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

In the Matter of the First Amended Accusation Against: **IMANOEL PHARMACY INC,** **DBA SUNSHINE PHARMACY,** **ELIAHOU SELEH, CEO and Secretary,** **MICHAEL IMANOEL, President and Treasurer** **357 N. Fairfax Avenue** **Los Angeles, CA 90036** **Pharmacy Permit No. PHY 44317** **AND** **ELIAHOU SELEH (PIC)** **8662 Cashio Street** **Los Angeles, CA 90035** **RPH 55937** Respondents.	Case No. 5719 **FIRST AMENDED ACCUSATION**

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 13, 1999, the Board of Pharmacy issued Pharmacy Permit Number PHY 44317 to Imanoel Pharmacy Inc, dba Sunshine Pharmacy, Michael Imanoel, as president/treasurer (51% shareholder) and Eliahou Seleh, PIC, Chief Executive Officer and Secretary (Respondent Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

3. On or about August 4, 2004, the Board of Pharmacy issued Original Pharmacist License Number RPH 55937 to Eliahou Seleh (Respondent Seleh). On August 1, 2005, Respondent Seleh became as PIC for Respondent Pharmacy. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed.

4. On or about March 20, 1992, the Board of Pharmacy issued Pharmacist License Number RPH 45182 Michael Imanoel (Respondent Imaneol). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, 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 4081 of the Code states in pertinent part:

"(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."

. . . . .

7. Section 4105 of the Code states in pertinent part:

"(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."

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

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

. . . .

(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.

. . . .

9. Section 4301 of the Code states:

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

. . . .

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

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

. . . . .

10. Section 4306.5 of the Code states in pertinent part:

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the

dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

11. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision

shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

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12. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

13. Section 111250 of the Health and Safety Code states:

"Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

14. Section 111295 of the Health and Safety Code states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

15. Section 111330 of the Health and Safety Code states:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

16. Section 111335 of the Health and Safety Code states:

"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. Section 111440 of the Health and Safety Code states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

REGULATIONS

18. 16 California Code of Regulations Section 1714 states in pertinent part:

. . . .

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly

lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

19. 16 California Code of Regulations Section 1735.2 states in pertinent part:

. . . .

"(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) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

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

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

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

. . . .

(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. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) 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."

20. 16 California Code of Regulations Section 1735.3 states in pertinent part:

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

. . . .

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

. . . .

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

21. 16 California Code of Regulations Section 1735.4 states in pertinent part:

. . . .

"(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient."

22. 16 California Code of Regulations Section 1735.5 states in pertinent part:

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented."

. . . . .

23. 16 California Code of Regulations Section 1735.6 states in pertinent part:

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

24. 16 California Code of Regulations Section 1735.7 states in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

. . . .

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product."

25. 16 California Code of Regulations Section 1735.8 states in pertinent part:

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula."

COST RECOVERY

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

FIRST CAUSE FOR DISCIPLINE

(Operational Standards and Security)

27. Respondents Pharmacy and Seleh are subject to disciplinary action under section California Code of Regulation (CCR) Section 1714(c) in that the pharmacy, fixtures and equipment for Sunshine Pharmacy, located at 357 N. Fairfax Ave., Los Angeles, CA 90036 were not maintained in clean and orderly condition as of the inspection on March 18, 2015.

SECOND CAUSE FOR DISCIPLINE

(Duty to Review the Policy and Procedures Manual)

28. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.5 subdivision (b)in that the policy and procedure manuals for Sunshine Pharmacy were not reviewed on an annual basis by the pharmacist-in-charge and had not been updated after changes in process had been implemented. During the pharmacy inspection on March 18, 2015 it was discovered that the manuals, including but not limited to the Cleaning and Maintenance of the Non-Sterile Compounding Area manual had not been reviewed by the pharmacist-in-charge for more than one year.

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THIRD CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

29. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.6 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, equipment used to compound drug products were not stored, used, and maintained in accordance with manufacturer's specifications.

FOURTH CAUSE FOR DISCIPLINE

(Adulterated Medications)

30. Respondents Pharmacy and Seleh are subject to disciplinary action under California Health and Safety Code sections 111250 and 111295 and Business & Professions Code section 4169 subdivision (a)(2) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several products were found in the active drug inventory without expiration dates listed or available for review.

FIFTH CAUSE FOR DISCIPLINE

(Misbranded Medications)

31. Respondents Pharmacy and Seleh are subject to disciplinary action under California Health and Safety Code sections 111330 and 111440 and Business and Professions Code section 4169 subdivision (a)(3) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several products found in the active drug inventory, including several drugs and bulk chemicals, were without expiration date listed on the label or available for review.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

32. Respondents Pharmacy and Seleh are subject to disciplinary action under California Business and Professions Code section 4301 subdivision (g) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several policy and procedure documents were discovered that falsely represented the existence of facts, including, but not limited to, the policy manual entitled "The Quality Assurance Program" which included information about sterile compounding, a clean room facility and process validation. The policy titled "Non-Sterile

Compounding Personnel Qualification" also included information about procedures that were not performed.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding Master Formula Requirements)

33. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.2 subdivision (d) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no complete master formulas consisting of elements listed above were available for review for drugs compounded at Sunshine Pharmacy.

EIGHTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

34. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.8 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of quantitative or qualitative analysis of compounded drugs were available for review.

NINTH CAUSE FOR DISCIPLINE

(Training of Compounding Staff)

35. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.7 subdivision (a) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of initial or ongoing training were available for review for PIC Seleh or his compounding personnel.

TENTH CAUSE FOR DISCIPLINE

(Maintenance of Records)

36. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Professions Code section 4081 in that as of the inspection of Sunshine Pharmacy on May 26, 2015, PIC Seleh failed to preserve records for three (3) years from the date of making and produce disposition records for the following lot numbers compounded at Sunshine Pharmacy: 03042015@1, 03102015@1, 03082015@6, 03182015@5, 03192015@5, 03192015@4, 03262015@3, 03252015@5, 03272015@4, 03272015@3.

ELEVENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug Products)

37. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.3 subdivision (a)(4) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, the identity of the pharmacist reviewing the final product was not listed for the following lot numbers compounded at Sunshine Pharmacy: 03042015@1, 03102015@1, 03182015@6, 03182015@5, 03192015@5, 03192015@4, 03262015@3, 03252015@5, 03272015@4, 03272015@3.

TWELFTH CAUSE FOR DISCIPLINE

(Duty to Complete Compounding Self-Assessment)

38. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.2 subdivision (j) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of compounding self-assessment by the pharmacist-in-charge were available for review.

THIRTEENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug Products)

39. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.3 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of certificates of purity or analysis of chemicals, bulk drug substances, drug products, and components used in compounding for drug products not approved by the Food and Drug Administration were available for review.

FOURTEENTH CAUSE FOR DISCIPLINE

(Labeling of the Compounded Drug Products)

40. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.4 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, none of the reviewed compounded drug labels or patient receipts contained a statement that the drug has been compounded.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

41. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code section 4301 subdivision (f) in that an audit of Sunshine Pharmacy for the period April 18, 2014 through April 18, 2015 showed that Sunshine Pharmacy repeatedly billed Medicare for cyclobenzaprine tablets for which Sunshine Pharmacy did not have equaling records of acquisition.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure or Refusal to Maintain or Produce Required Drug or Device Records)

42. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code section 4081 in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to produce records of acquisition for several NDCs of cyclobenzaprine tablets for which Sunshine billed Medicare for dispensing.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Retaining Records of Dangerous Drugs)

43. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code sections 4081 subdivision (a), 4105 subdivision (a) and 4332 as defined by CCR 1718, in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to preserve records for three years from the date of making and produce records of acquisition for several NDCs of cyclobenzaprine tablets, dangerous drugs, for which Respondent Sunshine billed Medicare.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Acts or Omissions by Pharmacist)

44. Respondent Seleh is subject to disciplinary action under Business and Profession Code section 4306.5 subdivision (b) in that in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to exercise professional

judgment as Respondent Seleh repeatedly billed Medicare for cyclobenzaprine tablets, dangerous drugs, for which he did not have equaling records of acquisition.

OTHER MATTERS

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44317 issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy, Michael Imanoel and Eliahou Seleh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if it is revoked.

46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44317 issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy while Michael Imanoel and Eliahou Seleh, and each of them had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Michael Imanoel and Eliahou Seleh, and each of them, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if it is revoked.

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 44317, issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy, with Michael Imanoel as president and treasurer and Eliahou Seleh as CEO and Secretary

2. Revoking or suspending Pharmacist License Number RPH 55937, issued to Eliahou Seleh;

3. Prohibiting Michael Imanoel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit

Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 44317 is revoked;

4. Prohibiting Eliahou Seleh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 44317 is revoked;

5. Ordering Imanoel Pharmacy Inc, dba Sunshine Pharmacy, and Eliahou Seleh, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 7/12/17

Virginia Herold

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: **IMANOEL PHARMACY INC, DBA SUNSHINE PHARMACY, ELIAHOU SELEH, CEO and Secretary, MICHAEL IMANOEL, President and Treasurer** **357 N. Fairfax Avenue** **Los Angeles, CA 90036** **Pharmacy Permit No. PHY 44317** **AND** **ELIAHOU SELEH (PIC)** **8662 Cashio Street** **Los Angeles, CA 90035** **RPH 55937** Respondents.	Case No. 5719 **A C C U S A T I O N**

Complainant alleges:

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dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

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REGULATIONS

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

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

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(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. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) 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."

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. . . .

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

20. 16 California Code of Regulations Section 1735.4 states in pertinent part:

. . . .

"(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient."

21. 16 California Code of Regulations Section 1735.5 states in pertinent part:

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented."

. . . . .

22. 16 California Code of Regulations Section 1735.6 states in pertinent part:

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

23. 16 California Code of Regulations Section 1735.7 states in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

. . . .

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product."

24. 16 California Code of Regulations Section 1735.8 states in pertinent part:

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula."

COST RECOVERY

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

FIRST CAUSE FOR DISCIPLINE

(Operational Standards and Security)

26. Respondents Pharmacy and Seleh are subject to disciplinary action under section California Code of Regulation (CCR) Section 1714(c) in that the pharmacy, fixtures and equipment for Sunshine Pharmacy, located at 357 N. Fairfax Ave., Los Angeles, CA 90036 were not maintained in clean and orderly condition as of the inspection on March 18, 2015.

SECOND CAUSE FOR DISCIPLINE

(Duty to Review the Policy and Procedures Manual)

27. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.5 subdivision (b)in that the policy and procedure manuals for Sunshine Pharmacy were not reviewed on an annual basis by the pharmacist-in-charge and had not been updated after changes in process had been implemented. During the pharmacy inspection on March 18, 2015 it was discovered that the manuals, including but not limited to the Cleaning and Maintenance of the Non-Sterile Compounding Area manual had not been reviewed by the pharmacist-in-charge for more than one year.

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THIRD CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

28. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.6 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, equipment used to compound drug products were not stored, used, and maintained in accordance with manufacturer's specifications.

FOURTH CAUSE FOR DISCIPLINE

(Adulterated Medications)

29. Respondents Pharmacy and Seleh are subject to disciplinary action under California Health and Safety Code sections 111250 and 111295 and Business & Professions Code section 4169 subdivision (a)(2) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several products were found in the active drug inventory without expiration dates listed or available for review.

FIFTH CAUSE FOR DISCIPLINE

(Misbranded Medications)

30. Respondents Pharmacy and Seleh are subject to disciplinary action under California Health and Safety Code sections 111330 and 111440 and Business and Professions Code section 4169 subdivision (a)(3) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several products found in the active drug inventory, including several drugs and bulk chemicals, were without expiration date listed on the label or available for review.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

31. Respondents Pharmacy and Seleh are subject to disciplinary action under California Business and Professions Code section 4301 subdivision (g) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, several policy and procedure documents were discovered that falsely represented the existence of facts, including, but not limited to, the policy manual entitled "The Quality Assurance Program" which included information about sterile compounding, a clean room facility and process validation. The policy titled "Non-Sterile

Compounding Personnel Qualification" also included information about procedures that were not performed.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding Master Formula Requirements)

32. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.2 subdivision (d) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no complete master formulas consisting of elements listed above were available for review for drugs compounded at Sunshine Pharmacy.

EIGHTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

33. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.8 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of quantitative or qualitative analysis of compounded drugs were available for review.

NINTH CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

34. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.6 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of calibration were found for any equipment used to compound drugs for which calibration was appropriate.

TENTH CAUSE FOR DISCIPLINE

(Training of Compounding Staff)

35. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.7 subdivision (a) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of initial or ongoing training were available for review for PIC Seleh or his compounding personnel.

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ELEVENTH CAUSE FOR DISCIPLINE

(Maintenance of Records)

36. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Professions Code section 4081 in that as of the inspection of Sunshine Pharmacy on May 26, 2015, PIC Seleh failed to preserve records for three (3) years from the date of making and produce disposition records for the following lot numbers compounded at Sunshine Pharmacy: 03042015@1, 03102015@1, 03082015@6, 03182015@5, 03192015@5, 03192015@4, 03262015@3, 03252015@5, 03272015@4, 03272015@3.

TWELFTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug Products)

37. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.3 subdivision (a)(4) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, the identity of the pharmacist reviewing the final product was not listed for the following lot numbers compounded at Sunshine Pharmacy: 03042015@1, 03102015@1, 03182015@6, 03182015@5, 03192015@5, 03192015@4, 03262015@3, 03252015@5, 03272015@4, 03272015@3.

THIRTEENTH CAUSE FOR DISCIPLINE

(Duty to Complete Compounding Self-Assessment)

38. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.2 subdivision (j) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of compounding self-assessment by the pharmacist-in-charge were available for review.

FOURTEENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug Products)

39. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.3 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, no records of certificates of purity or analysis of chemicals, bulk drug substances, drug

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products, and components used in compounding for drug products not approved by the Food and Drug Administration were available for review.

FIFTEENTH CAUSE FOR DISCIPLINE

(Labeling of the Compounded Drug Products)

40. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR section 1735.4 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18, 2015, none of the reviewed compounded drug labels or patient receipts contained a statement that the drug has been compounded.

SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

41. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code section 4301 subdivision (f) in that an audit of Sunshine Pharmacy for the period April 18, 2014 through April 18, 2015 showed that Sunshine Pharmacy repeatedly billed Medicare for cyclobenzaprine tablets for which Sunshine Pharmacy did not have equaling records of acquisition.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure or Refusal to Maintain or Produce Required Drug or Device Records)

42. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code section 4081 in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to produce records of acquisition for several NDCs of cyclobenzaprine tablets for which Sunshine billed Medicare for dispensing.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Retaining Records of Dangerous Drugs)

43. Respondents Pharmacy and Seleh are subject to disciplinary action under Business and Profession Code sections 4081 subdivision (a), 4105 subdivision (a) and 4332 as defined by CCR 1718, in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to preserve records for three years from the date of

making and produce records of acquisition for several NDCs of cyclobenzaprine tablets, dangerous drugs, for which Respondent Sunshine billed Medicare.

NINETEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Acts or Omissions by Pharmacist)

44. Respondent Seleh is subject to disciplinary action under Business and Profession Code section 4306.5 subdivision (b) in that in that for the audit of Sunshine Pharmacy during the period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to exercise professional judgment as Respondent Seleh repeatedly billed Medicare for cyclobenzaprine tablets, dangerous drugs, for which he did not have equaling records of acquisition.

OTHER MATTERS

34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44317 issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy, Michael Imanoel and Eliahou Seleh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if it is revoked.

35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44317 issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy while Michael Imanoel and Eliahou Seleh, and each of them had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Michael Imanoel and Eliahou Seleh, and each of them, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if it is revoked.

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 44317, issued to Imanoel Pharmacy Inc, dba Sunshine Pharmacy, with Michael Imanoel as president and treasurer and Eliahou Seleh as CEO and Secretary

2. Revoking or suspending Pharmacist License Number RPH 55937, issued to Eliahou Seleh;

3. Prohibiting Michael Imanoel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 44317 is revoked;

4. Prohibiting Eliahou Seleh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 44317 is revoked;

5. Ordering Imanoel Pharmacy Inc, dba Sunshine Pharmacy, and Eliahou Seleh, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 11/3/16

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

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