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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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