		•	
1	KAMALA D. HARRIS Attorney General of California		
2	GREGORY J. SALUTE		
3	Supervising Deputy Attorney General RITA M. LANE		
4	Deputy Attorney General State Bar No. 171352		
5	600 West Broadway, Suite 1800 San Diego, CA 92101		
6	P.O. Box 85266 San Diego, CA 92186-5266		
7	Telephone: (619) 645-2614 Facsimile: (619) 645-2061		
8	Attorneys for Complainant		
9	BEFORE THE BOARD OF PHARMACY		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11		1 · .	
12	In the Matter of the Accusation Against:	Case No. 5055	
13	SOUTH COAST SPECIALTY COMPOUNDING CORPORATION,	• •	
14	DBA PARK COMPOUNDING, DENNIS ELIAS SAADEH, PRESIDENT;	FIRST AMENDED ACCUSATION	
15	TINA MARIE SULIC SAÁDEH, SECRETARY AND TREASURER,		
16	PHARMACIST-IN-CHARGE 9257 Research Drive		
17	Irvine, CA 92618		
18	Original Pharmacy Permit No. PHY 41748		
19	Sterile Compounding License No. LSC 99026		
20	TINA MARIE SULIC SAADEH	·	
21	9257 Research Drive Irvine, CA 92618		
22	Original Pharmacist License No. RPH 41234		
23	Respondents.		
24	Complainant alleges:		
25	PARTIES		
26	Virginia Herold (Complainant) brings this First Amended Accusation solely in her		
27	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer		
28	Affairs.		
1		· •	

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

- 3. On or about August 1, 1996, the Board issued Original Pharmacy Permit Number PHY 41748 to Respondent Dennis Saadeh and Respondent Tina Saadeh, doing business as Park Pharmacy. On or about April 7, 2002, a Change of Permit was filed with the Board changing the name of the corporation to South Coast Specialty Compounding Corporation, doing business as Park Compounding, with Respondent Dennis Saadeh as the CEO and President and Respondent Tina Saadeh as the Secretary and Treasurer (Respondent Park Pharmacy). Respondent Tina Saadeh has been the Pharmacist-in-Charge for Respondent Park Pharmacy since May 21, 2009. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2015, unless renewed.
- 4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99026 to Respondent Park Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2015, unless renewed.

JURISDICTION

- 5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
 - 6. Section 4300 of the Code states:
 - (a) Every license issued 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 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. . .

COSTS

12. Section 125.3 of the Code states, 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.

DRUGS

- 13. Multitrace-4 concentrate compounded injection is a dangerous drug pursuant to Business and Professions Code section 4022 and is used as a supplement.
- 14. Multitrace-5 concentrate compounded injection is a dangerous drug pursuant to Business and Professions Code section 4022 and is used as a supplement.

FACTS

- 15. On or about August 2, 2013, Respondent Park Pharmacy issued a voluntary recall for the products Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate compounded injection lots #03212013@6 and #05212013@20, due to a higher than labeled content of zinc. The content of zinc as Sulfate was 25 mg/ml instead of the labeled amount of 5mg/ml.
- 16. The error resulted from the entry of the wrong salt conversion computation in the master formula. The incorrect salt conversion factor was stored in the pharmacy's computer and was used to determine the amount of zinc sulfate monohydrate powder for compounding Multitrace-5 concentrate and Multitrace-4 concentrate. The incorrect conversion ratio of zinc 1 mg: zinc sulfate monohydrate 13.9mg was entered into the computer's master formulas for compounding Multitrace-4 concentrate compounded injection and Multitrace-5 concentrate compounded injection, instead of the correct conversion ratio of zinc 1 mg: zinc sulfate monohydrate 2.78mg.
- 17. The computer used the incorrect zinc conversation ratio to generate compounding logs listing incorrect amounts of required zinc sulfate monohydrate powder, which contributed to Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate

б

22_.

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

- 18. Recall notices were sent by Respondent Park Pharmacy to customers to determine inventory and facilitate the return of the recalled products. Recall documents were sent to customers via FedEx with tracking. On August 2, 2013, all the customers had already been notified by FedEx and by telephone regarding the recalled Multitrace products.
- 19. Respondent Park Pharmacy corrected the master formulas used for compounding Multitrace-4 Concentrate and Multitrace-5 Concentrate with the correct zinc conversion ratio. Respondent Park Pharmacy also corrected the zinc formula conversion in their computer.

FIRST CAUSE FOR DISCIPLINE

(PARK PHARMACY PERMIT - Variation from Prescription)

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

SECOND CAUSE FOR DISCIPLINE

(PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription)

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

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

THIRD CAUSE FOR DISCIPLINE

(PHARMACIST TINA SAADEH - Variation from Prescription)

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

DISCIPLINE CONSIDERATIONS

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

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:

27 | ///

28 | ///

1	KAMALA D. HARRIS		
2	Attorney General of California LINDA K. SCHNEIDER		
3	Supervising Deputy Attorney General RITA M. LANE		
4	Deputy Attorney General State Bar No. 171352		
5	110 West "A" Street, Suite 1100 San Diego, CA 92101		
6	P.O. Box 85266 San Diego, CA 92186-5266		
7	Telephone: (619) 645-2614 Facsimile: (619) 645-2061		
8	Attorneys for Complainant		
9	BEFORE THE BOARD OF PHARMACY		
	DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALIFORNIA		
11			
12	In the Matter of the Accusation Against:	Case No. 5055	
13	SOUTH COAST SPECIALTY COMPOUNDING CORPORATION,		
14	DBA PARK COMPOUNDING, DENNIS ELIAS SAADEH, PRESIDENT;	ACCUSATION	
15	TINA MARIE SULIC SAADEH, SECRETARY AND TREASURER,		
16	PHARMACIST-IN-CHARGE 9257 Research Drive		
17	Irvine, CA 92618		
18	Original Pharmacy Permit No. PHY 41748		
19	Sterile Compounding License No. LSC 99026		
20	TINA MARIE SULIC SAADEH		
21	9257 Research Drive Irvine, CA 92618		
22	Original Pharmacist License No. RPH 41234		
23	Respondents.	·	
24			
25	Complainant alleges:		
26	PARTIES		
27	Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
28	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.		
		I	

- 2. On or about August 24, 1987, the Board issued Original Pharmacist License Number RPH 41234 to Tina Marie Sulic Saadeh (Respondent Tina Saadeh). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2015, unless renewed.
- 3. On or about August 1, 1996, the Board issued Original Pharmacy Permit Number PHY 41748 to Respondent Dennis Saadeh and Respondent Tina Saadeh, doing business as Park Pharmacy. On or about April 7, 2002, a Change of Permit was filed with the Board changing the name of the corporation to South Coast Specialty Compounding Corporation, doing business as Park Compounding, with Respondent Dennis Saadeh as the CEO and President and Respondent Tina Saadeh as the Secretary and Treasurer (Respondent Park Pharmacy). Respondent Tina Saadeh has been the Pharmacist-in-Charge for Respondent Park Pharmacy since May 21, 2009. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2015, unless renewed.
- 4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99026 to Respondent Park Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2015, unless renewed.

JURISDICTION

- 5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
 - 6. Section 4300 of the Code states:
 - (a) Every license issued 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 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. . .

- [][

COSTS

12. Section 125.3 of the Code states, 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.

DRUGS

- 13. Multitrace-4 concentrate compounded injection is a dangerous drug pursuant to Business and Professions Code section 4022 and is used as a supplement.
- 14. Multitrace-5 concentrate compounded injection is a dangerous drug pursuant to Business and Professions Code section 4022 and is used as a supplement.

FACTS

- 15. On or about August 2, 2013, Respondent Park Pharmacy issued a voluntary recall for the products Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate compounded injection lots #03212013@6 and #05212013@20, due to a higher than labeled content of zinc. The content of zinc as Sulfate was 25 mg/ml instead of the labeled amount of 5mg/ml.
- 16. The error resulted from the entry of the wrong salt conversion computation in the master formula. The incorrect salt conversion factor was stored in the pharmacy's computer and was used to determine the amount of zinc sulfate monohydrate powder for compounding Multitrace-5 concentrate and Multitrace-4 concentrate. The incorrect conversion ratio of zinc 1 mg: zinc sulfate monohydrate 13.9mg was entered into the computer's master formulas for compounding Multitrace-4 concentrate compounded injection and Multitrace-5 concentrate compounded injection, instead of the correct conversion ratio of zinc 1 mg: zinc sulfate monohydrate 2.78mg.
- 17. The computer used the incorrect zinc conversation ratio to generate compounding logs listing incorrect amounts of required zinc sulfate monohydrate powder, which contributed to Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate ///

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

- 18. Recall notices were sent by Respondent Park Pharmacy to customers to determine inventory and facilitate the return of the recalled products. Recall documents were sent to customers via FedEx with tracking. On August 2, 2013, all the customers had already been notified by FedEx and by telephone regarding the recalled Multitrace products.
- 19. Respondent Park Pharmacy corrected the master formulas used for compounding Multitrace-4 Concentrate and Multitrace-5 Concentrate with the correct zinc conversion ratio. Respondent Park Pharmacy also corrected the zinc formula conversion in their computer.

FIRST CAUSE FOR DISCIPLINE

(PARK PHARMACY PERMIT - Variation from Prescription)

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

SECOND CAUSE FOR DISCIPLINE

(PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription)

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

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

THIRD CAUSE FOR DISCIPLINE

(PHARMACIST TINA SAADEH - Variation from Prescription)

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

DISCIPLINE CONSIDERATIONS

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

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:

27 | ///

28 | ///