

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

**In the Matter of the Petition for Early Termination of
Probation by:**

**IMANOEL PHARMACY INC, DBA SUNSHINE PHARMACY,
AND ELIAHOU SELEH, Petitioners**

Case No. 5719

OAH No. 2020090403

DECISION

This matter was heard by video conference before a quorum of the Board of Pharmacy (Board) in Sacramento, California, on September 17, 2020. Marcie Larson, Administrative Law Judge, Office of Administrative Hearings (OAH), presided at the hearing.

Summer Haro, Deputy Attorney General, appeared pursuant to Government Code section 11522.

Herbert Weinberg, Attorney at Law represented petitioner Imanoel Pharmacy Inc., doing business as Sunshine Pharmacy (Sunshine) and petitioner Eliahou Seleh

(petitioner) Chief Executive Officer of Sunshine (collectively “petitioners”), who was present at the hearing.

Evidence was received, the record was closed, and the matter was submitted for decision on September 17, 2020.

FACTUAL FINDINGS

Background and Procedural History

1. On October 13, 1999, the Board issued Sunshine Permit No. PHY 44317 (permit), with Michael Imanoel as President and Treasurer of Sunshine, and petitioner as CEO and Secretary of Sunshine. Sunshine’s permit is valid and will expire on October 1, 2021, unless renewed or revoked. On August 4, 2004, the Board issued petitioner Original Pharmacist License Number RPH 55937 (license). Petitioner’s license is valid and will expire on June 30, 2022, unless renewed or revoked.

2. On July 12, 2017, complainant Virginia K. Herold, a former Executive Officer for the Board, issued a First Amended Accusation against Sunshine, Mr. Imanoel, and petitioner, in both his capacity as an officer of Sunshine and an individual license holder. Complainant alleged that, based on an inspection conducted in March 2015, Sunshine and petitioner engaged in several violations of the California Code of Regulations related to pharmacy operations and violations of Business and Professions Code sections 4301, subdivisions (f) and (g), 4169, subdivisions (a)(2) and (a)(3), 4081, 4105, subdivision (a), and 4332, for in part, failing to: review Sunshine’s policy and procedures manual on an annual basis; properly store and maintain compounding equipment; list expiration dates on drugs; complete master formulas, recording

quantitative or qualitative analysis of compounded drugs; and maintain training, disposition, acquisition, and compounding self-assessment records.

3. On August 24, 2017, Mr. Imanoel and petitioner, individually and on behalf of Sunshine, signed a Stipulated Settlement and Disciplinary Order (Stipulated Settlement). Sunshine and petitioner admitted that the charges and allegations in the First Amended Accusation, if proven at hearing, constituted cause for imposing discipline on Sunshine's permit and petitioner's license. Sunshine's permit was revoked. The revocation was stayed and the permit was placed on probation for five years, subject to various terms and conditions, including to obey all laws, submit quarterly reports, reimburse the Board \$23,042 for investigation and enforcement costs jointly with petitioner, complete remedial education related to compounding, and retain an independent consultant to review pharmacy operations on a monthly basis to ensure compliance with state and federal laws.

Petitioner's license was also revoked. The revocation was stayed and petitioner's license was placed on probation for five years, subject to various terms and conditions including, including to obey all laws, submit quarterly reports, not supervise interns, not serve as a pharmacist in charge (PIC) or consultant, reimburse the Board \$23,042 for investigation and enforcement costs jointly with Sunshine, complete remedial continuing education, and complete a Board-approved ethics course. The Stipulated Settlement was adopted by the Board and was effective on November 17, 2017.

Petitions for Early Termination of Probation

4. On September 26, 2019, petitioner, on behalf of Sunshine and individually, signed and thereafter filed with the Board, two Petitions for Early Termination of Probation (Petitions). Sunshine and petitioner have not applied

previously for termination of probation. Petitioners submitted in support of the Petitions detailed information and policies implemented concerning operational changes made at Sunshine to address the violations identified in the First Amended Accusation, evidence of over 300 hours of continuing education, and several letters of recommendation. In the Petitions, and during testimony at hearing, petitioner explained the circumstances surrounding the events that gave rise to the discipline imposed on Sunshine's permit and his license, and the steps he has taken to address those issues to prevent future violations.

5. Petitioners are currently in compliance with the terms and conditions of Board probation. Petitioners have completed almost three years of probation, which is scheduled to end on or about November 17, 2022. Petitioners also completed the required remedial education and paid the investigation and enforcement costs.

6. Petitioner explained that after his license and Sunshine's permit were placed on probation, he hired a pharmacy consultant with Licensed Protection Consultants, Inc., who reviewed the First Amended Accusation and Sunshine's existing policies and procedures. The consultant made many recommendations and helped Sunshine and petitioner create and implement new policies and procedures to address the violations. The consultant also performs mock audits to help ensure compliance with the Board's laws and regulations. Sunshine pays for an additional service which give owners and staff access to the consultants for an unlimited amount of assistance. Petitioner explained that the process of working with the consultant has been "eye opening." The result is a "100 percent improvement" in Sunshine's operations.

7. Petitioner also replaced Sunshine's cleaning team with a new cleaning company at an additional cost to ensure the pharmacy meets or exceeds the safety and sanitization standards expected by the Board. Petitioner further implemented

policies and procedures to address issues with expired medication and to ensure proper labeling of medication. Additionally, Audrey Toledano, Sunshine's PIC, is very knowledgeable about pharmacy law and ensures that Sunshine is complying with applicable laws and regulations. Sunshine no longer performs compounding, nor does petitioner have any intent to resume compounding. However, petitioner watched over 100 hours of compounding videos to become more knowledgeable. Petitioner also completed over 300 hours of continuing education. He hopes to become board-certified in medication therapy management and turn Sunshine into a medication therapy management pharmacy.

8. Petitioner is requesting early termination of his and Sunshine's probation because of the finance loss that has been sustained as a result of their probationary status. Five pharmacy benefit managers (PBM), terminated their agreements with Sunshine because they will not work with entities on Board probation, including if a shareholder is on probation. Additionally, three prospective PBM's declined to work with Sunshine because of their probation status. Petitioner is concerned Sunshine's remaining PBM's also will terminate their agreements if they are not released from probation. Petitioner explained that Sunshine only has enough business to allow him to work a total of two days per week. Because his license is on probation he cannot find additional work. Petitioner is concerned that if he and Sunshine are not released from probation, the pharmacy will have to close.

Recommendations

9. Pursuant to Business and Professions Code section 4309, subdivision (b)¹ petitioner on behalf of himself and Sunshine submitted five letters of recommendation

¹ Business and Professions Code section 4309, subdivision (b), provides:

from individuals licensed by the Board and private citizens. All of the authors are aware of the discipline imposed on Sunshine's permit and petitioner's license. Ms. Toledano wrote two letters, one in support of Sunshine and another for petitioner, explaining that she has worked with petitioner to ensure compliance with the Board's laws and regulations. Changes that have been made to include updating policies and procedures, ensuring all records are maintained as required, staying current with changes to pharmacy laws, and implementing any recommendations made during routine probation inspections. Ms. Toledano also described petitioner as a pharmacist who acts in the best interest of his profession and promptly implements recommendations from the Board and Sunshine's consultant.

10. Petitioners also submitted a letter from License Protection Consultants, Inc., attesting to the changes petitioner made at Sunshine to ensure the violations identified by the Board were corrected and no future violations would occur. Petitioner has requested the consultants to perform mock inspections to further assure continued compliance. The author explained that petitioner is responsive to implementing recommendations to improve the quality and performance of Sunshine.

The petition shall state any facts required by the Board, and the petition shall be accompanied by two or more verified recommendations from holders of licenses issued by the Board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the Board and the activities of the petitioner since the disciplinary penalty was imposed.

11. The authors of the additional letters of recommendation describe petitioner as knowledgeable and prompt in addressing any issues that arise at Sunshine. The authors also describe the efforts petitioner has undertaken to educate himself on the Board's laws and regulations, as well as changing pharmaceutical developments. Each of the authors recommends Sunshine and petitioner's probation be terminated.

Analysis

12. Petitioner and Sunshine have completed almost three years of Board probation. During that time, they have undertaken extensive efforts to address the violations set forth in the First Amended Accusation. Petitioner hired a consultant who helped petitioner address and correct the violations. Policies and procedures have been implemented to prevent future violations. Petitioner also has made the decision to cease compounding at Sunshine. Finally, petitioner has dedicated hundreds of hours completing continuing education to ensure he understands and abides by the Boards laws and regulations.

13. When all the evidence is considered, no further public interest will be served by continuing Sunshine and petitioner on probation at this time. Petitioner demonstrated that he and Sunshine can operate and engage in licensed activity without restrictions, and without harm to the public.

LEGAL CONCLUSIONS

1. In a proceeding for reinstatement of a license, including early termination of probation, the burden at all times is on the petitioner to establish rehabilitation. (See *Flanzer v. Board of Dental Examiners* (1990) 220 Cal.App.3d 1392, 1398, citing

Housman v. Board of Medical Examiners (1948) 84 Cal.App.2d 308, 315.) The standard of proof is clear and convincing evidence to a reasonable certainty. (*Hippard v. State Bar* (1989) 49 Cal.3d 1084, 1091-1092; *Feinstein v. State Bar* (1952) 39 Cal.2d 541.)

2. Business and Professions Code section 4309, subdivision (d), sets forth the following factors for consideration when the Board reviews a petition for early termination of probation:

- (1) All the activities of the petitioner since the disciplinary action was taken.
- (2) The offense for which the petitioner was disciplined.
- (3) The petitioner's activities during the time the license was in good standing.
- (4) The petitioner's documented rehabilitative efforts.
- (5) The petitioner's general reputation for truth and professional ability.

3. When all the relevant rehabilitation criteria set forth in Business and Professions Code section 4309, subdivision (d), are considered, petitioners established that it would be consistent with the public health, safety and welfare to terminate their probation.

ORDER

1. The petition for early termination of probation of Imanoel Pharmacy Inc., doing business as Sunshine Pharmacy, Permit No. PHY 44317, is GRANTED.

2. The petition for early termination of probation of Eliahou Seleh, Original Pharmacist License Number RPH 55937, is GRANTED.

This Decision shall become effective at 5:00 p.m. on December 15, 2020.

It is so ORDERED on January 14, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe
Board President

**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
357 N. Fairfax Avenue
Los Angeles, CA 90036**

Pharmacy Permit No. PHY 44317

and

**ELIAHOU SELEH
8662 Cashio Street
Los Angeles, CA 90035**

Pharmacist License No. RPH 55937

Case No. 5719

OAH No. 2017020555

**STIPULATED SETTLEMENT
AND DISCIPLINARY ORDER**

Respondents.

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on November 17, 2017.

It is so ORDERED on October 18, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____

Amy Gutierrez, Pharm.D.
Board President

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1 XAVIER BECERRA
 Attorney General of California
 2 MARC D. GREENBAUM
 Supervising Deputy Attorney General
 3 GILLIAN E. FRIEDMAN
 Deputy Attorney General
 4 State Bar No. 169207
 300 So. Spring Street, Suite 1702
 5 Los Angeles, CA 90013
 Telephone: (213) 897-2564
 6 Facsimile: (213) 897-2804
Attorneys for Complainant

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

10 In the Matter of the First Amended Accusation
 11 Against:

Case No. 5719

OAH No. 2017020555

12 **IMANOEL PHARMACY INC,**
DBA SUNSHINE PHARMACY,
 13 **ELIAHOU SELEH, CEO and Secretary,**
MICHAEL IMANOEL, President and
 14 **Treasurer**
 357 N. Fairfax Avenue
 15 Los Angeles, CA 90036

**STIPULATED SETTLEMENT AND
 DISCIPLINARY ORDER**

16 Pharmacy Permit No. PHY 44317

17 AND

18 **ELIAHOU SELEH (PIC)**
 8662 Cashio Street
 19 Los Angeles, CA 90035

20 RPH 55937

21 Respondents.

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 23
 24 **IT IS HEREBY STIPULATED AND AGREED** by and between the parties to the above-
 25 entitled proceedings that the following matters are true:

26 **PARTIES**

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

1 Xavier Becerra, Attorney General of the State of California, by Gillian E. Friedman, Deputy
2 Attorney General.

3 2. Respondent Imanoel Pharmacy Inc, dba Sunshine Pharmacy, Michael Imanoel,
4 Eliahou Seleh (Respondent) is represented in this proceeding by attorney Herbert L. Weinberg,
5 whose address is: FENTON LAW GROUP, LLP, 1990 S Bundy Drive Suite 777, Los Angeles,
6 CA 90025.

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

12 4. On or about August 4, 2004, the Board of Pharmacy issued Original Pharmacist
13 License Number RPH 55937 to Eliahou Seleh (Respondent Seleh). On August 1, 2005,
14 Respondent Seleh became PIC for Respondent Pharmacy. The Original Pharmacist License was
15 in full force and effect at all times relevant to the charges brought herein and will expire on June
16 30, 2018, unless renewed.

17 5. On or about March 20, 1992, the Board of Pharmacy issued Pharmacist License
18 Number RPH 45182 Michael Imanoel. The Pharmacy License was in full force and effect at all
19 times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.
20 No disciplinary action is being sought against Michael Imanoel's Pharmacy License.

21 JURISDICTION

22 6. First Amended Accusation No. 5719 was filed before the Board, and is currently
23 pending against Respondents. The Accusation and all other statutorily required documents were
24 properly served on Respondents on November 8, 2016. The First Amended Accusation was filed
25 on July 11, 2017 removing the cause for discipline under CCR section 1735.6 subdivision (c)
26 relating the lack of calibration records for equipment used to compound drugs. The First
27 Amended Accusation also referenced the updated license renewals. Respondents timely filed
28

1 their Notice of Defense. A copy of First Amended Accusation No. 5719 is attached as exhibit A
2 and incorporated herein by reference.

3 **ADVISEMENT AND WAIVERS**

4 7. Respondents have carefully read, fully discussed with counsel, and understand the
5 charges and allegations in First Amended Accusation No. 5719. Respondents have also carefully
6 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
7 Disciplinary Order.

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

15 9. Respondents voluntarily, knowingly, and intelligently waive and gives up each and
16 every right set forth above.

17 **CULPABILITY**

18 10. Respondents understand and agree that the charges and allegations in First Amended
19 Accusation No. 5719, if proven at a hearing, constitute cause for imposing discipline upon their
20 Pharmacy Permit and Original Pharmacist License.

21 11. For the purpose of resolving the First Amended Accusation without the expense and
22 uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could
23 establish a factual basis for the charges in the First Amended Accusation, and that Respondents
24 hereby gives up their right to contest those charges.

25 12. Respondents agree that their Pharmacy Permit and Original Pharmacist License are
26 subject to discipline and they agree to be bound by the Board's probationary terms as set forth in
27 the Disciplinary Order below.

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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 their 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 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 AGAINST SUNSHINE PHARMACY

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 44317 issued to Respondent Imanoel Pharmacy Inc, dba Sunshine Pharmacy, Michael Imanoel, as president/treasurer and Eliahou Seleh, PIC, Chief Executive Officer and Secretary (Respondent Pharmacy or Respondent owner) is revoked. However, the revocation is stayed and Respondent Pharmacy is placed on

1 probation for five (5) years on the following terms and conditions.

2 **1. Obey All Laws**

3 Respondent owner shall obey all state and federal laws and regulations. Respondent owner
4 shall report any of the following occurrences to the board, in writing, within seventy-two (72)
5 hours of such occurrence:

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

17 **2. Report to the Board**

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

26 **3. Interview with the Board**

27 Upon receipt of reasonable prior notice, respondent owner shall appear in person for
28 interviews with the board or its designee, at such intervals and locations as are determined by the

1 board or its designee. Failure to appear for any scheduled interview without prior notification to
2 board staff, or failure to appear for two (2) or more scheduled interviews with the board or its
3 designee during the period of probation, shall be considered a violation of probation.

4 **4. Cooperate with Board Staff**

5 Respondent owner shall cooperate with the board's inspection program and with the board's
6 monitoring and investigation of respondent's compliance with the terms and conditions of his
7 probation. Failure to cooperate shall be considered a violation of probation.

8 **5. Reimbursement of Board Costs**

9 As a condition precedent to successful completion of probation, respondent owner shall
10 jointly and severally with Respondent Seleh be responsible to pay to the Board its costs of
11 investigation and prosecution in the amount of \$23,042.00. Costs may be paid on a payment plan
12 approved in writing by the board. Failure to pay costs by the deadline(s) as directed shall be
13 considered a violation of probation.

14 The filing of bankruptcy by respondent owner shall not relieve respondent of his
15 responsibility to reimburse the board its costs of investigation and prosecution.

16 **6. Probation Monitoring Costs**

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

21 **7. Status of License**

22 Respondent owner shall, at all times while on probation, maintain current licensure with the
23 board. If respondent owner submits an application to the board, and the application is approved,
24 for a change of location, change of permit or change of ownership, the board shall retain
25 continuing jurisdiction over the license, and the respondent shall remain on probation as
26 determined by the board. Failure to maintain current licensure shall be considered a violation of
27 probation.

28 If respondent license expires or is cancelled by operation of law or otherwise at any time

1 during the period of probation, including any extensions thereof or otherwise, upon renewal or
2 reapplication respondent's license shall be subject to all terms and conditions of this probation not
3 previously satisfied.

4 **8. License Surrender While on Probation/Suspension**

5 Following the effective date of this decision, should respondent owner discontinue
6 business, respondent owner may tender the premises license to the board for surrender. The board
7 or its designee shall have the discretion whether to grant the request for surrender or take any
8 other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the
9 license, respondent will no longer be subject to the terms and conditions of probation.

10 Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and
11 renewal license to the board within ten (10) days of notification by the board that the surrender is
12 accepted. Respondent owner shall further submit a completed Discontinuance of Business form
13 according to board guidelines and shall notify the board of the records inventory transfer.

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

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

26 Respondent owner further stipulates that he shall reimburse the board for its costs of
27 investigation and prosecution prior to the acceptance of the surrender.

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1 **9. Notice to Employees**

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

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

15 **10. Owners and Officers: Knowledge of the Law**

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

22 **11. Posted Notice of Probation**

23 Respondent owner shall prominently post a probation notice provided by the board in a
24 place conspicuous and readable to the public. The probation notice shall remain posted during the
25 entire period of probation.

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

1 of the licensed entity.

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

3 **12. Violation of Probation**

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

9 If respondent owner violates probation in any respect, the board, after giving respondent
10 owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary
11 order that was stayed. Notice and opportunity to be heard are not required for those provisions
12 stating that a violation thereof may lead to automatic termination of the stay and/or revocation of
13 the license. If a petition to revoke probation or an accusation is filed against respondent during
14 probation, the board shall have continuing jurisdiction and the period of probation shall be
15 automatically extended until the petition to revoke probation or accusation is heard and decided,
16 and the charges and allegations in the First Amended Accusation shall be deemed true and
17 correct.

18 **13. Completion of Probation**

19 Upon written notice by the board or its designee indicating successful completion of
20 probation, respondent license will be fully restored.

21 **14. Consultant for Owner or Pharmacist-In-Charge**

22 If during the period of probation Respondent Seleh serves as a pharmacist-in-charge,
23 Respondent Pharmacy shall retain an independent consultant at its own expense who shall be
24 responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent
25 with state and federal laws and regulations governing the practice of pharmacy and for
26 compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be
27 a pharmacist licensed by and not on probation with the board and whose name shall be submitted
28 to the board or its designee, for prior approval, within thirty (30) days of the effective date of this

1 decision. The Consultant must have compounding experience. Respondent shall not be a
 2 pharmacist-in-charge at more than one pharmacy. Failure to timely retain, seek approval of, or
 3 ensure timely reporting by the consultant shall be considered a violation of probation.

4 **15. Remedial Education**

5 Within sixty (60), days of the effective date of this decision, respondent shall submit to the
 6 board or its designee, for prior approval, an appropriate program of remedial education related to
 7 compounding to be completed by all pharmacy staff. The program of remedial education shall
 8 consist of at least two (2) hours, which shall be completed on an annual basis for each year of the
 9 probation, at respondent's own expense. All remedial education shall be in addition to, and shall
 10 not be credited toward, continuing education (CE) courses used for license renewal purposes.

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

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

20 **DISCIPLINARY ORDER AGAINST ELIAHOU SELEH**

21 **IT IS HEREBY ORDERED** that Original Pharmacist License Number RPH 55937 issued
 22 to Eliahou Seleh (Respondent Seleh) is revoked. However, the revocation is stayed and
 23 Respondent Seleh is placed on probation for five (5) years on the following terms and conditions.

24 **16. Obey All Laws**

25 Respondent shall obey all state and federal laws and regulations.

26 Respondent shall report any of the following occurrences to the board, in writing, within
 27 seventy-two (72) hours of such occurrence:
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- 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 contendere 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 Original 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.

17. Report to the Board

Respondent 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, respondent 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.

18. Interview with the Board

Upon receipt of reasonable prior notice, respondent 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.

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1 **19. Cooperate with Board Staff**

2 Respondent shall cooperate with the board's inspection program and with the board's
3 monitoring and investigation of respondent's compliance with the terms and conditions of his
4 probation. Failure to cooperate shall be considered a violation of probation.

5 **20. Continuing Education**

6 Respondent shall provide evidence of efforts to maintain skill and knowledge as a
7 pharmacist as directed by the board or its designee.

8 **21. Notice to Employers**

9 During the period of probation, respondent shall notify all present and prospective
10 employers of the decision in case number 5719 and the terms, conditions and restrictions imposed
11 on respondent by the decision, as follows:

12 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
13 respondent undertaking any new employment, respondent shall cause her direct supervisor,
14 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
15 tenure of employment) and owner to report to the board in writing acknowledging that the listed
16 individual(s) has/have read the decision in case number 5719, and terms and conditions imposed
17 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
18 submit timely acknowledgment(s) to the board.

19 If respondent works for or is employed by or through a pharmacy employment service,
20 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
21 licensed by the board of the terms and conditions of the decision in case number 5719 in advance
22 of the respondent commencing work at each licensed entity. A record of this notification must be
23 provided to the board upon request.

24 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
25 (15) days of respondent undertaking any new employment by or through a pharmacy employment
26 service, respondent shall cause his direct supervisor with the pharmacy employment service to
27 report to the board in writing acknowledging that he has read the decision in case number 5719
28

1 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
2 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

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

12 During the period of probation, respondent shall not supervise any intern pharmacist, be the
13 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
14 other than Imanoei Pharmacy Inc, dba Sunshine Pharmacy nor serve as a consultant unless
15 otherwise specified in this order. Assumption of any such unauthorized supervision
16 responsibilities shall be considered a violation of probation.

17 **23. Reimbursement of Board Costs**

18 As a condition precedent to successful completion of probation, Respondent Seleh shall pay
19 to the board its costs of investigation and prosecution in the amount of \$23,042.00. Respondent
20 Seleh shall be jointly and severally responsible for payment of costs with Respondent Pharmacy.
21 Costs may be paid on a payment plan approved in writing by the board.

22 Failure to pay costs by the deadline(s) as directed shall be considered a violation of
23 probation.

24 The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
25 reimburse the board its costs of investigation and prosecution.

26 **24. Probation Monitoring Costs**

27 Respondent shall pay any costs associated with probation monitoring as determined by the
28 board each and every year of probation. Such costs shall be payable to the board on a schedule as

1 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
2 be considered a violation of probation.

3 **25. Status of License**

4 Respondent shall, at all times while on probation, maintain an active, current license with
5 the board, including any period during which suspension or probation is tolled. Failure to
6 maintain an active, current license shall be considered a violation of probation.

7 If respondent's license expires or is cancelled by operation of law or otherwise at any time
8 during the period of probation, including any extensions thereof due to tolling or otherwise, upon
9 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
10 probation not previously satisfied.

11 **26. License Surrender While on Probation/Suspension**

12 Following the effective date of this decision, should respondent cease practice due to
13 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
14 respondent may tender her license to the board for surrender. The board or its designee shall have
15 the discretion whether to grant the request for surrender or take any other action it deems
16 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
17 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
18 record of discipline and shall become a part of the respondent's license history with the board.

19 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
20 the board within ten (10) days of notification by the board that the surrender is accepted.
21 Respondent may not reapply for any license from the board for three (3) years from the effective
22 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
23 of the date the application for that license is submitted to the board, including any outstanding
24 costs.

25 **27. Notification of a Change in Name, Residence Address, Mailing Address or**
26 **Employment**

27 Respondent shall notify the board in writing within ten (10) days of any change of
28 employment. Said notification shall include the reasons for leaving, the address of the new

1 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
2 shall further notify the board in writing within ten (10) days of a change in name, residence
3 address, mailing address, or phone number.

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

6 **28. Tolling of Probation**

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

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

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

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

26 **29. Violation of Probation**

27 If a respondent has not complied with any term or condition of probation, the board shall
28 have continuing jurisdiction over respondent, and probation shall automatically be extended, until

1 all terms and conditions have been satisfied or the board has taken other action as deemed
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
3 to impose the penalty that was stayed.

4 If respondent violates probation in any respect, the board, after giving respondent notice
5 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
6 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
7 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
8 a petition to revoke probation or an accusation is filed against respondent during probation, the
9 board shall have continuing jurisdiction and the period of probation shall be automatically
10 extended until the petition to revoke probation or accusation is heard and decided, and the charges
11 and allegations in the First Amended Accusation shall be deemed true and correct.

12 30. Completion of Probation

13 Upon written notice by the board or its designee indicating successful completion of
14 probation, respondent's license will be fully restored.

15 31. Remedial Education

16 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
17 board or its designee, for prior approval, an appropriate program of remedial education related to
18 pharmacy law, pharmacy operations and compounding. The program of remedial education shall
19 consist of at least five (5) hours, which shall be completed on an annual basis at respondent's own
20 expense during each of the years of probation. All remedial education shall be in addition to, and
21 shall not be credited toward, continuing education (CE) courses used for license renewal
22 purposes. The remedial education described in paragraph 15 above may be applied to satisfy two
23 (2) hours of the required five (5) hours of remedial education. The total hours required for
24 remedial education for the period of probation is 25 hours, of which at least 50% (12.5 hours) of
25 the remedial education shall be completed in person.

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

Box

1 is provided to the board or its designee.

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


7 **32. Ethics Course**

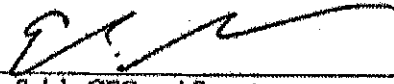
8 Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
9 in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
10 Failure to initiate the course during the first year of probation, and complete it within the second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

12 Respondent shall submit a certificate of completion to the board or its designee within five
13 days after completing the course.

14 **ACCEPTANCE**

15 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
16 discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it
17 will have on the Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order
18 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
19 Board of Pharmacy.

20
21 DATED: Aug/24/17 
22 Michael Imanoel, President and Treasurer,
23 IMANOEL PHARMACY INC, DBA SUNSHINE
24 PHARMACY,
25 Respondent

26 DATED: Aug/24/17 
27 Elishou Seleh, CEO and Secretary
28 IMANOEL PHARMACY INC, DBA SUNSHINE
PHARMACY,
Respondent

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1 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
 2 discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it
 3 will have on my Original Pharmacist License. I enter into this Stipulated Settlement and
 4 Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
 5 Decision and Order of the Board of Pharmacy.

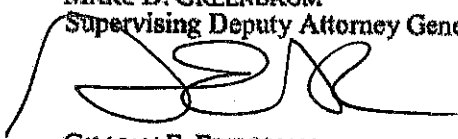
6
 7 DATED: Aug/24/2017 
 8 Eliahou Seleh,
 9 Respondent

10 I have read and fully discussed with Respondent Imanoel Pharmacy Inc, dba Sunshine
 11 Pharmacy, Michael Imanoel and Eliahou Seleh the terms and conditions and other matters
 12 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and
 13 content.

14 DATED: 8/24/2017 
 15 HERBERT L. WEINBERG
 16 Attorney for Respondent

ENDORSEMENT

17
 18 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
 19 submitted for consideration by the Board of Pharmacy.

20 Dated: 8/25/17 Respectfully submitted,
 21
 22 XAVIER BECERRA
 23 Attorney General of California
 24 MARC D. GREENBAUM
 25 Supervising Deputy Attorney General
 26 
 27 GILLIAN E. FRIEDMAN
 28 Deputy Attorney General
 Attorneys for Complainant

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 Imanoel Stip Rev. (Final).docx

Exhibit A

First Amended Accusation No. 5719

1 KAMALA D. HARRIS
Attorney General of California
2 MARC D. GREENBAUM
Supervising Deputy Attorney General
3 GILLIAN E. FRIEDMAN
Deputy Attorney General
4 State Bar No. 169207
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2564
6 Facsimile: (213) 897-2804
E-mail: Gillian.Friedman@doj.ca.gov
7 *Attorneys for Complainant*

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

11 In the Matter of the First Amended Accusation
12 Against:

Case No. 5719

13 **IMANOEL PHARMACY INC,**
14 **DBA SUNSHINE PHARMACY,**
15 **ELIAHOU SELEH, CEO and Secretary,**
16 **MICHAEL IMANOEL, President and**
17 **Treasurer**
18 **357 N. Fairfax Avenue**
19 **Los Angeles, CA 90036**

FIRST AMENDED ACCUSATION

20 **Pharmacy Permit No. PHY 44317**

21 **AND**

22 **ELIAHOU SELEH (PIC)**
23 **8662 Cashio Street**
24 **Los Angeles, CA 90035**

25 **RPH 55937**

26 Respondents.

27 Complainant alleges:

28 **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.

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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:

1 “(b) Acts or omissions that involve, in whole or in part, the failure to exercise or
2 implement his or her best professional judgment or corresponding responsibility with regard to
3 the
4 dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with
5 regard to the provision of services.”

6 11. Section 4307 of the Code states:

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

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

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

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

23 (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to
24 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.
25 However, no order may be issued in that case except as to a person who is named in the caption,
26 as to whom the pleading alleges the applicability of this section, and where the person has been
27 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part
28 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision

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

3 ///

4 12. Section 4332 of the Code states:

5 "Any person who fails, neglects, or refuses to maintain the records required by Section
6 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects,
7 or refuses to produce or provide the records within a reasonable time, or who willfully produces
8 or furnishes records that are false, is guilty of a misdemeanor."

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

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

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

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

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

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

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

18 "Any drug or device is misbranded if its labeling or packaging does not conform to the
19 requirements of Chapter 4 (commencing with Section 110290)."

20 17. Section 111440 of the Health and Safety Code states:

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

23 **REGULATIONS**

24 18. 16 California Code of Regulations Section 1714 states in pertinent part:

25

26 (c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly
27 condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly
28

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

3 19. 16 California Code of Regulations Section 1735.2 states in pertinent part:

4

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

7 (1) Active ingredients to be used.

8 (2) Equipment to be used.

9 (3) Expiration dating requirements.

10 (4) Inactive ingredients to be used.

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

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

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

14

15 (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-
16 charge shall complete a self-assessment for compounding pharmacies developed by the board.
17 (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy
18 Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section
19 applicable to all compounding, and a second section applicable to sterile injectable compounding.
20 The first section must be completed by the pharmacist-in-charge before any compounding is
21 performed in the pharmacy. The second section must be completed by the pharmacist-in-charge
22 before any sterile injectable compounding is performed in the pharmacy. The applicable sections
23 of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year,
24 within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a
25 new pharmacy license. The primary purpose of the self-assessment is to promote compliance
26 through self-examination and education.”

27 20. 16 California Code of Regulations Section 1735.3 states in pertinent part:

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

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(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.

....

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

3 25. 16 California Code of Regulations Section 1735.8 states in pertinent part:

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

8 **COST RECOVERY**

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

13 **FIRST CAUSE FOR DISCIPLINE**

14 (Operational Standards and Security)

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

19 **SECOND CAUSE FOR DISCIPLINE**

20 (Duty to Review the Policy and Procedures Manual)

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

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1 **THIRD CAUSE FOR DISCIPLINE**

2 (Compounding Facilities and Equipment)

3 29. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
4 section 1735.6 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18,
5 2015, equipment used to compound drug products were not stored, used, and maintained in
6 accordance with manufacturer's specifications.

7 **FOURTH CAUSE FOR DISCIPLINE**

8 (Adulterated Medications)

9 30. Respondents Pharmacy and Seleh are subject to disciplinary action under California
10 Health and Safety Code sections 111250 and 111295 and Business & Professions Code section
11 4169 subdivision (a)(2) in that as of the inspection of Sunshine Pharmacy on March 18, 2015,
12 several products were found in the active drug inventory without expiration dates listed or
13 available for review.

14 **FIFTH CAUSE FOR DISCIPLINE**

15 (Misbranded Medications)

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

21 **SIXTH CAUSE FOR DISCIPLINE**

22 (Unprofessional Conduct)

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

1 Compounding Personnel Qualification” also included information about procedures that were not
2 performed.

3 **SEVENTH CAUSE FOR DISCIPLINE**

4 (Compounding Master Formula Requirements)

5 33. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
6 section 1735.2 subdivision (d) in that as of the inspection of Sunshine Pharmacy on March 18,
7 2015, no complete master formulas consisting of elements listed above were available for review
8 for drugs compounded at Sunshine Pharmacy.

9 **EIGHTH CAUSE FOR DISCIPLINE**

10 (Compounding Quality Assurance)

11 34. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
12 section 1735.8 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18,
13 2015, no records of quantitative or qualitative analysis of compounded drugs were available for
14 review.

15 **NINTH CAUSE FOR DISCIPLINE**

16 (Training of Compounding Staff)

17 35. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
18 section 1735.7 subdivision (a) in that as of the inspection of Sunshine Pharmacy on March 18,
19 2015, no records of initial or ongoing training were available for review for PIC Seleh or his
20 compounding personnel.

21 **TENTH CAUSE FOR DISCIPLINE**

22 (Maintenance of Records)

23 36. Respondents Pharmacy and Seleh are subject to disciplinary action under Business
24 and Professions Code section 4081 in that as of the inspection of Sunshine Pharmacy on May 26,
25 2015, PIC Seleh failed to preserve records for three (3) years from the date of making and
26 produce disposition records for the following lot numbers compounded at Sunshine Pharmacy:
27 03042015@1, 03102015@1, 03082015@6, 03182015@5, 03192015@5, 03192015@4,
28 03262015@3, 03252015@5, 03272015@4, 03272015@3.

1 **ELEVENTH CAUSE FOR DISCIPLINE**

2 (Records of Compounded Drug Products)

3 37. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
4 section 1735.3 subdivision (a)(4) in that as of the inspection of Sunshine Pharmacy on March 18,
5 2015, the identity of the pharmacist reviewing the final product was not listed for the following
6 lot numbers compounded at Sunshine Pharmacy: 03042015@1, 03102015@1, 03182015@6,
7 03182015@5, 03192015@5, 03192015@4, 03262015@3, 03252015@5, 03272015@4,
8 03272015@3.

9 **TWELFTH CAUSE FOR DISCIPLINE**

10 (Duty to Complete Compounding Self-Assessment)

11 38. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
12 section 1735.2 subdivision (j) in that as of the inspection of Sunshine Pharmacy on March 18,
13 2015, no records of compounding self-assessment by the pharmacist-in-charge were available for
14 review.

15 **THIRTEENTH CAUSE FOR DISCIPLINE**

16 (Records of Compounded Drug Products)

17 39. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
18 section 1735.3 subdivision (c) in that as of the inspection of Sunshine Pharmacy on March 18,
19 2015, no records of certificates of purity or analysis of chemicals, bulk drug substances, drug
20 products, and components used in compounding for drug products not approved by the Food and
21 Drug Administration were available for review.

22 **FOURTEENTH CAUSE FOR DISCIPLINE**

23 (Labeling of the Compounded Drug Products)

24 40. Respondents Pharmacy and Seleh are subject to disciplinary action under CCR
25 section 1735.4 subdivision (b) in that as of the inspection of Sunshine Pharmacy on March 18,
26 2015, none of the reviewed compounded drug labels or patient receipts contained a statement that
27 the drug has been compounded.

28

1 **FIFTEENTH CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct)

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

8 **SIXTEENTH CAUSE FOR DISCIPLINE**

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

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

15 **SEVENTEENTH CAUSE FOR DISCIPLINE**

16 (Retaining Records of Dangerous Drugs)

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

23 **EIGHTEENTH CAUSE FOR DISCIPLINE**

24 (Unprofessional Conduct-Acts or Omissions by Pharmacist)

25 44. Respondent Seleh is subject to disciplinary action under Business and Profession
26 Code section 4306.5 subdivision (b) in that in that for the audit of Sunshine Pharmacy during the
27 period April 18, 2014 through April 18, 2015, Sunshine Pharmacy failed to exercise professional
28

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

3 **OTHER MATTERS**

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

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

18 **PRAYER**

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

21 1. Revoking or suspending Pharmacy Permit Number PHY 44317, issued to Imanoel
22 Pharmacy Inc, dba Sunshine Pharmacy, with Michael Imanoel as president and treasurer and
23 Eliahou Seleh as CEO and Secretary

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

26 3. Prohibiting Michael Imanoel from serving as a manager, administrator, owner,
27 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
28

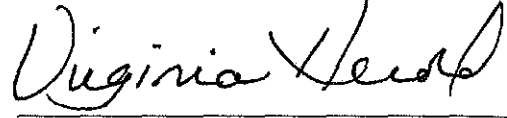
1 Number PHY 44317 is placed on probation or until Pharmacy Permit Number PHY 44317 is
2 reinstated if Pharmacy Permit Number 44317 is revoked;

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

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

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

11
12 DATED: 7/12/17



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

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17 FIRST AMENDED ACCUSATION IMANOEL.docx