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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 **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

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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:

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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: 5-19-15

*Virginia Heroled*

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

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**A C C U S A T I O N**

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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  
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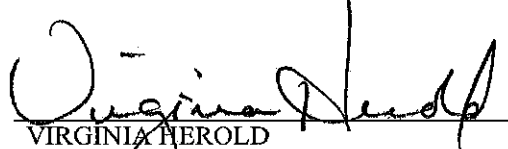
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5 Park Pharmacy; Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh, Secretary and  
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7           3.    Revoking or suspending Pharmacist License Number RPH 41234, issued to Tina  
8 Marie 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*

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