

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

In the Matter of the Accusation Against:

Case No. 5055

**SOUTH COAST SPECIALTY
COMPOUNDING CORPORATION,
DBA PARK COMPOUNDING,
DENNIS ELIAS SAADEH, PRESIDENT;
TINA MARIE SULIC SAADEH,
SECRETARY AND TREASURER,
PHARMACIST-IN-CHARGE
9257 Research Drive
Irvine, CA 92618**

**Pharmacy License No. PHY 41748
Sterile Compounding License No. LSC 99026**

**TINA MARIE SULIC SAADEH
9257 Research Drive
Irvine, CA 92618
Original Pharmacist License No. RPH 41234**

Respondents.

DECISION AND ORDER

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

This Decision shall become effective on September 4, 2015.

It is so ORDERED on August 5, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

August 5, 2015

Dennis and Tina Marie Saadeh
South Coast Specialty Compounding
Corporation dba Park Compounding
9257 Research Drive
Irvine, CA 92618

Re: LETTER OF PUBLIC REPROVAL
In the Matter of the Accusation Against: Park Compounding; Dennis Elias Saadeh; and
Tina Marie Sulic Saadeh
Pharmacy License No. PHY 41748, Sterile Compounding License No. LSC 99026, and
Pharmacist License No. RPH 41232

Dear Mr. and Ms. Saadeh:

On or about May 20, 2015, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed a First Amended Accusation against South Coast Specialty Compounding Corporation, dba Park Compounding, with Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh as Secretary and Treasurer (Respondent Park Compounding). The First Amended Accusation was also filed against Pharmacist Tina Marie Sulic Saadeh. The First Amended Accusation alleged that you engaged in unprofessional conduct for variation from prescription under Business and Professions Code section 4301(o). On August 2, 2013, you violated regulations regarding pharmacy law when you deviated from the requirements of a prescription when an error was made entering data into Park Pharmacy's computer that resulted in an incorrect salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.

You admit that the charges and allegations in First Amended Accusation No. 5055, if proven at a hearing, constitute cause for imposing discipline upon your Original Pharmacy Permit No. PHY 41748 and your Sterile Compounding License No. LSC 99026. It also would constitute cause to impose discipline upon Ms. Saadeh's Original Pharmacist License Number RPH 41234. The Board has decided that the charges warrant a public reproof.

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproof.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 RITA M. LANE
Deputy Attorney General
4 State Bar No. 171352
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2614
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5055

12 **SOUTH COAST SPECIALTY**
13 **COMPOUNDING CORPORATION,**
14 **DBA PARK COMPOUNDING,**
15 **DENNIS ELIAS SAADEH, PRESIDENT;**
16 **TINA MARIE SULIC SAADEH,**
17 **SECRETARY AND TREASURER,**
18 **PHARMACIST-IN-CHARGE**
19 **9257 Research Drive**
Irvine, CA 92618

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL

[Bus. & Prof. Code § 495]

20 **Original Pharmacy Permit No. PHY 41748**

21 **Sterile Compounding License No. LSC**
22 **99026**

23 **TINA MARIE SULIC SAADEH**
24 **9257 Research Drive**
25 **Irvine, CA 92618**
26 **Original Pharmacist License No. RPH 41234**

27 Respondents.

28
IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
entitled proceedings that the following matters are true:

///

///

1 PARTIES

2 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Kamala D. Harris, Attorney General of the State of California, by Rita M. Lane, Deputy Attorney
5 General.

6 2. Respondent South Coast Specialty Compounding Corporation, dba Park
7 Compounding, Dennis Elias Saadeh, President, Tina Marie Sulic Saadeh, Secretary and Treasurer
8 (Respondent Park Compounding) and Pharmacist Tina Marie Sulic Saadeh (Respondent Tina
9 Saadeh) are represented in this proceeding by attorney Tony J. Park, whose address is: Law
10 Offices of Tony J. Park, Inc., 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

11 3. On or about August 24, 1987, the Board issued Original Pharmacist License Number
12 RPH 41234 to Respondent Tina Saadeh. The Pharmacist License was in full force and effect at
13 all times relevant to the charges brought herein and will expire on March 31, 2016, unless
14 renewed.

15 4. On or about August 1, 1996, the Board issued Original Pharmacy Permit Number
16 PHY 41748 to Respondent Dennis Saadeh and Respondent Tina Saadeh, doing business as Park
17 Pharmacy. On or about April 7, 2002, a Change of Permit was filed with the Board changing the
18 name of the corporation to South Coast Specialty Compounding Corporation, doing business as
19 Park Compounding, with Respondent Dennis Saadeh as the CEO and President and Respondent
20 Tina Saadeh as the Secretary and Treasurer (Respondent Park Pharmacy). Respondent Tina
21 Saadeh has been the Pharmacist-in-Charge for Respondent Park Pharmacy since May 21, 2009.
22 The Original Pharmacy Permit was in full force and effect at all times relevant to the charges
23 brought herein and will expire on August 1, 2015, unless renewed.

24 JURISDICTION

25 5. Accusation No. 5055 was filed before the Board and the Accusation and all other
26 statutorily required documents were properly served on Respondents on February 19, 2015.

27 Respondents timely filed their Notice of Defense contesting the Accusation. Thereafter, a First

28 ///

1 Amended Accusation was filed and served on Respondents. A copy of First Amended
2 Accusation No. 5055 is attached as Exhibit A and incorporated herein by reference.

3 ADVISEMENT AND WAIVERS

4 6. Respondents have carefully read, fully discussed with counsel, and understand the
5 charges and allegations in First Amended Accusation No. 5055. Respondents have also carefully
6 read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and
7 Disciplinary Order for Public Repeval.

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

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

17 CULPABILITY

18 9. Respondent Park Compounding understands and agrees that the charges and
19 allegations in First Amended Accusation No. 5055, if proven at a hearing, constitute cause for
20 imposing discipline upon their Original Pharmacy Permit No. PHY 41748 and their Sterile
21 Compounding License No. LSC 99026.

22 10. Respondent Tina Saadeh understands and agrees that the charges and allegations in
23 First Amended Accusation No. 5055, if proven at a hearing, constitute cause for imposing
24 discipline upon her Original Pharmacist License Number RPH 41234.

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

1 17. In consideration of the foregoing admissions and stipulations, the parties agree that
2 the Board may, without further notice or formal proceeding, issue and enter the following
3 Disciplinary Order:

4 DISCIPLINARY ORDER


5 IT IS HEREBY ORDERED that Original Pharmacist License Number RPH 41234 issued
6 to Respondent Tina Saadeh and Original Pharmacy Permit Number PHY 41748 and Sterile
7 Compounding License No. LSC 99026, issued to Respondent Dennis Saadeh and Respondent
8 Tina Saadeh, doing business as Park Pharmacy, shall, by way of letter from the Board's
9 Executive Officer, be publicly reprovved. The letter shall be in substantially the same form as the
10 letter attached as Exhibit B to this stipulation.

11 IT IS FURTHER ORDERED that Respondents shall pay \$8,500 to the Board for its costs
12 associated with the investigation and enforcement of this matter. Respondents shall be permitted
13 to pay these costs in a payment plan approved by the Board. If Respondents fail to pay the Board
14 costs as ordered, Respondents shall not be allowed to renew their Pharmacy Licenses until
15 Respondents pay the costs in full.

16 ACCEPTANCE

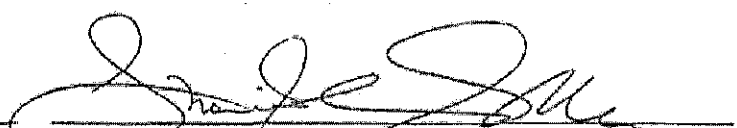
17 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
18 Repeval and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation
19 and the effect it will have on my Original Pharmacy Permit No. PHY 41748 and my Sterile
20 Compounding License No. LSC 99026. I enter into this Stipulated Settlement and Disciplinary
21 Order for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the
22 Decision and Order of the Board of Pharmacy.

23
24 DATED: 5-26-15


25 DENNIS ELIAS SAADEH, PRESIDENT OF PARK
26 COMPOUNDING, AND ON BEHALF OF PARK
27 COMPOUNDING
28 Respondent

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

DATED: 5-26-15


TINA MARIE SULIC SAADEH, SECRETARY AND
TREASURER OF PARK COMPOUNDING, AND
ON BEHALF OF PARK COMPOUNDING
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Repeval and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Original Pharmacist License No. RPH 41234. I enter into this Stipulated Settlement and Disciplinary Order for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5-26-15


TINA MARIE SULIC SAADEH, PHARMACIST
Respondent

I have read and fully discussed with Respondents Park Compounding, Dennis Elias Saadeh and Tina Marie Sulic Saadeh the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I approve its form and content.

DATED: 05/27/2015


TONY J. PARK
Attorney for Respondents

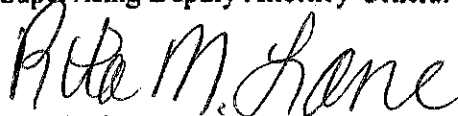
///
///
///
///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Repeval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 5-28-15

Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

RITA M. LANE
Deputy Attorney General
Attorneys for Complainant

SD2014706524
71072409.doc

Exhibit A

First Amended Accusation No. 5055

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 RITA M. LANE
Deputy Attorney General
4 State Bar No. 171352
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2614
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5055

12 **SOUTH COAST SPECIALTY**
13 **COMPOUNDING CORPORATION,**
14 **DBA PARK COMPOUNDING,**
15 **DENNIS ELIAS SAADEH, PRESIDENT;**
16 **TINA MARIE SULIC SAADEH,**
17 **SECRETARY AND TREASURER,**
18 **PHARMACIST-IN-CHARGE**
19 **9257 Research Drive**
20 **Irvine, CA 92618**

FIRST AMENDED ACCUSATION

21 **Original Pharmacy Permit No. PHY 41748**

22 **Sterile Compounding License No. LSC**
23 **99026**

24 **TINA MARIE SULIC SAADEH**
25 **9257 Research Drive**
26 **Irvine, CA 92618**
27 **Original Pharmacist License No. RPH 41234**

28 Respondents.

Complainant alleges:

PARTIES

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

1 2. On or about August 24, 1987, the Board issued Original Pharmacist License Number
2 RPH 41234 to Tina Marie Sulic Saadeh (Respondent Tina Saadeh). The Pharmacist License was
3 in full force and effect at all times relevant to the charges brought herein and will expire on
4 March 31, 2015, unless renewed.

5 3. On or about August 1, 1996, the Board issued Original Pharmacy Permit Number
6 PHY 41748 to Respondent Dennis Saadeh and Respondent Tina Saadeh, doing business as Park
7 Pharmacy. On or about April 7, 2002, a Change of Permit was filed with the Board changing the
8 name of the corporation to South Coast Specialty Compounding Corporation, doing business as
9 Park Compounding, with Respondent Dennis Saadeh as the CEO and President and Respondent
10 Tina Saadeh as the Secretary and Treasurer (Respondent Park Pharmacy). Respondent Tina
11 Saadeh has been the Pharmacist-in-Charge for Respondent Park Pharmacy since May 21, 2009.
12 The Original Pharmacy Permit was in full force and effect at all times relevant to the charges
13 brought herein and will expire on August 1, 2015, unless renewed.

14 4. On or about July 1, 2003, the Board issued Sterile Compounding License Number
15 LSC 99026 to Respondent Park Pharmacy. The Sterile Compounding License was in full force
16 and effect at all times relevant to the charges brought herein and will expire on August 1, 2015,
17 unless renewed.

18 JURISDICTION

19 5. This Accusation is brought before the Board under the authority of the following
20 laws. All section references are to the Business and Professions Code (Code) unless otherwise
21 indicated.

22 6. Section 4300 of the Code states:

23 (a) Every license issued may be suspended or revoked.

24 7. Section 4300.1 of the Code states:

25 The expiration, cancellation, forfeiture, or suspension of a board-issued
26 license by operation of law or by order or decision of the board or a court of law,
27 the placement of a license on a retired status, or the voluntary surrender of a
28 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.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18

STATUTORY PROVISIONS

8. Section 4301 of the Code states:

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

.....

(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.

9. 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.

REGULATIONS

10. California Code of Regulations, title 16, section 1709.1 provides:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

.....

11. California Code of Regulations, title 16, section 1716 provides:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. . .

///

1 **COSTS**

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

6 **DRUGS**

7 13. Multitrace-4 concentrate compounded injection is a dangerous drug pursuant to
8 Business and Professions Code section 4022 and is used as a supplement.

9 14. Multitrace-5 concentrate compounded injection is a dangerous drug pursuant to
10 Business and Professions Code section 4022 and is used as a supplement.

11 **FACTS**

12 15. On or about August 2, 2013, Respondent Park Pharmacy issued a voluntary recall
13 for the products Multitrace-4 concentrate compounded injection lot #06252013@52 and
14 Multitrace-5 concentrate compounded injection lots #03212013@6 and #05212013@20, due to a
15 higher than labeled content of zinc. The content of zinc as Sulfate was 25 mg/ml instead of the
16 labeled amount of 5mg/ml.

17 16. The error resulted from the entry of the wrong salt conversion computation in the
18 master formula. The incorrect salt conversion factor was stored in the pharmacy's computer and
19 was used to determine the amount of zinc sulfate monohydrate powder for compounding
20 Multitrace-5 concentrate and Multitrace-4 concentrate. The incorrect conversion ratio of zinc 1
21 mg : zinc sulfate monohydrate 13.9mg was entered into the computer's master formulas for
22 compounding Multitrace-4 concentrate compounded injection and Multitrace-5 concentrate
23 compounded injection, instead of the correct conversion ratio of zinc 1 mg : zinc sulfate
24 monohydrate 2.78mg.

25 17. The computer used the incorrect zinc conversion ratio to generate compounding
26 logs listing incorrect amounts of required zinc sulfate monohydrate powder, which contributed to
27 Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate

28 ///

1 compound injection lots #03212013@6 and #05212013@20 to be compounded with a zinc
2 concentration of 25mg/ml, which is 5 times higher than the prescribed 5mg/ml zinc concentration.

3 18. Recall notices were sent by Respondent Park Pharmacy to customers to determine
4 inventory and facilitate the return of the recalled products. Recall documents were sent to
5 customers via FedEx with tracking. On August 2, 2013, all the customers had already been
6 notified by FedEx and by telephone regarding the recalled Multitrace products.

7 19. Respondent Park Pharmacy corrected the master formulas used for compounding
8 Multitrace-4 Concentrate and Multitrace-5 Concentrate with the correct zinc conversion ratio.
9 Respondent Park Pharmacy also corrected the zinc formula conversion in their computer.

10 **FIRST CAUSE FOR DISCIPLINE**

11 (PARK PHARMACY PERMIT - Variation from Prescription)

12 20. Respondent Park Pharmacy's Original Pharmacy Permit Number PHY 41748 is
13 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
14 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations
15 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake
16 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect
17 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.
18 The circumstances are set forth in paragraphs 15 through 19, above, and incorporated as though
19 fully set forth herein.

20 **SECOND CAUSE FOR DISCIPLINE**

21 (PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription)

22 21. Respondent Park Pharmacy's Sterile Compounding License Number LSC 99026 is
23 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
24 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations
25 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake
26 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect
27 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.

28 ///

1 The circumstances are set forth in paragraphs 15 through 19, above, and incorporated as though
2 fully set forth herein.

3 **THIRD CAUSE FOR DISCIPLINE**

4 (PHARMACIST TINA SAADEH - Variation from Prescription)

5 22. Respondent Tina Saadeh's Original Pharmacist License Number RPH 41234 is
6 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
7 Regulations, title 16, sections 1709.1(a) and (b) and 1716, in that she was the Pharmacist-in-
8 Charge at Park Pharmacy, when Park Pharmacy violated regulations regarding pharmacy law
9 when it deviated from the requirements of a prescription when a mistake was made entering data
10 into Respondent Park Pharmacy's computer that resulted in an incorrect salt conversion into the
11 master formula for Multitrace-4 concentrate and Multitrace-5 concentrate. The circumstances are
12 set forth in paragraphs 15 through 19, above, and incorporated as though fully set forth herein.

13 **DISCIPLINE CONSIDERATIONS**

14 23. To determine the degree of discipline, if any, to be imposed on Respondent Park
15 Pharmacy, Complainant alleges that on or about August 13, 2008, in a prior disciplinary action
16 entitled *In the Matter of the First Amended Accusation Against Park Pharmacy and Dennis Elias*
17 *Saadeh* before the Board of Pharmacy, in Case Number 2924, Respondent Park Pharmacy's
18 Original Pharmacy Permit No. PHY 41748 was revoked, placed on probation for 5 years with
19 various terms and conditions of probation. That decision is now final and is incorporated by
20 reference as if fully set forth herein. The discipline was based on Park Pharmacy missing
21 controlled substances and dangerous drugs from its inventory, failing to keep a complete
22 accounting of all drugs in the pharmacy and failing to report the drug loss to the appropriate
23 agencies as required by law.

24 **PRAYER**

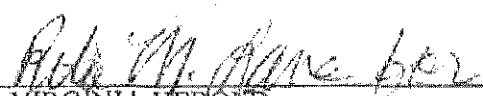
25 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
26 and that following the hearing, the Board of Pharmacy issue a decision:

27 ///

28 ///

- 1 1. Revoking or suspending Original Pharmacy Permit Number PHY 41748, issued to
- 2 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and
- 3 Treasurer;
- 4 2. Revoking or suspending Sterile Compounding License Number LSC 99026, issued to
- 5 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and
- 6 Treasurer;
- 7 3. Revoking or suspending Pharmacist License Number RPH 41234, issued to Tina
- 8 Marie Sulic Saadeh;
- 9 4. Ordering Park Pharmacy and Tina Marie Sulic Saadeh, jointly and severally, to pay
- 10 the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
- 11 pursuant to Business and Professions Code section 125.3; and
- 12 5. Taking such other and further action as deemed necessary and proper.

13
14 DATED: 5-17-15


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

15
16
17
18
19
20
21 SD2014706524
70955327.docx

1 KAMALA D. HARRIS
Attorney General of California
2 LINDA K. SCHNEIDER
Supervising Deputy Attorney General
3 RITA M. LANE
Deputy Attorney General
4 State Bar No. 171352
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2614
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5055

12 **SOUTH COAST SPECIALTY**
13 **COMPOUNDING CORPORATION,**
14 **DBA PARK COMPOUNDING,**
15 **DENNIS ELIAS SAADEH, PRESIDENT;**
16 **TINA MARIE SULIC SAADEH,**
17 **SECRETARY AND TREASURER,**
18 **PHARMACIST-IN-CHARGE**
19 **9257 Research Drive**
Irvine, CA 92618

A C C U S A T I O N

20 **Original Pharmacy Permit No. PHY 41748**

21 **Sterile Compounding License No. LSC**
22 **99026**

23 **TINA MARIE SULIC SAADEH**
24 **9257 Research Drive**
25 **Irvine, CA 92618**
26 **Original Pharmacist License No. RPH 41234**

27 Respondents.

28 Complainant alleges:

PARTIES

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

1 2. On or about August 24, 1987, the Board issued Original Pharmacist License Number
2 RPH 41234 to Tina Marie Sulic Saadeh (Respondent Tina Saadeh). The Pharmacist License was
3 in full force and effect at all times relevant to the charges brought herein and will expire on
4 March 31, 2015, unless renewed.

5 3. On or about August 1, 1996, the Board issued Original Pharmacy Permit Number
6 PHŸ 41748 to Respondent Dennis Saadeh and Respondent Tina Saadeh, doing business as Park
7 Pharmacy. On or about April 7, 2002, a Change of Permit was filed with the Board changing the
8 name of the corporation to South Coast Specialty Compounding Corporation, doing business as
9 Park Compounding, with Respondent Dennis Saadeh as the CEO and President and Respondent
10 Tina Saadeh as the Secretary and Treasurer (Respondent Park Pharmacy). Respondent Tina
11 Saadeh has been the Pharmacist-in-Charge for Respondent Park Pharmacy since May 21, 2009.
12 The Original Pharmacy Permit was in full force and effect at all times relevant to the charges
13 brought herein and will expire on August 1, 2015, unless renewed.

14 4. On or about July 1, 2003, the Board issued Sterile Compounding License Number
15 LSC 99026 to Respondent Park Pharmacy. The Sterile Compounding License was in full force
16 and effect at all times relevant to the charges brought herein and will expire on August 1, 2015,
17 unless renewed.

18 **JURISDICTION**

19 5. This Accusation is brought before the Board under the authority of the following
20 laws. All section references are to the Business and Professions Code (Code) unless otherwise
21 indicated.

22 6. Section 4300 of the Code states:
23 (a) Every license issued may be suspended or revoked.

24 7. Section 4300.1 of the Code states:

25 The expiration, cancellation, forfeiture, or suspension of a board-issued
26 license by operation of law or by order or decision of the board or a court of law,
27 the placement of a license on a retired status, or the voluntary surrender of a
28 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.

1 **STATUTORY PROVISIONS**

2 8. Section 4301 of the Code states:

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

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

12 9. Section 4022 of the Code states

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

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

17 (b) Any device that bears the statement: "Caution: federal law restricts this
18 device to sale by or on the order of a _____," "Rx only," or words of similar
19 import, the blank to be filled in with the designation of the practitioner licensed to
20 use or order use of the device.

21 (c) Any other drug or device that by federal or state law can be lawfully
22 dispensed only on prescription or furnished pursuant to Section 4006.

23 **REGULATIONS**

24 10. California Code of Regulations, title 16, section 1709.1 provides:

25 (a) The pharmacist-in-charge of a pharmacy shall be employed at that
26 location and shall have responsibility for the daily operation of the pharmacy.

27 (b) The pharmacy owner shall vest the pharmacist-in-charge with adequate
28 authority to assure compliance with the laws governing the operation of a
29 pharmacy.

30 11. California Code of Regulations, title 16, section 1716 provides:

31 Pharmacists shall not deviate from the requirements of a prescription
32 except upon the prior consent of the prescriber or to select the drug product in
33 accordance with Section 4073 of the Business and Professions Code. . .

34 ///

1 **COSTS**

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

6 **DRUGS**

7 13. Multitrace-4 concentrate compounded injection is a dangerous drug pursuant to
8 Business and Professions Code section 4022 and is used as a supplement.

9 14. Multitrace-5 concentrate compounded injection is a dangerous drug pursuant to
10 Business and Professions Code section 4022 and is used as a supplement.

11 **FACTS**

12 15. On or about August 2, 2013, Respondent Park Pharmacy issued a voluntary recall
13 for the products Multitrace-4 concentrate compounded injection lot #06252013@52 and
14 Multitrace-5 concentrate compounded injection lots #03212013@6 and #05212013@20, due to a
15 higher than labeled content of zinc. The content of zinc as Sulfate was 25 mg/ml instead of the
16 labeled amount of 5mg/ml.

17 16. The error resulted from the entry of the wrong salt conversion computation in the
18 master formula. The incorrect salt conversion factor was stored in the pharmacy's computer and
19 was used to determine the amount of zinc sulfate monohydrate powder for compounding
20 Multitrace-5 concentrate and Multitrace-4 concentrate. The incorrect conversion ratio of zinc 1
21 mg : zinc sulfate monohydrate 13.9mg was entered into the computer's master formulas for
22 compounding Multitrace-4 concentrate compounded injection and Multitrace-5 concentrate
23 compounded injection, instead of the correct conversion ratio of zinc 1 mg : zinc sulfate
24 monohydrate 2.78mg.

25 17. The computer used the incorrect zinc conversation ratio to generate compounding
26 logs listing incorrect amounts of required zinc sulfate monohydrate powder, which contributed to
27 Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate

28 ///

1 compound injection lots #03212013@6 and #05212013@20 to be compounded with a zinc
2 concentration of 25mg/ml, which is 5 times higher than the prescribed 5mg/ml zinc concentration.

3 18. Recall notices were sent by Respondent Park Pharmacy to customers to determine
4 inventory and facilitate the return of the recalled products. Recall documents were sent to
5 customers via FedEx with tracking. On August 2, 2013, all the customers had already been
6 notified by FedEx and by telephone regarding the recalled Multitrace products.

7 19. Respondent Park Pharmacy corrected the master formulas used for compounding
8 Multitrace-4 Concentrate and Multitrace-5 Concentrate with the correct zinc conversion ratio.
9 Respondent Park Pharmacy also corrected the zinc formula conversion in their computer.

10 **FIRST CAUSE FOR DISCIPLINE**

11 (PARK PHARMACY PERMIT - Variation from Prescription)

12 20. Respondent Park Pharmacy's Original Pharmacy Permit Number RPH 41748 is
13 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
14 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations
15 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake
16 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect
17 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.
18 The circumstances are set forth in paragraphs 15 through 19, above, and incorporated as though
19 fully set forth herein.

20 **SECOND CAUSE FOR DISCIPLINE**

21 (PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription)

22 21. Respondent Park Pharmacy's Sterile Compounding License Number LSC 99026 is
23 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
24 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations
25 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake
26 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect
27 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.

28 ///

1 The circumstances are set forth in paragraphs 15 through 19, above, and incorporated as though
2 fully set forth herein.

3 **THIRD CAUSE FOR DISCIPLINE**

4 (PHARMACIST TINA SAADEH - Variation from Prescription)

5 22. Respondent Tina Saadeh's Original Pharmacist License Number RPH 41234 is
6 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of
7 Regulations, title 16, sections 1709.1(a) and (b) and 1716, in that she was the Pharmacist-in-
8 Charge at Park Pharmacy, when Park Pharmacy violated regulations regarding pharmacy law
9 when it deviated from the requirements of a prescription when a mistake was made entering data
10 into Respondent Park Pharmacy's computer that resulted in an incorrect salt conversion into the
11 master formula for Multitrace-4 concentrate and Multitrace-5 concentrate. The circumstances are
12 set forth in paragraphs 15 through 19, above, and incorporated as though fully set forth herein.

13 **DISCIPLINE CONSIDERATIONS**

14 23. To determine the degree of discipline, if any, to be imposed on Respondent Park
15 Pharmacy, Complainant alleges that on or about August 13, 2008, in a prior disciplinary action
16 entitled *In the Matter of the First Amended Accusation Against Park Pharmacy and Dennis Elias*
17 *Saadeh* before the Board of Pharmacy, in Case Number 2924, Respondent Park Pharmacy's
18 Original Pharmacy Permit No. PHY 41748 was revoked, placed on probation for 5 years with
19 various terms and conditions of probation. That decision is now final and is incorporated by
20 reference as if fully set forth herein. The discipline was based on Park Pharmacy missing
21 controlled substances and dangerous drugs from its inventory, failing to keep a complete
22 accounting of all drugs in the pharmacy and failing to report the drug loss to the appropriate
23 agencies as required by law.

24 **PRAYER**

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

27 ///

28 ///

1 1. Revoking or suspending Original Pharmacy Permit Number PHY 41748, issued to
2 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and
3 Treasurer;

4 2. Revoking or suspending Sterile Compounding License Number LSC 99026, issued to
5 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and
6 Treasurer;

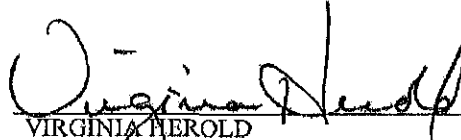
7 3. Revoking or suspending Pharmacist License Number RPH 41234, issued to Tina
8 Marie Sulic Saadeh;

9 4. Ordering Park Pharmacy and Tina Marie Sulic Saadeh, jointly and severally, to pay
10 the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
11 pursuant to Business and Professions Code section 125.3; and

12 5. Taking such other and further action as deemed necessary and proper.

13
14 DATED:

2/10/15



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

15
16
17
18
19
20 SD2014706524
70955327.docx

Exhibit B

Letter of Public Reproval in Case No. 5055

Date: _____

Dennis and Tina Marie Saadeh
South Coast Specialty Compounding
Corporation dba Park Compounding
9257 Research Drive
Irvine, CA 92618

Re: LETTER OF PUBLIC REPROVAL

In the Matter of the Accusation Against: Park Compounding; Dennis Elias Saadeh; and
Tina Marie Sulic Saadeh
Pharmacy License No. PHY 41748, Sterile Compounding License No. LSC 99026, and
Pharmacist License No. RPH 41232

Dear Mr. and Ms. Saadeh:

On or about May 20, 2015, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed a First Amended Accusation against South Coast Specialty Compounding Corporation, dba Park Compounding, with Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh as Secretary and Treasurer (Respondent Park Compounding). The First Amended Accusation was also filed against Pharmacist Tina Marie Sulic Saadeh. The First Amended Accusation alleged that you engaged in unprofessional conduct for variation from prescription under Business and Professions Code section 4301(o). On August 2, 2013, you violated regulations regarding pharmacy law when you deviated from the requirements of a prescription when an error was made entering data into Park Pharmacy's computer that resulted in an incorrect salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.

You admit that the charges and allegations in First Amended Accusation No. 5055, if proven at a hearing, constitute cause for imposing discipline upon your Original Pharmacy Permit No. PHY 41748 and your Sterile Compounding License No. LSC 99026. It also would constitute cause to impose discipline upon Ms. Saadeh's Original Pharmacist License Number RPH 41234. The Board has decided that the charges warrant a public reproof.

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproof.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs