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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.	Case No. 6083 **ACCUSATION**

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.

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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 manger, 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 manger, 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[1]

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.

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[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

20. Since June 9, 2004, Respondent Samih Botros has been the Pharmacist-in-Charge of Respondent Tower Pharmacy. Respondents compounded non-sterile drug products.

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 Sivergate 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(c), in that they compounded drug products which were commercially available, as set forth in paragraphs 19 through 27, which are incorporated herein by reference.

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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 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 Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy;

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

3. Prohibiting Botrosons 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 Botrosons 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 Botrosons 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

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