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

11 **BOTROSONS PHARMACEUTICAL, INC.,**
12 **DBA TOWER PHARMACY**
13 **26732 Crown Valley Parkway #101**
Mission Viejo, CA 92691

Case No. 6083

14 **Pharmacy Permit No. PHY 46688**

A C C U S A T I O N

15 **SAMIH NABIL BOTROS**
16 **26732 Crown Valley Parkway #101 Mission**
Viejo, CA 92691

17 **Pharmacist License No. RPH 48680**

18 Respondents.

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21 Complainant alleges:

22 **PARTIES**

- 23 1. Virginia K. Herold (Complainant) brings this Accusation solely in her official
24 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
25 2. On or about June 9, 2004, the Board of Pharmacy issued Pharmacy Permit Number
26 PHY 46688 to Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy with Samih
27 Nabil Botros designated as the Pharmacist-in-Charge (Tower Pharmacy). The Pharmacy Permit
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1 was in full force and effect at all times relevant to the charges brought herein and will expire on
2 June 1, 2017, unless renewed.

3 3. On or about April 15, 1996, the Board of Pharmacy issued Pharmacist License
4 Number RPH 48680 to Samih Nabil Botros (Samih Botros). The Pharmacist License was in full
5 force and effect at all times relevant to the charges brought herein and will expire on July 31,
6 2017, unless renewed.

7 JURISDICTION

8 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
9 Consumer Affairs, under the authority of the following laws. All section references are to the
10 Business and Professions Code unless otherwise indicated.

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

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

16 7. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license
18 by operation of law or by order or decision of the board or a court of law, the
19 placement of a license on a retired status, or the voluntary surrender of a license by a
20 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.

21 STATUTORY PROVISIONS

22 8. Section 4022 of the Code states:

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

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

26 (b) Any device that bears the statement: "Caution: federal law restricts this
27 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
28 order use of the device.

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

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

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

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

19 REGULATORY PROVISIONS¹

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

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

- 25 (1) Altering the dosage form or delivery system of a drug
- 26 (2) Altering the strength of a drug
- 27 (3) Combining components or active ingredients
- 28 (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.

1 15. Title 16, California Code of Regulations, section 1735.2, subdivision (h)
2 states:

3 (h) Every compounded drug product shall be given an expiration date
4 representing the date beyond which, in the professional judgment of the pharmacist
5 performing or supervising the compounding, it should not be used. This "beyond use
6 date" of the compounded drug product shall not exceed 180 days from preparation or
7 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.

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

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

11

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

13

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

15 A statement that the drug has been compounded by the pharmacy shall be
16 included on the container or on the receipt provided to the patient.

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

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

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

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

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

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

27 (3) The procedures for maintaining, storing, calibrating, cleaning, and
28 disinfecting equipment used in compounding, and for training on those procedures as
part of the staff training and competency evaluation process.

1 (4) Documentation of the methodology used to test integrity, potency, quality,
and labeled strength of compounded drug products.

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

4 COST RECOVERY

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

9 FACTUAL ALLEGATIONS

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

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

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

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

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

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

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

10 27. On August 12, 2016, Respondents dispensed Rx No. 469995 which listed the wrong
11 strength of the medication (8/0.1% instead of 6/0 1% as prescribed) on its label.

12 **FIRST CAUSE FOR DISCIPLINE**

13 **(Inadequate Record-Keeping)**

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

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

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

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

23 **SECOND CAUSE FOR DISCIPLINE**

24 **(Failure to Assign Proper Beyond Use Date)**

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

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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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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct)**

3 34. Respondents are subject to disciplinary action under Code section 4301 for
4 unprofessional conduct in that they engaged in the activities described in paragraphs 19 through
5 27 above, which are incorporated herein by reference.

6 **OTHER MATTERS**

7 35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
8 PHY 46688 issued to Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy,
9 Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy shall be prohibited from
10 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
11 licensee for five years if Pharmacy Permit Number PHY 46688 is placed on probation or until
12 Pharmacy Permit Number PHY 46688 is reinstated if it is revoked.

13 36. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
14 PHY 46688 issued to Botrosos Pharmaceutical, Inc., doing business as Tower Pharmacy while
15 Samih Nabil Botros has been an officer and owner and had knowledge of or knowingly
16 participated in any conduct for which the licensee was disciplined, Samih Nabil Botros shall be
17 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,
18 or partner of a licensee for five years if Pharmacy Permit Number PHY 46688 is placed on
19 probation or until Pharmacy Permit Number PHY 46688 is reinstated if it is revoked.

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

25 **DISCIPLINARY CONSIDERATIONS**

26 38. To determine the degree of discipline, if any, to be imposed on Respondents,
27 Complainant alleges that on February 14, 2013, the Board issued Citation number CI 2011 51219
28 against Respondent Tower Pharmacy for violating California Code of Regulations, title 16,

1 sections 1793.7(3) (failing to supervise pharmacy technicians), 1735.4-7 (failing to adhere to
2 multiple compounding regulations) and 1735.2(f) (failure to complete a compounding self-
3 assessment). The Board issued a fine which Respondent paid.

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

10 PRAYER

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

13 1. Revoking or suspending Pharmacy Permit Number PHY 46688, issued to Botros
14 Pharmaceutical, Inc., doing business as Tower Pharmacy;

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

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

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

27 5. Prohibiting Samih Nabil Botros from serving as a manager, administrator, owner,
28 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License

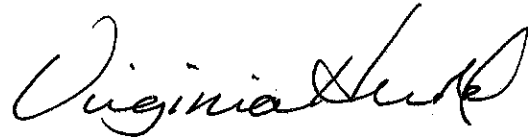
1 Number RPH 48680 is placed on probation or until Pharmacist License Number RPH 48680 is
2 reinstated if Pharmacist License Number RPH 48680 issued to Samih Nabil Botros is revoked;

3 6. Ordering Botrosons Pharmaceutical, Inc., doing business as Tower Pharmacy and
4 Samih Nabil Botros to pay the Board of Pharmacy the reasonable costs of the investigation and
5 enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

6 7. Taking such other and further action as deemed necessary and proper.
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8
9 DATED:

5/27/17



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

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