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

In the Matter of the Accusation Against:

BOTROSONS PHARMACEUTICAL, INC.,
DBA TOWER PHARMACY,
26732 Crown Valley Parkway #101
Mission Viejo, CA 92691

Pharmacy Permit No. PHY 46688

SAMIH NABIL BOTROS
26732 Crown Valley Parkway #101
Mission Viejo, CA 92691

Pharmacist License No. RPH 48680

Respondents.

Case No. 6083
OAH No. 2017061103

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on January 12, 2018.

It is so ORDERED on December 13, 2017.

BOARDS OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Amy Gutierrez, Pharm.D.
Board President
IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

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

2. Respondent Botrosons Pharmaceutical, Inc., dba Tower Pharmacy and Samih Nabil Botros (Respondents) are represented in this proceeding by attorney Herbert L. Weinberg of Fenton Law Group, LLP, whose address is: 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025.

3. On or about June 9, 2004, the Board issued Pharmacy Permit No. PHY 46688 to Botrosons Pharmaceutical, Inc., dba Tower Pharmacy (Respondent Tower Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6083, and will expire on June 1, 2018, unless renewed.

4. On or about April 15, 1996, the Board issued Pharmacist License Number RPH 48680 to Samih Nabil Botros (Samih Botros). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2019, unless renewed.

JURISDICTION

5. Accusation No. 6083 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 8, 2017. Respondents timely filed their Notices of Defense contesting the Accusation.

6. A copy of Accusation No. 6083 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 6083. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

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

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

CULPABILITY

10. Respondents understand and agree that the charges and allegations in Accusation No.
6083, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit
and Pharmacist License.

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

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

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondents understand
and agree that counsel for Complainant and the staff of the Board 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**

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 46688 issued to Respondent Botrosons Pharmaceutical, Inc., dba Tower Pharmacy and Pharmacist License No. RPH 48680 issued to Samih Nabil Botros are revoked. However, the revocation as to each is stayed and Respondents are placed on probation for three (3) years on the following terms and conditions.

1. **Obey All Laws**

   Respondents shall obey all state and federal laws and regulations.

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

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

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

2. **Report to the Board**

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

3. **Interview with the Board**

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

4. **Cooperate with Board Staff**

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

5. **Continuing Education**

Respondent Samih Botros shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.
6. Notice to Employers

During the period of probation, Respondent Samih Botros shall notify all present and prospective employers of the decision in Case Number 6083 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent Samih Botros' tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in Case Number 6083, and terms and conditions imposed thereby. It shall be Respondent Samih Botros' responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent Samih Botros works for or is employed by or through a pharmacy employment service, Respondent Samih Botros must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in Case Number 6083 in advance of Respondent Samih Botros commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Samih Botros undertaking any new employment by or through a pharmacy employment service, Respondent Samih Botros shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they had read the decision in Case Number 6083 and the terms and conditions imposed thereby. It shall be Respondent Samih Botros's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

7. Notice to Employees

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

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

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

During the period of probation, Respondent Samih Botros shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation. Respondent Samih Botros may continue as the Pharmacist-in-Charge of Respondent Tower Pharmacy only.

9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondents shall pay to the Board its costs of investigation and prosecution in the amount of $9,355.25. Respondents
shall be jointly and severally liable for payment of these costs. Respondents shall make said
payments in a payment plan to be approved by the Board.

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

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

10. **Probation Monitoring Costs**

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

11. **Status of License**

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

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

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

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

   Following the effective date of this decision, should Respondent Tower Pharmacy
   discontinue business, Respondents may tender the premises license to the Board for surrender.
   The Board or its designee shall have the discretion whether to grant the request for surrender or
take any other action it deems appropriate and reasonable. Upon formal acceptance of the
surrender of the license, Respondent Tower Pharmacy will no longer be subject to the terms and
conditions of probation.

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

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

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

Respondent owner further stipulates that he or she shall reimburse the Board for its costs of
investigation and prosecution prior to the acceptance of the surrender.

13. Pharmacist License Surrender While on Probation/Suspension

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

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

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

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

14. Owners and Officers: Knowledge of the Law

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

15. **Posted Notice of Probation**

   Respondent Tower Pharmacy shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

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

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

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

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

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

17. **Tolling of Probation**

   Except during periods of suspension, Respondent Samih Botros shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation.
Should Respondent Samih Botros, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

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

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

18. Violation of Probation

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

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

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

20. **Remedial Education**

Within sixty (60) days of the effective date of this decision, Respondent Samih Botros shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding and role of the pharmacist-in-charge. The program of remedial education shall consist of at least six (6) hours each year, fifty (50) percent of which shall be in person, which shall be completed within six months at Respondent Samih Botros' own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

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

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

21. **No Ownership of Licensed Premises**

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

22. Consultant Pharmacist Review of Pharmacy Operations

During the period of probation, Respondent Tower Pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Tower Pharmacy with state and federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the board or its designee retains the discretion to reduce the frequency of the pharmacist consultant’s review of Respondent Tower Pharmacy’s operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

23. Ethics Course

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

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

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it
will have on my Pharmacy Permit No. PHY 46688 and Pharmacist License No. RPH 48680. I
enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and
intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 9/8/17

SAMIH NABIL BOTROS, as an individual and as
authorized agent on behalf of BOTROSONS
PHARMACEUTICAL, INC., DBA TOWER
PHARMACY
Respondents

I have read and fully discussed with Respondent Botrosons Pharmaceutical, Inc., dba
Tower Pharmacy and Samih Nabil Botros the terms and conditions and other matters contained in
the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 9/8/2017

HERBERT L. WEINBERG
Attorney for Respondent

ENDORSEMENT

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

DATED: 9/8/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant
BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

BOTROSONS PHARMACEUTICAL, INC.,
DBA TOWER PHARMACY
26732 Crown Valley Parkway #101
Mission Viejo, CA 92691
Pharmacy Permit No. PHY 46688

SAMIH NABIL BOTROS
26732 Crown Valley Parkway #101 Mission Viejo, CA 92691
Pharmacist License No. RPH 48680

Respondents.

Complainant alleges:

PARTIES

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

2. On or about June 9, 2004, the Board of Pharmacy issued Pharmacy Permit Number PHY 46688 to Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy with Samih Nabil Botros designated as the Pharmacist-in-Charge (Tower Pharmacy). The Pharmacy Permit
was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

3. On or about April 15, 1996, the Board of Pharmacy issued Pharmacist License Number RPH 48680 to Samih Nabil Botros (Samih Botros). The Pharmacist 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

4. 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.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

8. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____, "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

9. Sections 4076, subdivision (a)(7) and subdivision (a)(9) of the Code state:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

....

(7) The strength of the drug or drugs dispensed.

....

(9) The expiration date of the effectiveness of the drug dispensed.

....

10. Section 4113, subdivision (c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

11. Section 4169, subdivision (a)(4) of the Code states:

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

....

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

....

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

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

....

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

....
13. Section 4307(a) of the Code states that:

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, partner, or any other person with management or control 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, partner, or any other person with management or control had knowledge 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, partner, or any other person with management or control 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.

REGULATORY PROVISIONS

14. Title 16, California Code of Regulations, section 1735, subdivisions (a) and (c) states in pertinent part:

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

1) Altering the dosage form or delivery system of a drug
2) Altering the strength of a drug
3) Combining components or active ingredients
4) Preparing a drug product from chemicals or bulk drug substances...

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

1 The Board's compounding regulations were amended, effective January 1, 2017. The regulations cited in this Accusation refer to the regulations in effect at the time of the violations alleged herein.
15. Title 16, California Code of Regulations, section 1735.2, subdivision (h) states:

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

16. Title 16, California Code of Regulations, section 1735.3, subdivision (a)(6) states in pertinent part:

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

....

The manufacturer, expiration date and lot number of each component.

....

17. Title 16, California Code of Regulations, section 1735.4, subdivision (b) states:

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.

18. Title 16, California Code of Regulations, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedures manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(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.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedures manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on those procedures as part of the staff training and competency evaluation process.
(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

COST RECOVERY

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

FACTUAL ALLEGATIONS


21. Respondents did not possess documentation showing that Respondent Samih Botros reviewed Respondent Tower Pharmacy's compounding policies and procedures on an annual basis. Moreover, the compounding policies and procedures were deficient, in that they required the floor of the compounding area to be mopped with a dry mop followed by a sponge mop with bleach solution and to be swept on a daily basis. However, the floor of the compounding area was carpeted. The policies required the cleaning of a powder hood but there was no powder hood.

22. Respondents did not possess documentation: (a) recording and monitoring the temperature and humidity in the compounding area; (b) showing Respondent Samih Botros signed and dated the cleaning and maintenance of the compounding area monthly (i.e., a cleaning log); and (3) the completion of tasks on a daily basis, as required by the compounding policies and procedures.

23. From January 1, 2016 through August 12, 2016, Respondents' compounding logs did not list the expiration dates of each component used in compounding non-sterile drug products.

24. From January 1, 2016 through August 12, 2016, Respondents maintained expired compounding drug products on their shelves, along with other inventory. They compounded
batches of drug products with expired components (i.e., active pharmaceutical ingredients and/or excipients). Those compounded drug products were dispensed to patients.

25. From May 1, 2016 through August 8, 2016, Respondents assigned beyond use dates to compounded drug products which exceeded the shortest expiration date of components which were used to make those drugs. These drugs were therefore labeled with the wrong expiration date and dispensed to patients.

26. From January 1, 2016 through August 8, 2016, Respondents compounded enalapril 1mg/ml suspension which was commercially available as Epaned manufactured by Silvergate Pharmaceuticals and approved by the FDA.

27. On August 12, 2016, Respondents dispensed Rx No. 469995 which listed the wrong strength of the medication (8/0.1% instead of 6/0.1% as prescribed) on its label.

FIRST CAUSE FOR DISCIPLINE
(Inadequate Record-Keeping)

28. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, sections 1735.5(a) and (b), as set forth in paragraphs 20 through 27, which are incorporated herein by reference and as described below:

a. California Code of Regulations, title 16, section 1735.3(a)(6): Failure to list the expiration date of each component used to compound, in the compounding logs.

b. California Code of Regulations, title 16, section 1735.5(a): Failure to maintain current written policies and procedures for compounding.

c. California Code of Regulations, title 16, section 1735.5(b): Failure to review the policy and procedures compounding manual on an annual basis and update it.

SECOND CAUSE FOR DISCIPLINE
(Failure to Assign Proper Beyond Use Date)

29. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, section 1735.2(h), in that they did not assign an appropriate beyond use date for certain non-sterile drug products, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.
THIRD CAUSE FOR DISCIPLINE

(Compounding and Dispensing of Drugs Containing Expired Components)

30. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4169(a)(4), in that they dispensed compounded drug products which were prepared using expired components, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Dispensing Drugs Labeled with Wrong Strength)

31. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4076(a)(7), in that they dispensed compounded drug products labeled with the wrong strength, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Dispensing of Drugs Labeled with Wrong Expiration Dates)

32. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4076(a)(9), in that they dispensed compounded drug products labeled with the wrong expiration dates, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Compounding of Commercially Available Drug Products)

33. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1735(e), in that they compounded drug products which were commercially available, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.
SIXTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct)

34. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 19 through 27 above, which are incorporated herein by reference.

OTHER MATTERS

35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46688 issued to Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy, Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy 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 46688 is placed on probation or until Pharmacy Permit Number PHY 46688 is reinstated if it is revoked.

36. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46688 issued to Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy while Samih Nabil Botros has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Samih Nabil Botros 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 46688 is placed on probation or until Pharmacy Permit Number PHY 46688 is reinstated if it is revoked.

37. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 48680 issued to Samih Nabil Botros, Samih Nabil Botros shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 48680 is placed on probation or until Pharmacist License Number RPH 48680 is reinstated if it is revoked.

DISCIPLINARY CONSIDERATIONS

38. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on February 14, 2013, the Board issued Citation number CI 2011 51219 against Respondent Tower Pharmacy for violating California Code of Regulations, title 16,
sections 1793.7(3) (failing to supervise pharmacy technicians), 1735.4-7 (failing to adhere to multiple compounding regulations) and 1735.2(f) (failure to complete a compounding self-assessment). The Board issued a fine which Respondent paid.

39. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on February 14, 2013, the Board issued Citation number CI 2012 55589 against Respondent Samih Nabil Botros for violating California Code of Regulations, title 16, sections 1793.7(3) (failing to supervise pharmacy technicians), 1735.4-7 (failing to adhere to multiple compounding regulations) and 1735.2(f) (failure to complete a compounding self-assessment). The Board issued a fine which Respondent paid.

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 46688, issued to Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 48680, issued to Samih Nabil Botros;

3. Prohibiting Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46688 is placed on probation or until Pharmacy Permit Number PHY 46688 is reinstated if Pharmacy Permit Number PHY 46688 issued to Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy is revoked;

4. Prohibiting Samih Nabil Botros from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46688 is placed on probation or until Pharmacy Permit Number PHY 46688 is reinstated if Pharmacy Permit Number PHY 46688 issued to Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy is revoked;

5. Prohibiting Samih Nabil Botros from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License...
Number RPH 48680 is placed on probation or until Pharmacist License Number RPH 48680 is reinstated if Pharmacist License Number RPH 48680 issued to Samih Nabil Botros is revoked;

6. Ordering Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy and Samih Nabil Botros 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; and,

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

DATED: 5/27/17

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