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

In the Matter of the Accusation Against: **MASHAY INC., DBA LA JOLLA DISCOUNT PHARMACY;** **AHMAD MASHAYEKAN, PRES/PIC** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** Pharmacy Permit No. PHY 38070 Sterile Compounding Permit No. LSC 99245 and **AHMAD MASHAYEKAN** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** Pharmacist License No. RPH 37980 Respondents.	Case No. 4572 OAH No. 2013050161

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 April 17, 2014.

It is so ORDERED on April 10, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
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Attorneys for Complainant

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

In the Matter of the Accusation Against: **MASHAY INC., DBA LA JOLLA DISCOUNT PHARMACY;** **AHMAD MASHAYEKAN, PRES/PIC** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** **Pharmacy Permit No. PHY 38070** **Sterile Compounding Permit No. LSC 99245** **and** **AHMAD MASHAYEKAN** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** **Pharmacist License No. RPH 37980** Respondents.	Case No. 4572 OAH No. 2013050161 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala

D. Harris, Attorney General of the State of California, by Nicole R. Trama, Deputy Attorney General.

2. Respondent Mashay Inc., dba La Jolla Discount Pharmacy and Ahmad Mashayekan ("Respondents") are represented in this proceeding by attorney Peter S. Gregorovic, whose address is: 5720 Oberlin Drive, San Diego, CA 92121-1723.

3. On or about October 8, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 38070 to Mashay Inc., dba La Jolla Discount Pharmacy; with Ahmad Mashayekan as President and Pharmacist-in-Charge (PIC) (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 4572 and will expire on October 1, 2014, unless renewed.

4. On or about June 30, 2004, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99245 to Mashay Inc., dba La Jolla Discount Pharmacy (Respondent). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 4572 and will expire on October 1, 2014, unless renewed.

5. On or about September 7, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37980 to Ahmad Mashayekan (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 4572 and will expire on November 30, 2015, unless renewed.

JURISDICTION

6. Accusation No. 4572 was filed before the Board of Pharmacy (Board) , Department of Consumer Affairs, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on April 22, 2013. Respondents timely filed their Notice of Defense contesting the Accusation. First Amended Accusation No. 4572 was filed before the Board on January 23, 2014.

7. A copy of First Amended Accusation No. 4572 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 4572. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

9. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

11. Respondents admit the truth of each and every charge and allegation in Accusation No. 4572.

12. Respondents agree that Pharmacy Permit Number PHY 38070, Sterile Compounding Permit Number LSC 99245, and Pharmacist License Number RPH 37980 are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or Respondents' counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt

this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit Number PHY 38070, Sterile Compounding Permit Number LSC 99245, and Pharmacist License Number RPH 37980 are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. **Suspension**

As part of probation, Respondent Ahmad Mashayekan is suspended from the practice of pharmacy for fourteen (14) days beginning the effective date of this decision.

During suspension, Respondent Ahmad Mashayekan shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent Ahmad

Mashayekan shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall Respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent Ahmad Mashayekan shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent Ahmad Mashayekan shall not direct or control any aspect of the practice of pharmacy. Respondent Ahmad Mashayekan shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the Board.

Subject to the above restrictions, Respondent Ahmad Mashayekan may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. **Obey All Laws**

Respondents shall obey all state and federal laws and regulations.

Respondents shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's pharmacy permit or pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

3. **Report to the Board**

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

4. **Interview with the Board**

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

5. **Cooperate with Board Staff**

Respondents shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondents' compliance with the terms and conditions of probation. Failure to cooperate shall be considered a violation of probation.

6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondents shall pay to the Board its costs of investigation and prosecution in the amount of $18,828.00. Respondents shall be jointly and severally liable for payment of these costs. Commencing on the effective date of this Decision, Respondents shall make payments of $500.00 per month until paid in full.

There shall be no deviation from this payment plan absent prior written approval by the Board or its designee. Failure to pay costs by the deadline as directed shall be considered a violation of probation.

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

7. **Probation Monitoring Costs**

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

8. **Status of License**

Respondents shall, at all times while on probation, maintain active, current licenses with the Board, including any period during which suspension or probation is tolled. Failure to maintain active, current licenses shall be considered a violation of probation.

If Respondent La Jolla Discount Pharmacy submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent La Jolla Discount Pharmacy shall remain on probation as determined by the Board.

If Respondents' licenses expire or are cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondents' licenses shall be subject to all terms and conditions of this probation not previously satisfied.

9. **Pharmacy Permit Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent La Jolla Discount Pharmacy discontinue business, Respondent owner may tender the premises license to the Board for surrender. 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, Respondent La Jolla Discount Pharmacy will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is

accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent owner shall also reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. **Pharmacist License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Ahmad Mashayekan cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Ahmad Mashayekan may tender his Pharmacist License to the Board for surrender. 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, Respondent Ahmad Mashayekan will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent Ahmad Mashayekan's license history with the Board.

Upon acceptance of the surrender, Respondent Ahmad Mashayekan shall relinquish his pocket and wall license to the Board within ten (10) days of notification by the Board that the

surrender is accepted. Respondent Ahmad Mashayekan may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent Ahmad Mashayekan shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

11. **Notice to Employees**

Respondent La Jolla Discount Pharmacy shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent owner shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

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

12. **Owners and Officers: Knowledge of the Law**

Respondent La Jolla Discount Pharmacy shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **Posted Notice of Probation**

Respondent La Jolla Discount Pharmacy shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain

posted during the entire period of probation.

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

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

14. **Violation of Probation**

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

If Respondents violate probation in any respect, the Board, after giving Respondents notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondents during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondents' licenses will be fully restored.

16. **Restricted Practice**

With the exception of the listed variety of preparations of the two sterile products human chorionic gonadotropin (hCG) and leuprolide, Respondent shall not prepare, oversee, or participate in the preparation of sterile products during the first four (4) years of probation. During Respondents' fifth (5^{th}) year of probation and upon permission from the Board, Respondents may prepare, oversee or participate in the preparation of additional sterile products.

Respondents shall submit proof satisfactory to the Board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the Board of compliance therewith shall be considered a violation of probation.

17. **Administrative Fine**

Respondents shall pay an administrative fine to the Board in the amount of $20,000.00. Respondents shall be jointly and severally liable for payment of these costs. Respondents shall pay the administrative fine pursuant to the following payment plan: Commencing on the effective date of this Decision, Respondents shall pay $500.00 per month, until the amount is paid in full. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay fines by the deadline(s) as directed shall be considered a violation of probation.

Respondents understand and agree that such administrative fine is not dischargeable in bankruptcy. Respondents further understand and agree that the filing of bankruptcy by Respondents shall not relieve Respondents of the obligation to pay the balance of the administrative fine to the Board.

18. **Continuing Education**

Respondent Ahmad Mashayekan shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

19. **Notice to Employers**

During the period of probation, Respondent Ahmad Mashayekan shall notify all present and prospective employers of the decision in case number 4569 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Ahmad Mashayekan undertaking any new employment, Respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4569, and terms and conditions imposed thereby. It shall be Respondent Ahmad Mashayekan's

responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent Ahmad Mashayekan works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 4569 in advance of Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent Ahmad Mashayekan shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he has read the decision in case number 4569 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

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

20. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, Respondent Ahmad Mashayekan shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

21. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent Ahmad Mashayekan shall notify the Board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent Ahmad Mashayekan shall further notify the Board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

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

22. **Tolling of Probation**

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

Should Respondent Ahmad Mashayekan, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California, Respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

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

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

23. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent Ahmad Mashayekan shall submit to the Board or its designee, for prior approval, a community service program in which Respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least sixteen (16) hours per year for the first three (3) years of probation. Within thirty (30) days of Board approval thereof, Respondent Ahmad Mashayekan shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the Board upon request. Respondent Ahmad Mashayekan shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

24. **Remedial Education**

Within thirty (30) days of the effective date of this decision, Respondent Ahmad Mashayekan shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy management, sterile compounding or general compounding. The program of remedial education shall consist of at least fifteen (15) hours per year for the first three (3) years of probation, which shall be completed Respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

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

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

25. **No Ownership of Licensed Premises**

Respondent Ahmad Mashayekan shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If Respondent Ahmad Mashayekan currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board, Respondent Ahmad Mashayekan may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

26. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, Respondent Ahmad Mashayekan shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board. Respondent Ahmad Mashayekan may be the pharmacist-in-charge of Respondent La Jolla Discount Pharmacy. However, if during the period of probation Respondent Ahmad Mashayekan serves as a pharmacist-in-charge, Respondent Ahmad Mashayekan shall retain an independent consultant who is knowledgeable about compounding, at his own expense, who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Ahmad Mashayekan with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent Ahmad Mashayekan the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent Ahmad Mashayekan shall not be a pharmacist-in-charge at more than one pharmacy. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

27. **Tolling of Suspension**

During the period of suspension, Respondent Ahmad Mashayekan shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such

absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days Respondent is absent from California. During any such period of tolling of suspension, Respondent Ahmad Mashayekan must nonetheless comply with all terms and conditions of probation.

Respondent Ahmad Mashayekan must notify the Board in writing within ten (10) days of departure, and must further notify the Board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, Respondent Ahmad Mashayekan shall not resume the practice of pharmacy until notified by the Board that the period of suspension has been satisfactorily completed.

28. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent Ahmad Mashayekan shall enroll in a course in ethics, at Respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent Ahmad Mashayekan shall submit a certificate of completion to the Board or its designee within five days after completing the course.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Peter S. Gregorovic. I understand the stipulation and the effect it will have on Pharmacy Permit Number PHY 38070, Sterile Compounding Permit Number LSC 99245, and Pharmacist License Number RPH 37980. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 2/26/14

AHMAD MASHAYEKAN, As an individual and as the President and authorized agent on behalf of MASHAY INC., DBA LA JOLLA DISCOUNT PHARMACY
Respondents

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

DATED: 2/26/2014

PETER S. GREGOROVIC
Attorney for Respondent

ENDORSEMENT

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

Dated: 2/26/2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General

NICOLE R. TRAMA
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4572

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Complainant alleges:

PARTIES

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

2. On or about October 8, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 38070 to Mashay Inc., dba La Jolla Discount Pharmacy; with Ahmad Mashayekan as President and Pharmacist-in-Charge (PIC) (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2014, unless renewed.

3. On or about June 30, 2004, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99245 to Mashay Inc., dba La Jolla Discount Pharmacy (Respondent). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2014, unless renewed.

4. On or about September 7, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37980 to Ahmad Mashayekan (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2015, unless renewed.

JURISDICTION

5. This First Amended 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 of the Code 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.

STATUTORY PROVISIONS

7. Section 4081 of the Code states:

> (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution,

or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

8. Section 4169 of the Code states in pertinent part:

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

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

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

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

. . . .

9. Section 4301 of the Code states in pertinent part:

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

. . . .

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . . .

(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.

. . . .

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

. . . .

10. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

. . . .

11. Health and Safety Code section 111250 provides that any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

12. Health and Safety Code section 111255 states that any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

13. Health and Safety Code section 111295 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

14. Health and Safety Code section 111330 states that any drug or device is misbranded if its labeling is false or misleading in any particular.

15. Health and Safety Code section 111335 states that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

16. Health and Safety Code section 111395 provides:

Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

17. Health and Safety Code section 111440 states that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

STATE REGULATORY PROVISIONS

18. California Code of Regulations, title 16, section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

19. California Code of Regulations, title 16, section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

20. California Code of Regulations, title 16, section 1735 states:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need,

preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

21. California Code of Regulations, title 16, section 1735.2: [1]

. . . .

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

(3) Process and/or procedure used to prepare the drug.

(4) Quality reviews required at each step in preparation of the drug.

(5) Post-compounding process or procedures required, if any.

(6) Expiration dating requirements.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the

[1] The California Code of Regulations sections listed above are from the prior version of the Regulations. In 2013, the Regulations were renumbered and reorganized and the following pertinent revisions were made: California Code of Regulations, title 16, section 1735.2, subsection (d)(2), (equipment to be used) was added to the section in 2013 (filed 2-6-2013; operative 4-1-2013). California Code of Regulations, title 16, section 1735.3, subsection (a)(7), (the equipment used in compounding the drug product) was removed from the section in 2013 and the section was renumbered (renumbering filed 2-6-2013; operative 4-1-2013). In addition, California Code of Regulations, title 16, section 1735.3, subsections (a)(8) (assigned lot) and (a)(9) (expiration date) were renumbered in 2013 to 1735.3 subsections (a)(7) and (a)(8).

pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board Form 17M-39 (Rev. 01/11). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

22. California Code of Regulations, title 16, section 1735.3 states in pertinent part:

(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 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 twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) The equipment used in compounding the drug product.

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

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

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

. . . .

23. California Code of Regulations, title 16, section 1751.7 provides:

(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.

COST RECOVERY

24. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

25. Follistim AQ and Gonal F, are the brand names for follitropin beta, and are dangerous drugs pursuant to Business and Professions Code section 4022.

26. Lupron, the brand name for leuprolide is a dangerous drug pursuant to Business and Professions Code section 4022.

27. Progesterone is a dangerous drug pursuant to Business and Professions Code section 4022.

28. Trimix, the brand name for phentolamine, papaverine and alprostadil, is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

Original Investigation

29. On July 12, 2012, Board inspectors performed a routine inspection of La Jolla Discount Pharmacy located at 9850 Genesee Avenue, Suite 160, in San Diego, California. The President and Pharmacist-in-Charge (PIC) Ahmad Mashayekan was not present during the inspection, and instead another pharmacist was present that day.

30. During this inspection, the Board inspectors discovered a prescription (number 677 252) for Gonal F RRG Pen 900UI/1.5 ml number 4 sitting on the window sill behind the pick-up area in the pharmacy and not in the refrigerator, even though this product is labeled, "keep in refrigerator DO NOT FREEZE." The pharmacy technician told inspectors that this prescription (number 677 252) was out of the refrigerator for shipping to the patient. However, the prescription label showed that the drug was filled on June 1, 2012, over a month prior. Inspectors

discovered that Respondents were not refrigerating Gonal F and Follistim AQ[2] as required by the FDA approved package insert. The pharmacist told inspectors that he had questioned the PIC why the Gonal F and Follistim AQ were not refrigerated, and that the PIC told him it was "ok." Because the Gonal F and Follistim AQ were being stored contrary to the manufacturer's package insert, the Board inspectors found that the improperly stored drugs were adulterated and embargoed all of Respondent's Gonal F and Follistim AQ inventory on July 12, 2012 as follows:

Drug	Lot	Expiration Date	Quantity
Follistim AQ 900UI NDC 0052-0326-01	H010938	1/15	48
Follistim AQ 900UI NDC 0052-0326-01	900358 lot 2 H010938	1/15	6
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8603	11/14	2
Follistim AQ 900UI NDC 0052-0326-01	H010938	1/15	10
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8903	11/14	48
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8903	11/14	31
Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	24
Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	24
Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	15
Follistim AQ 300UI NDC 0052-0326-01	H011642	11/14	120
Follistim AQ 300UI NDC 0052-0326-01	913795 H011642	11/14	1
Follistim AQ 300UI NDC 0052-0326-01	913795 H011643	11/14	6
Gonal F RFF Pen 900UI	BA009965	11/13	1
Gonal F RFF Pen 900UI	BA00913	11/13	1
Gonal F RFF Pen 450UI	BA008811	6/13	4

[2] Follistim AQ is a drug filled cartridge which is ready-for-use, prefilled with solution, and disposable. The cartridge contains follitropin beta in aqueous solution for multiple dose use. Gonal F RFF Pen is a prefilled pen for injection.

Gonal F RFF Pen 450UI	BA009177	6/13	6
Gonal F RFF Pen 300UI	BA008280	5/13	4
Gonal F RFF Pen 300UI	BA009112	5/13	5
			TOTAL: 356 units

31. The inspectors also discovered a prescription (number 681 156) for patient HF for Lupron 1mg/0.2 ml (14 day kit) in the pharmacy. Board inspectors compared Respondent's compounding log to the FDA approved package insert for LUPRON® INJECTION (leuprolide acetate) NDC 0074-3612-34 by Abbott Laboratories. Respondents were making an imitation of Abbott's LUPRON® INJECTION. Upon further investigation, the Board inspectors determined that La Jolla Discount Pharmacy manufactured, held, or offered for sale at least 171 vials of leuprolide acetate 1mg/0.2cc 3cc from August 17, 2011 to June 26, 2012.

32. In reviewing the compounding records, the Board inspectors discovered that the pharmacy was compounding non-sterile to sterile progesterone 100 mg/ml in sesame oil 10 ml and leuprolide acetate 1 mg/0.2ml 3ml in batches of fifty or more and failed to document pyrogen testing. The inspectors also discovered that the pharmacy had two master formulas for progesterone 100 mg/ml in sesame oil 10 ml and leuprolide acetate 1 mg/0.2ml 3ml in their policy and procedure binder; however, neither of those formulas matched the ingredients or procedures on the compounding log. The pharmacy staff present on July 12, 2012 could not answer questions about the compounded products because, according to staff, only the PIC compounded sterile products.

33. On July 12, 2012, Board inspectors notified Respondent Mashayekan to provide several records including a current compounding self-assessment, the updated master formula for several products, documents showing the embargoed items were being held under the conditions specified by the manufacturer, compounding logs for several products, and the drug utilization reviews and purchasing records for one year for the Follistim AQ and Gonal F products. After reviewing and comparing records of acquisition and disposition for 2012, Board inspectors

determined that Respondents sold, held, or offered for sale at least 1,404 units of adulterated Follistim AQ units from February 29, 2012 through June 7, 2012, which La Jolla Discount Pharmacy had no capacity of storing under refrigeration (as required by the FDA approved package insert.) In addition, after reviewing the records of acquisition and disposition from July 12, 2011 to July 12, 2012, the Board inspectors discovered that there were no records of acquisition for 9 units Gonal-F 450 units vial, 25 units Gonal-F RFF 900 units pen 1ml, 9 units Gonal-F RFF 450 units pen 1 ml, and 18 units Gonal-F RFF 900 units pen. Even though the Board inspector made a request for records of acquisition for the Gonal-F drug products, Respondent failed to produce those records to the inspector.

34. On July 13, 2012, the Board inspectors returned to La Jolla Discount Pharmacy for a follow-up inspection. The PIC was not present during this investigation. During this inspection, the inspectors discovered that Respondents were compounding non-sterile to sterile TriMix, even though neither a master formula nor compounding log for non-sterile to sterile TriMix was available. Board inspectors determined that Respondents had used the sterile to sterile master formula and compound log for the non-sterile to sterile compounding of TriMix assigned lot 722012. Board inspectors also observed in the restroom, less than three feet from the toilet, a new refrigerator which housed Follistim AQ and Gonal F products, as well as other products. All medications housed in the restroom refrigerator were determined to be adulterated and were embargoed.

35. On July 17, 2012, the Board inspectors returned to La Jolla Discount Pharmacy for another follow-up inspection. The PIC was present during this inspection. The PIC was questioned about why the TriMix lot 722012 compounding log and master formulas did not match with respect to the ingredients or procedures used. The PIC stated that he was performing sterile to sterile compounding of this product until the sterile products became unavailable. The PIC admitted that the batch compounded on July 2, 2012 for lot 722012 of TriMix was compounded from non-sterile alprostadil and phentolamine powder from Medisca. The PIC told inspectors that this compounded lot was in quarantine until the sterility and potency data returned; however, the product was found by inspectors in the dispensing refrigerator and was not marked

as "quarantine." Inspectors directed Respondents to send out lot 722012 of TriMix for destruction because the compounds were made from non-sterile ingredients, and the master formula and compounding log used to compound them was for sterile to sterile preparation.

36. Respondents were also repeatedly asked to produce records for items La Jolla Discount Pharmacy sold to wholesalers within the last three years. The PIC admitted to selling injectables to a wholesaler, Optima Pharmaceuticals, approximately one year prior. The Board inspector allowed Respondents an extension to produce the requested records; however, Respondents would not produce to the Board inspector any records of disposition for the drugs sold to Optima Pharmaceuticals.

37. Board inspectors also reviewed the PIC's self assessment dated June 30, 2011, which represented that La Jolla Discount Pharmacy was in compliance with all applicable laws and regulations. The PIC marked "yes" to ten statements relating to compounding (sections 2.3, 3.1, 3.5, 5.2, 8.1, 12.2, 14.2, 14.5.7, 18.1, and 18.4) even though those statements were not true.

38. In addition, Board inspectors reviewed Respondents' policy and procedure with respect to the cleaning schedule for the "clean room" (controlled area and the equipment in the controlled area where the non-sterile to sterile compounded products were prepared.) Respondents' policy and procedure sets forth that the "clean room" shall "be cleaned each day the room is to be used, hood, work area and floors shall be cleaned and sanitized before room is used, weekly walls and ceiling will be sanitized." However, when the inspectors reviewed Respondents' "clean room log," they discovered that Respondents were not following their own policies and procedures. The "clean room log" showed that cleaning was performed on 1/18/12, 2/12/12, 3/15/12, 4/10/12, 5/19/12, 6/15/12 and 6/30/12. As such, the walls and ceiling were not being sanitized weekly. Further, Respondents compounded on 3/13/12, 6/26/12, 7/2/12, and 7/26/12 and did not clean the room, hood, work area and floors on those dates as required by Respondents' policies and procedures.

39. At the conclusion of the investigation, including five site inspections (three of which the PIC was present), Board inspectors determined that the following non-sterile to sterile compounded drug products did not meet requirements as follows:

Date	Lot	Expiration Date	Drug	Amount Made	Investigation Revealed
8/17/11	8152011	12/1/11	Leuprolide 1 mg/0.2 ml 3ml	66	-No pyrogen testing done -No master formula found matching compounding log
3/13/12	6/10/2012	4/14/12	Leuprolide 1 mg/0.2 ml 3ml	50	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log -Quantity of each component missing
6/26/12	6272012	8/30/12	Leuprolide 1 mg/0.2 ml 3ml	55	-No sterility done before dispensing -Expiration of final product not listed on compounding log -No master formula found matching compounding log -Quantity of each component missing
3/12/12	0120212A	6/10/12	Leuprolide 1 mg/0.2 ml 3ml	66	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log
6/11/11	6112011	9/12/11	Leuprolide 1 mg/0.2 ml 3ml	66	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log
Unknown	762012A3	9/7/12	Progesterone 100mg/ml 10ml	60	-No compounded date on compounding log -No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log -Quantity of each component missing
Unknown	71211	9/13/11	Progesterone 100mg/ml 10ml	100	-No sterility or pyrogen testing done before dispensing -No compounding date on compounding log -No master formula found matching compounding log
Unknown	71211	9/13/11	Progesterone 100mg/ml 10ml	50	-No sterility or pyrogen testing done before dispensing -No compounded date on compounding log -No master formula found matching compounding log -Quantity of each component missing

Unknown	7602012ab	9/7/12	Progesterone 100mg/ml 10ml	25	-No compounded date on compounding log -No master formula found matching compounding log -Quantity of each component missing
7/2/12	722012	9/30/12	TriMix 5 ml	15	-Log used was for sterile to sterile, however non-sterile alprostadil and phentolammine was used from Medisca -No master formula found matching compounding log -Expiration of final product not listed on compounding log -Quantity of each component missing

Supplemental Investigation

40. During a supplemental investigation by a different set of Board inspectors determined that Respondents made Phentolamine sterile injectable solution from a non-sterile ingredient. Inspectors also discovered that Respondents dispensed four prescriptions of TriMix (Papaverine/Phentolamine/Alprostadil (PGE1)) before one of the ingredients (Phentolamine) finished its quarantine. Specifically, Respondents provided inspectors with a master formula and a compounding log for Phentolamine 5 mg/cc, which showed that the compound was made on November 1, 2012 (lot #110112). The DnyaLab certificate of analysis for sample W-1-37 showed that a sample of Phentolamine 5 mg/cc was received on November 8, 2012 and passed endotoxin and sterility tests on November 22, 2012. However, Respondents dispensed prescription numbers 696 124, 697 463, 697 943, and 641 415 before the Phentolamine finished its quarantine.

41. Board inspectors also discovered that Respondents dispensed ten prescriptions of TriMix with a concentration ratio different from what was written on the original prescription as follows:

RX Number	Medication Dispensed	Medication Written on Prescription	Date Medication Compounded and Dispensed
696 124	TriMix 22/1/20	TriMix 20/1/20	11/15/2012
697 463	TriMix 22/1/20	TriMix 20/1/20	11/15/2012

697 943	TriMix 22/1/20	TriMix 20/1/20	11/15/2012
641 415	TriMix 22/1/20	TriMix 20/1/20	11/16/2012
662 756	TriMix 22/1/20	TriMix 20/1/20	11/26/2012
699 427	TriMix 22/1/20	TriMix 20/1/20	11/29/2012
699 408	TriMix 22/1/20	TriMix 20/1/20	11/29/2012
699 495	TriMix 22/1/20	TriMix 20/1/20	11/29/2012
676 907	TriMix 22/1/20	TriMix 20/1/20	12/05/2012
659 319	TriMix 22/1/20	TriMix 20/1/20	12/03/2012

42. For each of the ten prescriptions, the physician ordered TriMix 20/1/20; however, Respondents compounded and dispensed 22/1/20.

FIRST CAUSE FOR DISCIPLINE

(Adulterated Drugs)

43. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4169(a)(2) and Health and Safety Code section 111295, for manufacturing, selling, delivering, holding, purchasing, trading, transferring or offering for sale adulterated drugs, in that Respondents held 356 adulterated medications in the pharmacy on July 12, 2012 and sold, held, or offered for sale at least 1,404 units of adulterated drugs from February 29, 2012 through June 7, 2012, as set forth in paragraphs 30, 33, and 34, which are incorporated herein as if fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Misbranded Drugs)

44. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4169(a)(3) and Health and Safety Code section 111440, for manufacturing, selling, delivering, holding, purchasing, trading, transferring or offering for sale a misbranded drug, in that Respondents manufactured an imitation of Abbott's LUPRON® Injection on 171 occasions, as set forth in paragraph 31, which is incorporated herein as if fully set forth.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Records of Acquisition & Disposition & Failure to Keep Current Inventory)

45. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4081, subdivision (a), for failure to maintain records of acquisition and disposition and failure to keep a current inventory, as set forth in paragraphs 33 and 36, which are incorporated herein by reference and as follows:

a. From July 12, 2011 to July 12, 2012, Respondents failed to keep a current inventory for GONAL-F 450 units vial, GONAL-F RFF 300 units pen 1 ml, GONAL-F RFF 450 units pen 1 ml, and GONAL-F RFF 900 units pen.

b. Respondents failed to maintain records of disposition for medications sold to Optima Pharmaceutical from August 10, 2009 to August 10, 2012.

c. Respondents failed to maintain records of acquisition for GONAL-F drug products from July 12, 2011 to July 12, 2012.

FOURTH CAUSE FOR DISCIPLINE

(Preparing or Signing a Document that Falsely Represents the Existence of a Fact)

46. Respondents are subject to disciplinary action under section 4301, subdivision (g) in that on or about June 30, 2011, the PIC prepared or signed a document that falsely represents the existence of a fact when he prepared and signed the compounding self assessment form attesting that the pharmacy was compliant with at least ten regulations, which was not true, as set forth in paragraphs 37 through 39, which is incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Prepare a Written Master Formula Prior to Compounding)

47. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.2, in that Respondents failed to prepare a written master formula prior to compounding ten non-sterile to sterile drug products, as set forth in paragraph 39, which is incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Pharmacy Compounding Records)

48. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.3, subdivision (a) in that Respondents failed to maintain adequate pharmacy compounding records, as set forth in paragraph 35 and 39, which are incorporated herein by reference; as follows:

a. Respondents failed to maintain the master formula records which corresponded to active/inactive ingredients and process and/or procedure used to prepare ten non-sterile to sterile compounds as required by section 1735.3, subdivision (a)(1);

b. Respondents failed to document the date the drug product was compounded as required by section 1735.3, subdivision (a)(2), for four lots of progesterone 100 mg/ml (Lots: 762012A3, 71211 (#50), 71211 (#100), and 7602012ab);

c. Respondents failed to document the quantity of each component used in compounding the drug product for six compounded products as required by section 1735.3, subdivision (a)(5);

d. Respondents assigned reference or lot numbers for the compounded drug product for two compounded products (progesterone 100 mg/ml lot 71211 (#50) and lot 71211 (#100)), which were assigned the same lot number even though each product used different lots of components in violation of section 1735.3, subdivision (a)(8); and

e. Respondents failed to document the expiration date of the final compounded drug product as required by section 1735.3, subdivision (a)(9) for two compounded items (leuprolide lot 6272012 and TriMix lot 722012).

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Batches of Non-Sterile to Sterile Products)

49. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1751.7, subdivision (c), in that Respondents failed to quarantine eight batches of non-sterile to sterile compounds until the end

product testing confirmed sterility and acceptable levels of pyrogens, as set forth in paragraph 39, which is incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Provide Ongoing Quality Assurance Program for Compounded Products)

50. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1751.7, subdivision (a), in that Respondents failed to provide an ongoing quality assurance program for its cleaning and sanitization of the parenteral medication preparation area, as set forth in paragraph 38, which is incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Subverting a Board Investigation)

51. Respondents are subject to disciplinary action under section 4301, subdivision (q), in that Respondents engaged in conduct that subverted or attempted to subvert an investigation of the Board when it failed to provide the purchasing records of Gonal-F products, and failed to provide the records of sales to wholesalers after repeated requests from the Board inspector, as set forth in paragraph 33 and 36, which is incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Against Respondent Mashayekan: Unprofessional Conduct)

52. Respondent Mashyaken is subject to disciplinary action for unprofessional conduct under section 4306.5, subdivision (a), in that Respondent failed to exercise or implement his best professional judgment as follows, as set forth in paragraphs 29 through 39, which are incorporated herein by reference:

a. Respondent allowed 356 medications to be stored contrary to the FDA approved package insert;

b. Respondent manufactured, held, or offered for sale at least 171 vials of misbranded leuprolide acetate 1mg/0.2cc 3cc from August 17, 2011 to June 26, 2012;

c. Respondent failed to keep records of disposition for medications sold to Optima Pharmaceutical from August 10, 2009 to August 10, 2012;

d. Respondent failed to keep a current inventory for Gonal-F 450 units vial, Gonal-F RFF 300 unit pen 1 ml, Gonal-F RFF 450 units pen 1 ml, and Gonal F Rff 900 units pen from July 12, 2011 to July 12, 2012;

e. Respondent failed to prepare a written master formula prior to compounding;

f. Respondent failed to keep complete pharmacy compounding records as required by law;

g. Respondent failed to quarantine batches of non-sterile to sterile injectables; and

h. Respondent failed to provide an ongoing quality assurance program for compounded products.

ELEVENTH CAUSE FOR DISCIPLINE

(Dispensing Medication Prior to Completing Quarantine)

53. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1751.7, subdivision (c) for dispensing four TriMix prescriptions prior to completing quarantine to confirm sterility and acceptable levels of pyrogens, as set forth in paragraph 40, which is incorporated herein by reference.

TWELFTH CAUSE FOR DISCIPLINE

(Variation from Prescriptions)

54. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1716 for dispensing ten prescriptions of TriMix with a concentration ration which was different from that ordered by the physician dispensing four TriMix prescriptions, as set forth in paragraphs 41 through 42, which are incorporated herein by reference.

DISCIPLINARY CONSIDERATIONS

55. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. On February 2, 2012, the Board issued Citation Number CI 2011 49511 against Respondent Mashay Inc., dba La Jolla Discount Pharmacy for violating California Code of Regulations, title 16, sections 1735.5(a) and 1735.7(a)(b) and (c).

b. On February 2, 2012, the Board issued Citation Number CI 2011 51182 against Respondent Ahmad Mashayekan for violating California Code of Regulations, title 16, sections 1735.5(a) and 1735.7(a)(b) and (c).

c. On October 11, 2012, the Board issued Citation Number CI 2011 50310 against Respondent Mashay Inc., dba La Jolla Discount Pharmacy for violating California Code of Regulations, title 16, section 1716 and Business and Professions Code sections 4077(a) and 4076(a)(2)(11)(A).

d. On October 11, 2012, the Board issued Citation Number CI 2012 54027 against Respondent Ahmad Mashayekan for violating California Code of Regulations, title 16, section 1716 and Business and Professions Code sections 4077(a) and 4076(a)(2)(11)(A) and ordered Respondent Ahmad Mashayekan to pay the fine in the amount of $500.00 by November 10, 2012. Respondent complied with the citation.

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 Pharmacy Permit Number PHY 38070, issued to Mashay Inc., dba La Jolla Discount Pharmacy.

2. Revoking or suspending Sterile Compounding Permit Number LSC 99245, issued to Mashay Inc., dba La Jolla Discount Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 37980 issued to Ahmad Mashayekan;

4. 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;

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

DATED: 1/23/14

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

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

In the Matter of the Accusation Against: **MASHAY INC., DBA LA JOLLA DISCOUNT PHARMACY;** **AHMAD MASHAYEKAN, PRES/PIC** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** **Pharmacy Permit No. PHY 38070** **Sterile Compounding Permit No. LSC 99245** **and** **AHMAD MASHAYEKAN** **9850 Genesee Ave., Ste. 160** **La Jolla, CA 92037** **Pharmacist License No. RPH 37980** Respondents.	Case No. 4572 **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 October 8, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 38070 to Mashay Inc., dba La Jolla Discount Pharmacy; with Ahmad Mashayekan as President and Pharmacist-in-Charge (PIC) (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2013, unless renewed.

3. On or about June 30, 2004, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99245 to Mashay Inc., dba La Jolla Discount Pharmacy (Respondent). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2013, unless renewed.

4. On or about September 7, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37980 to Ahmad Mashayekan (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2013, unless renewed.

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 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4300.1 of the Code 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.

STATUTORY PROVISIONS

8. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

9. Section 4169 of the Code states in pertinent part:

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

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

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

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

. . . .

10. Section 4301 of the Code states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
>
> . . . .
>
> (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.
>
> . . . .

11. Section 4306.5 of the Code states:

> Unprofessional conduct for a pharmacist may include any of the following:
>
> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
>
> . . . .

12. Health and Safety Code section 111250 provides that any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

13. Health and Safety Code section 111255 states that any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

14. Health and Safety Code section 111295 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

15. Health and Safety Code section 111330 states that any drug or device is misbranded if its labeling is false or misleading in any particular.

16. Health and Safety Code section 111335 states that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

17. Health and Safety Code section 111395 provides:

> Any drug is misbranded in any of the following cases:
>
> (a) It is an imitation of another drug.
>
> (b) It is offered for sale under the name of another drug.
>
> (c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

18. Health and Safety Code section 111440 states that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

STATE REGULATORY PROVISIONS

19. California Code of Regulations, title 16, section 1718 states:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

20. California Code of Regulations, title 16, section 1735.2:

> . . . .
>
> (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
>
> (1) Active ingredients to be used.
>
> (2) Inactive ingredients to be used.
>
> (3) Process and/or procedure used to prepare the drug.
>
> (4) Quality reviews required at each step in preparation of the drug.
>
> (5) Post-compounding process or procedures required, if any.
>
> (6) Expiration dating requirements.
>
> (e) Where a pharmacy does not routinely compound a particular drug

product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board Form 17M-39 (Rev. 01/11). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

21. California Code of Regulations, title 16, section 1735.3 states in pertinent part:[1]

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

[1] The California Code of Regulations sections listed above are from the prior version of the Regulations. In 2013, the Regulations were renumbered and reorganized and the following pertinent revisions were made: California Code of Regulations, title 16, section 1735.2, subsection (d)(2), (equipment to be used) was added to the section in 2013 (filed 2-6-2013; operative 4-1-2013). California Code of Regulations, title 16, section 1735.3, subsection (a)(7), (the equipment used in compounding the drug product) was removed from the section in 2013 and the section was renumbered (renumbering filed 2-6-2013; operative 4-1-2013). In addition, California Code of Regulations, title 16, section 1735.3, subsections (a)(8) (assigned lot) and (a)(9) (expiration date) were renumbered in 2013 to 1735.3 subsections (a)(7) and (a)(8).

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 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 twenty-four hours to an inpatient in a health care facility licensed under section section 1250 of the Health and Safety Code.

(7) The equipment used in compounding the drug product.

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

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

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

. . . .

22. California Code of Regulations, title 16, section 1751.7 provides:

(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.

COST RECOVERY

23. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

24. Follistim AQ and Gonal F, are the brand names for follitropin beta, and are dangerous drugs pursuant to Business and Professions Code section 4022.

25. Lupron, the brand name for leuprolide is a dangerous drug pursuant to Business and Professions Code section 4022.

26. Progesterone is a dangerous drug pursuant to Business and Professions Code section 4022.

27. Trimix, the brand name for phentolamine, papaverine and alprostadil, is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

28. On July 12, 2012, Board inspectors performed a routine inspection of La Jolla Discount Pharmacy located at 9850 Genesee Avenue, Suite 160, in San Diego, California. The President and Pharmacist-in-Charge (PIC) Ahmad Mashayekan was not present during the inspection, and instead another pharmacist was present that day.

29. During this inspection, the Board inspectors discovered a prescription (number 677 252) for Gonal F RRG Pen 900UI/1.5 ml number 4 sitting on the window sill behind the pick-up area in the pharmacy and not in the refrigerator, even though this product is labeled, "keep in refrigerator DO NOT FREEZE." The pharmacy technician told inspectors that this prescription (number 677 252) was out of the refrigerator for shipping to the patient. However, the prescription label showed that the drug was filled on June 1, 2012, over a month prior. Inspectors discovered that Respondents were not refrigerating Gonal F and Follistim AQ[2] as required by the FDA approved package insert. The pharmacist told inspectors that he had questioned the PIC why the Gonal F and Follistim AQ were not refrigerated, and that the PIC told him it was "ok." Because the Gonal F and Follistim AQ were being stored contrary to the manufacturer's package insert, the Board inspectors found that the improperly stored drugs were adulterated and embargoed all of Respondent's Gonal F and Follistim AQ inventory on July 12, 2012 as follows:

Drug	Lot	Expiration Date	Quantity
Follistim AQ 900UI NDC 0052-0326-01	H010938	1/15	48
Follistim AQ 900UI NDC 0052-0326-01	900358 lot 2 H010938	1/15	6
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8603	11/14	2
Follistim AQ 900UI NDC 0052-0326-01	H010938	1/15	10
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8903	11/14	48
Follistim AQ 900UI NDC 0052-0326-01	2-CO-8903	11/14	31

[2] Follistim AQ is a drug filled cartridge which is ready-for-use, prefilled with solution, and disposable. The cartridge contains follitropin beta in aqueous solution for multiple dose use. Gonal F RFF Pen is a prefilled pen for injection.

Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	24
Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	24
Follistim AQ 600UI NDC 0052-0326-01	2-CO-7600	7/14	15
Follistim AQ 300UI NDC 0052-0326-01	H011642	11/14	120
Follistim AQ 300UI NDC 0052-0326-01	913795 H011642	11/14	1
Follistim AQ 300UI NDC 0052-0326-01	913795 H011643	11/14	6
Gonal F RFF Pen 900UI	BA009965	11/13	1
Gonal F RFF Pen 900UI	BA00913	11/13	1
Gonal F RFF Pen 450UI	BA008811	6/13	4
Gonal F RFF Pen 450UI	BA009177	6/13	6
Gonal F RFF Pen 300UI	BA008280	5/13	4
Gonal F RFF Pen 300UI	BA009112	5/13	5
			TOTAL: 356 units

30. The inspectors also discovered a prescription (number 681 156) for patient HF for Lupron 1mg/0.2 ml (14 day kit) in the pharmacy. Board inspectors compared Respondent's compounding log to the FDA approved package insert for LUPRON® INJECTION (leuprolide acetate) NDC 0074-3612-34 by Abbott Laboratories. Board inspectors discovered that Respondents were making an imitation of Abbott's LUPRON® INJECTION. Upon further investigation, the Board inspectors determined that La Jolla Discount Pharmacy manufactured, held, or offered for sale at least 171 vials of leuprolide acetate 1mg/0.2cc 3cc from August 17, 2011 to June 26, 2012.

31. In reviewing the compounding records, the Board inspectors discovered that the pharmacy was compounding[3] non-sterile to sterile progesterone 100 mg/ml in sesame oil 10 ml

[3] Compounding is the pharmacy practice of mixing, combining, or altering ingredients to create a drug product. Pursuant to California Code of Regulations, title 16, section 1735, compounding is defined as: (1) altering the dosage form or delivery system of a drug; (2) altering (continued...)

and leuprolide acetate 1 mg/0.2ml 3ml in batches of fifty or more and failed to document pyrogen testing. The inspectors also discovered that the pharmacy had two master formulas for progesterone 100 mg/ml in sesame oil 10 ml and leuprolide acetate 1 mg/0.2ml 3ml in their policy and procedure binder; however, neither of those formulas matched the ingredients or procedures on the compounding log. The pharmacy staff present on July 12, 2012 could not answer questions about the compounded products because, according to staff, only the PIC compounded sterile products.

32. On July 12, 2012, Board inspectors notified Respondent Mashayekan to provide several records including a current compounding self-assessment, the updated master formula for several products, documents showing the embargoed items were being held under the conditions specified by the manufacturer, compounding logs for several products, and the drug utilization reviews and purchasing records for one year for the Follistim AQ and Gonal F products. After reviewing and comparing records of acquisition and disposition for 2012, Board inspectors determined that Respondents sold, held, or offered for sale at least 1,404 units of adulterated Follistim AQ units from February 29, 2012 through June 7, 2012, which La Jolla Discount Pharmacy had no capacity of storing under refrigeration (as required by the FDA approved package insert.) In addition, after reviewing the records of acquisition and disposition from July 12, 2011 to July 12, 2012, the Board inspectors discovered that there were no records of acquisition for 9 units Gonal-F 450 units vial, 25 units Gonal-F RFF 300 units pen 1ml, 9 units Gonal-F RFF 450 units pen 1 ml, and 18 units Gonal-F RFF 900 units pen.

33. On July 13, 2012, the Board inspectors returned to La Jolla Discount Pharmacy for a follow-up inspection. The PIC was not present during this investigation. During this inspection, the inspectors discovered that Respondents were compounding non-sterile to sterile TriMix, even though neither a master formula nor compounding log for non-sterile to sterile TriMix was available. Board inspectors determined that Respondents had used the sterile to sterile master formula and compound log for the non-sterile to sterile compounding of TriMix assigned lot

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the strength of a drug; (3) combining components or active ingredients; (4) preparing a drug product from chemicals or bulk drug substances.

722012. Board inspectors also observed in the restroom, less than three feet from the toilet, a new refrigerator which housed Follistim AQ and Gonal F products, as well as other products. All medications housed in the restroom refrigerator were determined to be adulterated and were embargoed.

34. On July 17, 2012, the Board inspectors returned to La Jolla Discount Pharmacy for another follow-up inspection. The PIC was present during this inspection. The PIC was questioned about why the TriMix lot 722012 compounding log and master formulas did not match with respect to the ingredients or procedures used. The PIC stated that he was performing sterile to sterile compounding of this product until the sterile products became unavailable. The PIC admitted that the batch compounded on July 2, 2012 for lot 722012 of TriMix was compounded from non-sterile alprostadil and phentolamine powder from Medisca. The PIC told inspectors that this compounded lot was in quarantine until the sterility and potency data returned; however, the product was found by inspectors in the dispensing refrigerator and was not marked as "quarantine." Inspectors directed Respondents to send out lot 722012 of TriMix for destruction because the compounds were made from non-sterile ingredients, and the master formula and compounding log used to compound them was for sterile to sterile preparation.

35. Respondents were also asked to produce records for items La Jolla Discount Pharmacy sold to wholesalers within the last three years. The PIC admitted to selling injectables to a wholesaler, Optima Pharmaceuticals, approximately one year prior; however, Respondents could not produce any records of disposition for the drugs sold to Optima Pharmaceuticals.

36. Board inspectors also reviewed the PIC's self assessment dated June 30, 2011, which represented that La Jolla Discount Pharmacy was in compliance with all applicable laws and regulations. The PIC marked "yes" to ten statements relating to compounding (sections 2.3, 3.1, 3.5, 5.2, 8.1, 12.2, 14.2, 14.5.7, 18.1, and 18.4) even though those statements were not true.

37. In addition, Board inspectors reviewed Respondents' policy and procedure with respect to the cleaning schedule for the "clean room" (controlled area and the equipment in the controlled area where the non-sterile to sterile compounded products were prepared.) Respondents' policy and procedure sets forth that the "clean room" shall "be cleaned each day the

room is to be used, hood, work area and floors shall be cleaned and sanitized before room is used, weekly walls and ceiling will be sanitized." However, when the inspectors reviewed Respondents' "clean room log," they discovered that Respondents were not following their own policies and procedures. The "clean room log" showed that cleaning was performed on 1/18/12, 2/12/12, 3/15/12, 4/10/12, 5/19/12, 6/15/12 and 6/30/12. As such, the walls and ceiling were not being sanitized weekly. Further, Respondents compounded on 3/12/12, 3/13/12, 6/26/12, 7/2/12, and 7/26/12 and did not clean the room, hood, work area and floors on those dates as required by Respondents' policies and procedures.

38. At the conclusion of the investigation, Board inspectors determined that the following non-sterile to sterile compounded drug products did not meet requirements as follows:

Date	Lot	Expiration Date	Drug	Amount Made	Investigation Revealed
8/17/11	8152011	12/1/11	Leuprolide 1 mg/0.2 ml 3ml	66	-No pyrogen testing done -No master formula found matching compounding log
3/13/12	6/10/2012	4/14/12	Leuprolide 1 mg/0.2 ml 3ml	50	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log -Quantity of each component missing
6/26/12	6272012	8/30/12	Leuprolide 1 mg/0.2 ml 3ml	55	-No sterility done before dispensing -Expiration of final product not listed on compounding log -No master formula found matching compounding log -Quantity of each component missing
3/12/12	0120212A	6/10/12	Leuprolide 1 mg/0.2 ml 3ml	66	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log
6/11/11	6112011	9/12/11	Leuprolide 1 mg/0.2 ml 3ml	66	-No sterility or pyrogen testing done before dispensing -No master formula found matching compounding log
Unknown	762012A3	9/7/12	Progesterone 100mg/ml 10ml	60	-No compounded date on compounding log -No sterility or pyrogen testing done before dispensing

					-No master formula found matching compounding log -Quantity of each component missing
Unknown	71211	9/13/11	Progesterone 100mg/ml 10ml	100	-No sterility or pyrogen testing done before dispensing -No compounding date on compounding log -No master formula found matching compounding log
Unknown	71211	9/13/11	Progesterone 100mg/ml 10ml	50	-No sterility or pyrogen testing done before dispensing -No compounded date on compounding log -No master formula found matching compounding log -Quantity of each component missing
Unknown	7602012ab	9/7/12	Progesterone 100mg/ml 10ml	25	-No compounded date on compounding log -No master formula found matching compounding log -Quantity of each component missing
7/2/12	722012	9/30/12	TriMix 5 ml	15	-Log used was for sterile to sterile, however non-sterile alprostadil and phentolammine was used from Medisca -No master formula found matching compounding log -Expiration of final product not listed on compounding log -Quantity of each component missing

FIRST CAUSE FOR DISCIPLINE

(Adulterated Drugs)

39. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4169(a)(2) and Health and Safety Code section 111295, for manufacturing, selling, delivering, holding, purchasing, trading, transferring or offering for sale adulterated drugs, in that Respondents held 356 adulterated medications in the pharmacy on July 12, 2012 and sold, held, or offered for sale at least 1,404 units of adulterated drugs from February 29, 2012 through June 7, 2012, as set forth in paragraphs 29, 32 and 33, which are incorporated herein as if fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Misbranded Drugs)

40. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4169(a)(3) and Health and Safety Code section 111440, for manufacturing, selling, delivering, holding, purchasing, trading, transferring or offering for sale a misbranded drug, in that Respondents manufactured an imitation of Abbott's LUPRON® Injection on 171 occasions, as set forth in paragraph 30, which is incorporated herein as if fully set forth.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Records of Acquisition & Disposition &

Failure to Keep Current Inventory)

41. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4081, subdivision (a), for failure to maintain records of acquisition and disposition and failure to keep a current inventory, as set forth in paragraphs 32 and 35, which are incorporated herein by reference, as follows:

a. From July 12, 2011 to July 12, 2012, Respondents failed to keep a current inventory for GONAL-F 450 units vial, GONAL-F RFF 300 units pen 1 ml, GONAL-F RFF 450 units pen 1 ml, and GONAL-F RFF 900 units pen.

b. Respondents failed to maintain records of disposition for medications sold to Optima Pharmaceutical from August 10, 2009 to August 10, 2012.

FOURTH CAUSE FOR DISCIPLINE

(Preparing or Signing a Document that Falsely Represents the Existence of a Fact)

42. Respondents are subject to disciplinary action under section 4301, subdivision (g) in that on or about June 30, 2011, the PIC prepared or signed a document that falsely represents the existence of a fact when he prepared and signed the compounding self assessment form attesting that the pharmacy was compliant with at least ten regulations, which was not true, as set forth in paragraphs 36, which is incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Prepare a Written Master Formula Prior to Compounding)

43. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.2, in that Respondents failed to prepare a written master formula prior to compounding ten non-sterile to sterile drug products, as set forth in paragraph 38, which is incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Pharmacy Compounding Records)

44. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.3, subdivision (a) in that Respondents failed to maintain adequate pharmacy compounding records, as set forth in paragraph 38, which is incorporated herein by reference; as follows:

a. Respondents failed to maintain the master formula records which corresponded to active/inactive ingredients and process and/or procedure used to prepare ten non-sterile to sterile compounds as required by section 1735.3, subdivision (a)(1);

b. Respondents failed to document the date the drug product was compounded as required by section 1735.3, subdivision (a)(2), for four lots of progesterone 100 mg/ml (Lots: 762012A3, 71211 (#50), 71211 (#100), and 7602012ab);

c. Respondents failed to document the quantity of each component used in compounding the drug product for six compounded products as required by section 1735.3, subdivision (a)(5);

d. Respondents assign reference or lot numbers for the compounded drug product for two compounded products (progesterone 100 mg/ml lot 71211 (#50) and lot 71211 (#100)), which were assigned the same lot number even though each product used different lots of components in violation of as section 1735.3, subdivision (a)(8); and

e. Respondent failed to document the expiration date of the final compounded drug product as required by section 1735.3, subdivision (a)(9) for two compounded items (leuprolide lot 6272012 and TriMix lot 722012).

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Batches of Non-Sterile to Sterile Products)

45. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1751.7, subdivision (c), in that Respondents failed to quarantine eight batches of non-sterile to sterile compounds until the end product testing confirmed sterility and acceptable levels of pyrogens, as set forth in paragraph 38, which is incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Provide Ongoing Quality Assurance Program for Compounded Products)

46. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1751.7, subdivision (a), in that Respondents failed to provide an ongoing quality assurance program for its cleaning and sanitization of the parenteral medication preparation area, as set forth in paragraph 37, which is incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Against Respondent Mashayekan: Unprofessional Conduct)

47. Respondent Mashyaken is subject to disciplinary action for unprofessional conduct under section 4306.5, subdivision (a), in that Respondent failed to exercise or implement his best professional judgment as follows, as set forth in paragraph 28 through 38, which are incorporated herein by reference:

a. Respondent allowed 356 medications to be stored contrary to the FDA approved package insert;

b. Respondent manufactured, held, or offered for sale at least 171 vials of misbranded leuprolide acetate 1mg/0.2cc 3cc from August 17, 2011 to June 26, 2012;

c. Respondent failed to keep records of disposition for medications sold to Optima Pharmaceutical from August 10, 2009 to August 10, 2012;

d. Respondent failed to keep a current inventory for Gonal-F 450 units vial, Gonal-F RFF 300 unit pen 1 ml, Gonal-F RFF 450 units pen 1 ml, and Gonal F Rff 900 units pen from July 12, 2011 to July 12, 2012;

e. Respondent failed to prepare a written master formula prior to compounding;

f. Respondent failed to keep complete pharmacy compounding records as required by law;

g. Respondent failed to quarantine batches of non-sterile to sterile injectables; and

h. Respondent failed to provide an ongoing quality assurance program for compounded products.

DISCIPLINARY CONSIDERATIONS

48. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. On February 2, 2012, the Board issued Citation Number CI 2011 49511 against Respondent Mashay Inc., dba La Jolla Discount Pharmacy for violating California Code of Regulations, title 16, sections 1735.5(a) and 1735.7(a)(b) and (c).

b. On February 2, 2012, the Board issued Citation Number CI 2011 51182 against Respondent Ahmad Mashayekan for violating California Code of Regulations, title 16, sections 1735.5(a) and 1735.7(a)(b) and (c).

c. On October 11, 2012, the Board issued Citation Number CI 2011 50310 against Respondent Mashay Inc., dba La Jolla Discount Pharmacy for violating California Code of Regulations, title 16, section 1716 and Business and Professions Code sections 4077(a) and 4076(a)(2)(11)(A).

d. On October 11, 2012, the Board issued Citation Number CI 2012 54027 against Respondent Ahmad Mashayekan for violating California Code of Regulations, title 16, section 1716 and Business and Professions Code sections 4077(a) and 4076(a)(2)(11)(A) and ordered Respondent Ahmad Mashayekan to pay the fine in the amount of $500.00 by November 10, 2012. Respondent complied with the citation.

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 Pharmacy Permit Number PHY 38070, issued to Mashay Inc., dba La Jolla Discount Pharmacy.

2. Revoking or suspending Sterile Compounding Permit Number LSC 99245, issued to Mashay Inc., dba La Jolla Discount Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 37980 issued to Ahmad Mashayekan;

4. 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;

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

DATED: 4/4/13

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

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