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9		RE THE PHARMACY
10		CONSUMER AFFAIRS 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;	FIRST AMENDED 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	Complainant alleges:	
25	PAR	TIES
26	1. Virginia Herold (Complainant) bring	s this First Amended Accusation solely in her
27	official capacity as the Executive Officer of the l	Board of Pharmacy, Department of Consumer
28	Affairs.	
		1
		First Amended Accusation (Case No. 5

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.

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

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.

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## 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.

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

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6. Section 4300 of the Code states:

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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.

First Amended Accusation (Case No. 5055)

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	
4	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:	
5	is not minod to, any of the following.	
6	(o) Violating or attempting to violate, directly or indirectly, or assisting in or	
7	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	
8	pharmacy, including regulations established by the board or by any other state or federal regulatory agency.	
9		
10	9. Section 4022 of the Code states	
11 12	Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:	
13	(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.	
14 15 16	(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.	
10	(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.	
18	REGULATIONS	
9	10. California Code of Regulations, title 16, section 1709.1 provides:	
20	(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.	
21	(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate	
2	authority to assure compliance with the laws governing the operation of a pharmacy.	
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25	11. California Code of Regulations, title 16, section 1716 provides:	
26 27	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	
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First Amended Accusation (Case No. 5055)

COSTS 1 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 enforcement of the case. 5 DRUGS б 13. Multitrace-4 concentrate compounded injection is a dangerous drug pursuant to 7 Business and Professions Code section 4022 and is used as a supplement. 8 14. 9 Multitrace-5 concentrate compounded injection is a dangerous drug pursuant to Business and Professions Code section 4022 and is used as a supplement. 10 FACTS -11 15. 12 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 13 Multitrace-5 concentrate compounded injection lots #03212013@6 and #05212013@20, due to a 14 higher than labeled content of zinc. The content of zinc as Sulfate was 25 mg/ml instead of the 15 labeled amount of 5mg/ml. 16 16. The error resulted from the entry of the wrong salt conversion computation in the 17 master formula. The incorrect salt conversion factor was stored in the pharmacy's computer and 18 was used to determine the amount of zinc sulfate monohydrate powder for compounding 19 Multitrace-5 concentrate and Multitrace-4 concentrate. The incorrect conversion ratio of zinc 1 2021 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 22 compounded injection, instead of the correct conversion ratio of zinc 1 mg : zinc sulfate 23 24 monohydrate 2.78mg. The computer used the incorrect zinc conversation ratio to generate compounding 17. 25 logs listing incorrect amounts of required zine sulfate monohydrate powder, which contributed to 26 Multitrace-4 concentrate compounded injection lot #06252013@52 and Multitrace-5 concentrate 27 111 28

compound injection lots #03212013@6 and #05212013@20 to be compounded with a zinc 1 2 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 3 inventory and facilitate the return of the recalled products. Recall documents were sent to 4 5 customers via FedEx with tracking. On August 2, 2013, all the customers had already been б notified by FedEx and by telephone regarding the recalled Multitrace products. 19. Respondent Park Pharmacy corrected the master formulas used for compounding 7 Multitrace-4 Concentrate and Multitrace-5 Concentrate with the correct zinc conversion ratio. 8 Respondent Park Pharmacy also corrected the zinc formula conversion in their computer. 9 FIRST CAUSE FOR DISCIPLINE 10 (PARK PHARMACY PERMIT - Variation from Prescription) 11 20. Respondent Park Pharmacy's Original Pharmacy Permit Number PHY 41748 is 12 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of 13 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations 14 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake 15 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect 16 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate. 17 The circumstances are set forth in paragraphs 15 through 19, above, and incorporated as though 18 fully set forth herein. 19 SECOND CAUSE FOR DISCIPLINE 20 (PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription) 21 21. Respondent Park Pharmacy's Sterile Compounding License Number LSC 99026 is 22 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of 23 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations 24 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake 25was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect 26 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate. 27III 28

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

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## 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 10 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.

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## **DISCIPLINE CONSIDERATIONS**

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

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## PRAYER

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

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

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

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

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DATED: 5-19-15 14

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

First Amended Accusation (Case No. 5055)

1	Kamala D. Harris		
2	Attorney General of California LINDA K. SCHNEIDER		
3	Supervising Deputy Attorney General RITA M, LANE		
	Deputy Attorney General		
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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		е тне	
9	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10		CALIFORNIA	
11		a x 5055	
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	PAR	TIES	
27	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
28 as the Executive Officer of the Board of Pharmacy, Department of		cy, Department of Consumer Affairs,	
		1	
		Accusation	

Accusation

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

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.

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## 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.

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Section 4300 of the Code states:

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

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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.

Section 4301 of the Code states: The board shall take action against any holder of a license who is guilty of rofessional conduct or whose license has been procured by fraud or expresentation or issued by mistake. Unprofessional conduct shall include, but of limited to, any of the following:  (o) Violating or attempting to violate, directly or indirectly, or assisting in or ting the violation of or conspiring to violate any provision or term of this oter or of the applicable federal and state laws and regulations governing maxy, including regulations established by the board or by any other state or ral regulatory agency. Section 4022 of the Code states Dangerous drug" or "dangerous device" means any drug or device unsafe for use in humans or animals, and includes the following:
The board shall take action against any holder of a license who is guilty of rofessional conduct or whose license has been procured by fraud or epresentation or issued by mistake. Unprofessional conduct shall include, but of limited to, any of the following:  (o) Violating or attempting to violate, directly or indirectly, or assisting in or ting the violation of or conspiring to violate any provision or term of this other or of the applicable federal and state laws and regulations governing macy, including regulations established by the board or by any other state or ral regulatory agency. Section 4022 of the Code states Dangerous drug" or "dangerous device" means any drug or device unsafe for use in humans or animals, and includes the following:
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(a) Any down that began the losses to Wanting fails -11-men -1.11.11
(a) Any drug that bears the legend: "Caution: federal law prohibits ensing without prescription," "Rx only," or words of similar import.
(b) Any device that bears the statement: "Caution: federal law restricts this
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(c) Any other drug or device that by federal or state law can be lawfully ensed only on prescription or furnished pursuant to Section 4006.
REGULATIONS
California Code of Regulations, title 16, section 1709.1 provides:
(a) The pharmacist-in-charge of a pharmacy shall be employed at that tion and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate ority to assure compliance with the laws governing the operation of a macy.
California Code of Regulations, title 16, section 1716 provides:
Pharmacists shall not deviate from the requirements of a prescription pt upon the prior consent of the prescriber or to select the drug product in rdance with Section 4073 of the Business and Professions Code
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Accusation

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 o		
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		
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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.

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.

#### FIRST CAUSE FOR DISCIPLINE

(PARK PHARMACY PERMIT - Variation from Prescription)

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

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#### SECOND CAUSE FOR DISCIPLINE

(PARK PHARMACY STERILE COMPOUNDING LICENSE - Variation from Prescription) 21 Respondent Park Pharmacy's Sterile Compounding License Number LSC 99026 is 21. 22 subject to disciplinary action under Code section 4301(o) in conjunction with California Code of 23 Regulations, title 16, section 1716, in that Respondent Park Pharmacy violated regulations 24 regarding pharmacy law when it deviated from the requirements of a prescription when a mistake 25 was made entering data into Respondent Park Pharmacy's computer that resulted in an incorrect 26 salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate. 27 111 28

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.

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#### **DISCIPLINE CONSIDERATIONS**

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

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1. Revoking or suspending Original Pharmacy Permit Number PHY 41748, issued to 1 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and 2 3 Treasurer; 2. Revoking or suspending Sterile Compounding License Number LSC 99026, issued to 4 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and 5 Treasurer; 6 3. Revoking or suspending Pharmacist License Number RPH 41234, issued to Tina 7 Marie Sulic Saadeh; 8 4. Ordering Park Pharmacy and Tina Marie Sulic Saadeh, jointly and severally, to pay 9 the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, 10 pursuant to Business and Professions Code section 125.3; and 11 5. Taking such other and further action as deemed necessary and proper. 12 13 2/10/15 DATED: 14 **VIRGINIA HEROLD** 15 Executive Officer Board of Pharmacy 16 Department of Consumer Affairs State of California 17 Complainant 18 19 SD2014706524 20 70955327.docx 21 22 23 24 25 26 27 28 7 Accusation