZAMBRANO  
Supervising Deputy Attorney General  
3 NANCY A. KAISER  
Deputy Attorney General  
4 State Bar No. 192083  
300 So. Spring Street, Suite 1702  
5 Los Angeles, CA 90013  
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6 Facsimile: (213) 897-2804

7 *Attorneys for Complainant*

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

12 In the Matter of the Accusation Against:

Case No. 5238

13 **Orlando's Fairmont Pharmacy dba**  
14 **Fairmont**  
15 **PIC Orlando Hernandez**  
50 Belle Fontaine Street  
Pasadena, CA 91105  
16 **Sterile Compounding Permit Number LSC**  
17 **99057**

**STIPULATED SETTLEMENT AND**  
**DISCIPLINARY ORDER**

18 and

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

Respondents.

21  
22 In the interest of a prompt and speedy settlement of this matter, consistent with the public  
23 interest and the responsibility of the California State Board of Pharmacy, Department of  
24 Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and  
25 Disciplinary Order, which will be submitted to the Board for approval and adoption as the final  
26 disposition of the Accusation.

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1 **PARTIES**

2 1. Virginia K. Herold ("Complainant") is the Executive Officer of the California State  
3 Board of Pharmacy. She brought this action solely in her official capacity and is represented in  
4 this matter by Kamala D. Harris, Attorney General of the State of California, by Nancy A. Kaiser,  
5 Deputy Attorney General.

6 2. Respondents Orlando's Fairmont Pharmacy dba Fairmont and Orlando Hernandez  
7 ("Respondents") are represented in this proceeding by attorney Ronald S. Marks, whose address  
8 is: 2625 Townsgate Rd., Suite 330, Westlake Village, CA 91361.

9 3. On or about May 6, 1986, the Board of Pharmacy issued Pharmacy Permit No. PHY  
10 32744 to Orlando's Fairmont Pharmacy dba Fairmont. Orlando Hernandez, RPH 37523 has been  
11 the President and the Pharmacist-in-Charge of Respondent Pharmacy since May 6, 1986. Maria  
12 Hernandez has been the Secretary of Respondent Pharmacy since May 6, 1986. The Pharmacy  
13 Permit will expire on May 1, 2016, unless renewed.

14 4. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding Permit  
15 Number LSC 99057 to Orlando's Fairmont Pharmacy dba Fairmont ("Respondent Pharmacy").  
16 The Sterile Compounding Permit will expire on May 1, 2016, unless renewed.

17 5. On or about January 10, 1983, the Board of Pharmacy issued pharmacist license RPH  
18 37523 to Orlando Hernandez ("Respondent Hernandez"). The pharmacist license will expire on  
19 February 29, 2016, unless renewed.

20 **JURISDICTION**

21 6. Accusation No. 5238 was filed before the California State Board of Pharmacy  
22 ("Board"), and is currently pending against Respondents. The Accusation and all other statutorily  
23 required documents were properly served on Respondents on March 16, 2015. Respondents  
24 timely filed their Notice of Defense contesting the Accusation.

25 7. A copy of Accusation No. 5238 is attached as Exhibit A and incorporated herein by  
26 reference.

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1 **ADVISEMENT AND WAIVERS**

2 8. Respondents have carefully read, fully discussed with counsel, and understand the  
3 charges and allegations in Accusation No. 5238. Respondents have also carefully read, fully  
4 discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary  
5 Order.

6 9. Respondents is fully aware of its legal rights in this matter, including the right to a  
7 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at  
8 its own expense; the right to confront and cross-examine the witnesses against them; the right to  
9 present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel  
10 the attendance of witnesses and the production of documents; the right to reconsideration and  
11 court review of an adverse decision; and all other rights accorded by the California  
12 Administrative Procedure Act and other applicable laws.

13 10. Respondents voluntarily, knowingly, and intelligently waive and gives up each and  
14 every right set forth above.

15 **CULPABILITY**

16 11. Respondents understand and agree that the charges and allegations in Accusation No.  
17 5238, if proven at a hearing, constitute cause for imposing discipline upon Original Pharmacist  
18 License Number RPH 37523 and Sterile Compounding Permit Number LSC 99057. Respondents  
19 hereby give up their rights to contest those charges. Respondents agree further that, should either  
20 Respondents come before the Board or any other board or bureau of the Department of Consumer  
21 Affairs in any further or future proceedings, all of the charges and allegations set forth in the  
22 Accusation shall be deemed true and correct.

23 12. Respondent Pharmacy agrees that its Sterile Compounding Permit is subject to  
24 discipline and it agrees to be bound by the Board's probationary terms as set forth in the  
25 Disciplinary Order below.

26 13. Respondent Hernandez agrees that its Pharmacist License is subject to discipline and  
27 he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order  
28 below.

CONTINGENCY

1  
2       14. This stipulation shall be subject to approval by the Board. Respondents understand  
3 and agree that counsel for Complainant and the staff of the Board may communicate directly with  
4 the Board regarding this stipulation and settlement, without notice to or participation by  
5 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that  
6 they may not withdraw their agreement or seek to rescind the stipulation prior to the time the  
7 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and  
8 Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for  
9 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall  
10 not be disqualified from further action by having considered this matter.

11       15. The parties understand and agree that Portable Document Format (PDF) and facsimile  
12 copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format  
13 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14       16. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an  
15 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
16 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
17 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary  
18 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a  
19 writing executed by an authorized representative of each of the parties.

20       17. In consideration of the foregoing admissions and stipulations, the parties agree that  
21 the Board may, without further notice or formal proceeding, issue and enter the following

22 Disciplinary Order:

23       ///

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1 **DISCIPLINARY ORDER**

2 IT IS HEREBY ORDERED that Sterile Compounding Permit Number LSC 99057 issued  
3 to Orlando's Fairmont Pharmacy dba Fairmont ("Respondent Pharmacy") and Pharmacist License  
4 Number RPH 37523 issued to Orlando Hernandez ("Respondent Hernandez") are revoked;  
5 however, the revocations are stayed and Respondents are placed on probation for **five (5) years**  
6 upon the following terms and conditions:

7 1. **Obey All Laws.** Respondents shall obey all state and federal laws and regulations.  
8 Respondents shall report any of the following occurrences to the Board, in writing, within  
9 seventy-two (72) hours of such occurrence:

- 10 a. an arrest or issuance of a criminal complaint for violation of any provision of the  
11 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances  
12 laws,  
13 b. a plea of guilty or nolo contendere in any state or federal criminal proceeding to any  
14 criminal complaint, information or indictment,  
15 c. a conviction of any crime, or  
16 d. discipline, citation, or other administrative action filed by any state or federal agency  
17 which involves Respondents' Sterile Compounding Permit or Pharmacist License or which is  
18 related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing,  
19 or charging for any drug, device or controlled substance. Failure to timely report such occurrence  
20 shall be considered a violation of probation.

21 2. **Report to the Board.** Respondents shall report to the Board quarterly, on a schedule  
22 as directed by the Board or its designee. The report shall be made either in person or in writing, as  
23 directed. Among other requirements, Respondents shall state in each report under penalty of  
24 perjury whether there has been compliance with all the terms and conditions of probation. Failure  
25 to submit timely reports in a form as directed shall be considered a violation of probation. Any  
26 period(s) of delinquency in submission of reports as directed may be added to the total period of  
27 probation. Moreover, if the final probation report is not made as directed, probation shall be  
28 automatically extended until such time as the final report is made and accepted by the Board.

1           3.     **Interview with the Board.** Upon receipt of reasonable prior notice, Respondents  
2 shall appear in person for interviews with the Board or its designee, at such intervals and  
3 locations as are determined by the Board or its designee. Failure to appear for any scheduled  
4 interview without prior notification to Board staff, or failure to appear for two (2) or more  
5 scheduled interviews with the Board or its designee during the period of probation, shall be  
6 considered a violation of probation.

7           4.     **Cooperate with Board Staff.** Respondents shall cooperate with the Board's  
8 inspection program and with the Board's monitoring and investigation of Respondents'  
9 compliance with the terms and conditions of his probation. Failure to cooperate shall be  
10 considered a violation of probation.

11          5.     **Continuing Education.** Respondent Hernandez shall provide evidence of efforts to  
12 maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

13          6.     **Notice to Employers.** During the period of probation, Respondent Hernandez shall  
14 notify all present and prospective employers of the decision in case number 5238 and the terms,  
15 conditions and restrictions imposed on Respondents by the decision, as follows:

16                 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of  
17 Respondent Hernandez undertaking any new employment, Respondent Hernandez shall cause his  
18 direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed  
19 during Respondent Hernandez's tenure of employment) and owner to report to the Board in  
20 writing acknowledging that the listed individual(s) has/have read the decision in case number  
21 5238, and terms and conditions imposed thereby. It shall be Respondent Hernandez's  
22 responsibility to ensure that his employer(s) and/or supervisor(s) submit timely  
23 acknowledgment(s) to the Board.

24                 If Respondent Hernandez works for or is employed by or through a pharmacy employment  
25 service, Respondent Hernandez must notify his direct supervisor, pharmacist-in-charge, and  
26 owner at every entity licensed by the Board of the terms and conditions of the decision in case  
27 number 5238 in advance of Respondent Hernandez commencing work at each licensed entity. A  
28 record of this notification must be provided to the Board upon request.



1 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen  
2 (15) days of Respondent Hernandez undertaking any new employment by or through a pharmacy  
3 employment service, Respondent Hernandez shall cause his direct supervisor with the pharmacy  
4 employment service to report to the Board in writing acknowledging that he has read the decision  
5 in case number 5238 and the terms and conditions imposed thereby. It shall be Respondent  
6 Hernandez's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely  
7 acknowledgment(s) to the Board.

8 Failure to timely notify present or prospective employer(s) or to cause that/those  
9 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of  
10 probation.

11 "Employment" within the meaning of this provision shall include any full-time, part-time,  
12 temporary, relief or pharmacy management service as a pharmacist or any position for which a  
13 pharmacist license is a requirement or criterion for employment, whether Respondent Hernandez  
14 is an employee, independent contractor or volunteer.

15 **7. Consultant for Owner or Pharmacist-In-Charge.** During the period of probation,  
16 Respondents shall not supervise any intern pharmacist, be the designated representative-in-charge  
17 of any entity licensed by the Board nor serve as a consultant licensed by the Board. Respondent  
18 Hernandez may be a pharmacist-in-charge. However, if during the period of probation  
19 Respondent Hernandez serves as a pharmacist-in-charge, Respondent Hernandez shall retain an  
20 independent consultant at his own expense who shall be responsible for reviewing pharmacy  
21 operations on a monthly basis for compliance by Respondent Hernandez with state and federal  
22 laws and regulations governing the practice of pharmacy and for compliance by Respondent  
23 Hernandez with the obligations of a pharmacist-in-charge. The basis for the review may re  
24 reduced to quarterly by Board designee. The consultant shall be a pharmacist licensed by and not  
25 on probation with the Board, who specializes in sterile compounding, and whose name shall be  
26 submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective  
27 date of this decision. Respondent Hernandez shall not be a pharmacist-in-charge at more than one  
28 pharmacy or at any pharmacy of which he is not the sole owner. Failure to timely retain, seek

1 approval of, or ensure timely reporting by the consultant shall be considered a violation of  
2 probation.

3       **8. Reimbursement of Board Costs.** As a condition precedent to successful completion  
4 of probation, Respondents shall pay to the Board its costs of investigation and prosecution in the  
5 amount of **\$5,500**. Respondents shall be jointly and severally responsible for paying these costs  
6 to the Board. Respondents shall be permitted to pay these costs in a payment plan approved by  
7 the Board, with payments to be completed no later than six (6) months prior to the end of the  
8 probation term.

9       There shall be no deviation from this schedule absent prior written approval by the Board or  
10 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of  
11 probation.

12       The filing of bankruptcy by Respondents shall not relieve Respondents of their  
13 responsibility to reimburse the Board its costs of investigation and prosecution.

14       **9. Probation Monitoring Costs.** Respondents shall pay any costs associated with  
15 probation monitoring as determined by the Board each and every year of probation. Such costs  
16 shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to  
17 pay such costs by the deadline(s) as directed shall be considered a violation of probation.

18       **10. Status of License.** Respondents shall, at all times while on probation, maintain an  
19 active, current license or permit, as applicable, with the Board, including any period during which  
20 suspension or probation is tolled. Failure to maintain an active, current license or permit shall be  
21 considered a violation of probation.

22       If Respondents' license or permit expires or is cancelled by operation of law or otherwise at  
23 any time during the period of probation, including any extensions thereof due to tolling or  
24 otherwise, upon renewal or reapplication Respondents' license or permit shall be subject to all  
25 terms and conditions of this probation not previously satisfied.

26       **11. License Surrender While on Probation/Suspension.** Following the effective date of  
27 this decision, should Respondents cease practice due to retirement or health, or be otherwise  
28 unable to satisfy the terms and conditions of probation, Respondents may tender their license or

1 permit to the Board for surrender. The Board or its designee shall have the discretion whether to  
2 grant the request for surrender or take any other action it deems appropriate and reasonable. Upon  
3 formal acceptance of the surrender of the license or permit, the applicable Respondent will no  
4 longer be subject to the terms and conditions of probation. This surrender constitutes a record of  
5 discipline and shall become a part of the applicable Respondent's license history with the Board.

6 Upon acceptance of the surrender, Respondent(s) shall relinquish his pocket and wall  
7 license to the Board within ten (10) days of notification by the Board that the surrender is  
8 accepted. Respondents may not reapply for any license from the Board for three (3) years from  
9 the effective date of the surrender. Respondents shall meet all requirements applicable to the  
10 license or permit sought as of the date the application for that license or permit is submitted to the  
11 Board, including any outstanding costs.

12 **12. Notice to Employees.** Respondent Pharmacy's owner shall, upon or before the  
13 effective date of this decision, ensure that all employees involved in permit operations are made  
14 aware of all the terms and conditions of probation, either by posting a notice of the terms and  
15 conditions, circulating such notice, or both. If the notice required by this provision is posted, it  
16 shall be posted in a prominent place and shall remain posted throughout the probation period.  
17 Respondent Pharmacy's owner shall ensure that any employees hired or used after the effective  
18 date of this decision are made aware of the terms and conditions of probation by posting a notice,  
19 circulating a notice, or both. Additionally, Respondent Pharmacy's owner shall submit written  
20 notification to the board, within fifteen (15) days of the effective date of this decision, that this  
21 term has been satisfied. Failure to submit such notification to the board shall be considered a  
22 violation of probation.

23 "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary  
24 and relief employees and independent contractors employed or hired at any time during  
25 probation.

26 **13. Owners and Officers: Knowledge of the Law.** Respondent Pharmacy shall provide,  
27 within thirty (30) days after the effective date of this decision, signed and dated statements from  
28 its owners, including any owner or holder of ten percent (10%) or more of the interest in

1 Respondent Pharmacy or Respondent Pharmacy's stock, and any officer, stating under penalty of  
2 perjury that said individuals have read and are familiar with state and federal laws and regulations  
3 governing the practice of pharmacy. The failure to timely provide said statements under penalty  
4 of perjury shall be considered a violation of probation.

5       **14. Posted Notice of Probation.** Respondent Pharmacy's owner shall prominently post a  
6 probation notice provided by the board in a place conspicuous and readable to the public. The  
7 probation notice shall remain posted during the entire period of probation.

8       Respondent Pharmacy's owner shall not, directly or indirectly, engage in any conduct or  
9 make any statement which is intended to mislead or is likely to have the effect of misleading any  
10 patient, customer, member of the public, or other person(s) as to the nature of and reason for the  
11 probation of the licensed entity.

12       Failure to post such notice shall be considered a violation of probation.

13       **15. Notification of a Change in Name, Residence Address, Mailing Address or**  
14 **Employment.** Respondent Hernandez shall notify the Board in writing within ten (10) days of  
15 any change of employment. Said notification shall include the reasons for leaving, the address of  
16 the new employer, the name of the supervisor and owner, and the work schedule if known.  
17 Respondents shall notify the Board in writing within ten (10) days of a change in name, residence  
18 address, mailing address, or phone number.

19       Failure to timely notify the Board of any change in employer(s), name(s), address(es), or  
20 phone number(s) shall be considered a violation of probation.

21       **16. Tolling of Probation.** Except during periods of suspension, Respondent Hernandez  
22 shall, at all times while on probation, be employed as a pharmacist in California for a minimum of  
23 forty (40) hours per calendar month. Any month during which this minimum is not met shall toll  
24 the period of probation, i.e., the period of probation shall be extended by one month for each  
25 month during which this minimum is not met. During any such period of tolling of probation,  
26 Respondent Hernandez must nonetheless comply with all terms and conditions of probation.

27       Should Respondent Hernandez, regardless of residency, for any reason (including vacation)  
28 cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in

1 California, Respondent Hernandez must notify the Board in writing within ten (10) days of the  
2 cessation of practice, and must further notify the Board in writing within ten (10) days of the  
3 resumption of practice. Any failure to provide such notification(s) shall be considered a violation  
4 of probation.

5 It is a violation of probation for Respondent Hernandez's probation to remain tolled  
6 pursuant to the provisions of this condition for a total period, counting consecutive and non-  
7 consecutive months, exceeding thirty-six (36) months.

8 "Cessation of practice" means any calendar month during which Respondent Hernandez is  
9 not practicing as a pharmacist for at least forty (40) hours, as defined by Business and Professions  
10 Code section 4000 et seq. "Resumption of practice" means any calendar month during which  
11 Respondent Hernandez is practicing as a pharmacist for at least forty (40) hours as a pharmacist  
12 as defined by Business and Professions Code section 4000 et seq.

13 **17. Violation of Probation.** If Respondents have not complied with any term or  
14 condition of probation, the Board shall have continuing jurisdiction over Respondents, and  
15 probation shall automatically be extended, until all terms and conditions have been satisfied or the  
16 Board has taken other action as deemed appropriate to treat the failure to comply as a violation of  
17 probation, to terminate probation, and to impose the penalty that was stayed.

18 If Respondents violate probation in any respect, the Board, after giving Respondents notice  
19 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that  
20 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a  
21 violation thereof may lead to automatic termination of the stay and/or revocation of the license or  
22 permit. If a petition to revoke probation or an accusation is filed against Respondents during  
23 probation, the Board shall have continuing jurisdiction and the period of probation shall be  
24 automatically extended until the petition to revoke probation or accusation is heard and decided,  
25 and the charges and allegations in Accusation No. 5238 shall be deemed true and correct.

26 **18. Completion of Probation.** Upon written notice by the Board or its designee  
27 indicating successful completion of probation, Respondents' license and permit will be fully  
28 restored.

1           19.   **Remedial Education.** Within thirty (30) days of the effective date of this decision,  
2 Respondent Hernandez shall submit to the Board or its designee, for prior approval, an  
3 appropriate program of remedial education related to sterile compounding testing, record keeping,  
4 and pharmacy operations. The program of remedial education shall consist of at least ten (10)  
5 hours per year, for the first two years of probation, with 50% of total to be completed in an “in-  
6 person” setting, which shall be related to sterile compounding and the other 50% shall be related  
7 to either sterile compounding or pharmacy operations, at Respondent Hernandez's own expense.  
8 All remedial education shall be in addition to, and shall not be credited toward, continuing  
9 education (CE) courses used for license renewal purposes.

10           Failure to timely submit or complete the approved remedial education shall be considered a  
11 violation of probation. The period of probation will be automatically extended until such remedial  
12 education is successfully completed and written proof, in a form acceptable to the Board, is  
13 provided to the Board or its designee.

14           Following the completion of each course, the Board or its designee may require Respondent  
15 Hernandez, at his own expense, to take an approved examination to test his knowledge of the  
16 course. If Respondent Hernandez does not achieve a passing score on the examination, this failure  
17 shall be considered a violation of probation. Any such examination failure shall require  
18 Respondent Hernandez to take another course approved by the Board in the same subject area.

19           20.   **No New Ownership of Licensed Premises.** Respondent Hernandez shall not acquire  
20 any new ownership, legal or beneficial interest nor serve as a manager, administrator, member,  
21 officer, director, trustee, associate, or partner of any additional business, firm, partnership, or  
22 corporation licensed by the Board. If Respondent Hernandez currently owns or has any legal or  
23 beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee,  
24 associate, or partner of any business, firm, partnership, or corporation currently or hereinafter  
25 licensed by the Board, Respondent Hernandez may continue to serve in such capacity or hold that  
26 interest, but only to the extent of that position or interest as of the effective date of this decision.  
27 Violation of this restriction shall be considered a violation of probation.

28

1 ACCEPTANCE

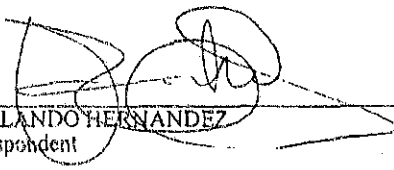
2 I have carefully read the Stipulated Settlement and Disciplinary Order and have fully  
3 discussed it with my attorney, Ronald S. Marks. I understand the stipulation and the effect it will  
4 have on my Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary  
5 Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order  
6 of the California State Board of Pharmacy.

7  
8 DATED: 8-19-15

  
9 ORLANDO'S FAIRMONT PHARMACY  
10 DBA FAIRMONT  
Respondent


11 I have carefully read the Stipulated Settlement and Disciplinary Order and have fully  
12 discussed it with my attorney, Ronald S. Marks. I understand the stipulation and the effect it will  
13 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order  
14 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the  
15 California State Board of Pharmacy.

16  
17 DATED: 8-19-15

  
18 ORLANDO HERNANDEZ  
19 Respondent

20 I have read and fully discussed with Respondents the terms and conditions and other  
21 matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form  
22 and content.

23  
24 DATED: 8/19/15

  
25 RONALD S. MARKS  
Attorney for Respondents

26 ///

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the California State Board of Pharmacy.

Dated: 8/19/15

Respectfully submitted,  
KAMALA D. HARRIS  
Attorney General of California  
ARMANDO ZAMBRANO  
Supervising Deputy Attorney General  
  
NANCY A. KAISER  
Deputy Attorney General  
*Attorneys for Complainant*

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**Exhibit A**

**Accusation No. 5238**

1 KAMALA D. HARRIS  
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7  
8

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

12 In the Matter of the Accusation Against:

Case No. 5238

13 **Orlando's Fairmont Pharmacy dba**  
**Fairmont**  
14 **PIC Orlando Hernandez**  
50 Belle Fontaine Street  
15 Pasadena, CA 91105  
**Sterile Compounding Permit Number LSC**  
16 **99057**

**A C C U S A T I O N**

17 and

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

20 Respondents.  
21  
22

23  
24 Complainant alleges:

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
27 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.  
28

1           2.    On or about May 6, 1986, the Board of Pharmacy issued Pharmacy Permit No. PHY  
2 32744 to Orlando's Fairmont Pharmacy dba Fairmont (Respondent Pharmacy), located at 50 Belle  
3 Fontaine Street, Pasadena, California. Orlando Hernandez, RPH 37523 has been the President and  
4 the Pharmacist-in-Charge of Respondent Pharmacy since May 6, 1986. Maria Hernandez has been  
5 the Secretary of Respondent Pharmacy since May 6, 1986. The Pharmacy Permit was in full force  
6 and effect at all times relevant to the charges brought herein and will expire on May 1, 2015,  
7 unless renewed.

8           3.    On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding Permit  
9 Number LSC 99057 to Orlando's Fairmont Pharmacy dba Fairmont (Respondent Pharmacy),  
10 located at 50 Belle Fontaine Street, Pasadena, California. The Sterile Compounding Permit was in  
11 full force and effect at all times relevant to the charges brought herein and will expire on May 1,  
12 2015, unless renewed.

13           4.    On or about January 10, 1983, the Board of Pharmacy issued pharmacist license RPH  
14 37523 to Orlando Hernandez (Respondent Hernandez). The pharmacist license was in full force  
15 and effect at all times relevant to the charges brought herein and will expire on February 29, 2016,  
16 unless renewed. Respondent Hernandez has been the designated Pharmacist-in-Charge of  
17 Respondent Pharmacy since May 6, 1986.

#### JURISDICTION

18  
19           5.    This Accusation is brought before the Board of Pharmacy (Board), Department of  
20 Consumer Affairs, under the authority of the following laws. All section references are to the  
21 Business and Professions Code unless otherwise indicated.

22           6.    Section 4300.1 states:

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

28           ///

1 **STATUTES**

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

5 8. Section 4301 states:

6 “The board shall take action against any holder of a license who is guilty of unprofessional  
7 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

8 Unprofessional conduct shall include, but is not limited to, any of the following:

9 ...

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

14 9. Section 4342 states:

15 “(a) The board may institute any action or actions as may be provided by law and that, in its  
16 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not  
17 conform to the standard and tests as to quality and strength, provided in the latest edition of the  
18 United States Pharmacopoeia or the National Formulary, or that violate any provision of the  
19 Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division  
20 104 of the Health and Safety Code).”

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

23 **REGULATIONS**

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

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

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

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

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

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

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

9 (b) Each individual involved in the preparation of sterile injectable products must first  
10 successfully complete a validation process on technique before being allowed to prepare sterile  
11 injectable products. The validation process shall be carried out in the same manner as normal  
12 production, except that an appropriate microbiological growth medium is used in place of the  
13 actual product used during sterile preparation. The validation process shall be representative of all  
14 types of manipulations, products and batch sizes the individual is expected to prepare. The same  
15 personnel, procedures, equipment, and materials must be involved. Completed medium samples  
16 must be incubated. If microbial growth is detected, then the sterile preparation process must be  
17 evaluated, corrective action taken, and the validation process repeated. Personnel competency  
18 must be revalidated at least every twelve months, whenever the quality assurance program yields  
19 an unacceptable result, when the compounding process changes, equipment used in the  
20 compounding of sterile injectable drug products is repaired or replaced, the facility is modified in  
21 a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are  
22 observed. Revalidation must be documented.

23 (c) Batch-produced sterile injectable drug products compounded from one or more non-  
24 sterile ingredients shall be subject to documented end product testing for sterility and pyrogens  
25 and shall be quarantined until the end product testing confirms sterility and acceptable levels of  
26 pyrogens.

27  
28

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

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

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

6 (1) The master formula record.

7 (2) The date the drug product was compounded.

8 (3) The identity of the pharmacy personnel who compounded the drug product.

9 (4) The identity of the pharmacist reviewing the final drug product.

10 (5) The quantity of each component used in compounding the drug product.

11 (6) The manufacturer, expiration date and lot number of each component. If the  
12 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

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

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

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

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

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

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

28

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

3 **COST RECOVERY**

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

8 **FIRST CAUSE FOR DISCIPLINE**

9 **(Violation of Compounding Requirements)**

10 13. Respondents are subject to disciplinary action under sections 4300 and 4301,  
11 subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section  
12 1751.7. The circumstances are that on or about on January 21, 2014, during an inspection of  
13 Respondent Pharmacy's facility, located at 50 Belle Fontaine Street, Pasadena, California, Board  
14 inspectors found that Respondents had batch produced Prostaglandin E1 500 mcg/ML injectable  
15 stock solution on October 30, 2013, and Papaverine 30 mg/ml injection stock solution on October  
16 31, 2013, and December 23, 2013, and did not perform sterility and pyrogen tests prior to using  
17 the drugs to compound medications.

18 **SECOND CAUSE FOR DISCIPLINE**

19 **(Nonconforming Compound Drugs)**

20 14. Respondents are subject to disciplinary action under sections 4300, 4301, subdivision  
21 (o), and 4342, in that they had produced compound drugs that did not conform to the required  
22 standard and tests as to quality and strength. The circumstances are that on or about on January  
23 21, 2014, during an inspection of Respondent Pharmacy's facility, located at 50 Belle Fontaine  
24 Street, Pasadena, California, Board inspectors found that Respondents had batch produced  
25 Prostaglandin E1 500 mcg/ML injectable stock solution on October 30, 2013, and Papaverine 30  
26 mg/ml injection stock solution on October 31, 2013, and December 23, 2013, and did not perform  
27 sterility and pyrogen tests prior to using the drugs to compound medications. Respondents used  
28 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	1/17/2014 PPP Trimix 16mg/.55mcg/ml intectable	No Mfg, lot#, exp date
1/7/2014	Cocaine 4% ophthalmic	No Mfg, lot#, exp date

1	10/1/2013	PPP 30-2-80 30mg/2mg/80mcg/ml injectable	No Mfg, lot#, exp date
2			
3	10/1/2013	PPP 30-1.5-50 Super 30/1.5mg/50mcg/ml injectable	No Mfg, lot#, exp date
4			
5	11/23/2013	PPP Trimix 16mg/.55mg/5.5mcg/ml injectable	No Mfg, lot#, exp date
6			
7	11/19/2013	PPP 30-2- 30mg/2mg/20mcg/ml injectable	No Mfg, lot#, exp date
8			
9	11/19/2013	Prostaglandin 20mcg/ml injectable	No Mfg, lot#, exp date
10			
11	11/18/2013	PPP Trimix 16mg/ .5 5mg/5 .5mcg/ml injectable	No Mfg, lot#, exp date
12			
13	11/15/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable	No Mfg, lot#, exp date
14			
15	11/14/2013	PPP 30-1-10 30mg/1mg/1 Omcg/ml injectable	No Mfg, lot#, exp date
16			
17	11/5/2013	PPP 30-1-60 30mg/1mg/60mcg/ml injectable	No Mfg, lot#, exp date
18			
19	10/31/2013	PPP Forte 27mg/.45mg/45mcg/ml injectable	No Mfg, lot#, exp date
20			
21	10/30/2013	PPP Forte 27mg/.45mcg/ml Injectable	No Mfg, lot#, exp date

22 \*mfg=manufacturer name; exp=expiration

23 **DISCIPLINE CONSIDERATIONS**

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

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

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

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

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

13 **PRAYER**

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

- 16 1. Revoking or suspending Sterile Compounding Permit Number LSC 99057, issued to  
17 Orlando's Fairmont Pharmacy dba Fairmont;
- 18 2. Revoking or suspending Pharmacist License RPH 37523 to Orlando Hernandez;
- 19 3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the  
20 investigation and enforcement of this case, pursuant to Business and Professions Code section  
21 125.3;

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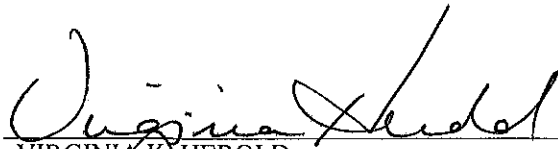
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- 27 4. Taking such other and further action as deemed necessary and proper.

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DATED: 2/26/15

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

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