

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

In the Matter of the Accusation Against:

Case No. 5138

**THE COMPOUNDING SHOP  
CORPORATION,  
dba THE COMPOUNDING SHOP  
MICHAEL HAULSEE, PRES./PIC  
REBECCA BRADLEY, V.P.  
4000 Park Street North  
St. Petersburg, FL 33709**

**Original Non Resident Pharmacy Permit  
No. NRP 701**

Respondent.

**DECISION AND ORDER**

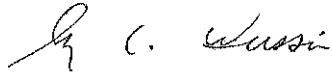
The attached Stipulated Settlement and Disciplinary Order for Surrender and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on January 28, 2015.

It is so ORDERED on January 21, 2015.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

By

  
\_\_\_\_\_  
STAN C. WEISSER  
Board President

1 KAMALA D. HARRIS  
Attorney General of California  
2 LINDA SCHNEIDER  
Senior Assistant Attorney General  
3 KENT D. HARRIS  
Supervising Deputy Attorney General  
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8  
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15 **REBECCA BRADLEY, V.P.**  
4000 Park Street North  
16 St. Petersburg, FL 33709

**STIPULATED SURRENDER OF  
LICENSE AND ORDER**

17 **Original Non-Resident Pharmacy Permit**  
**No. NRP 701**

18 Respondent.

19  
20 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
21 entitled proceedings that the following matters are true:

22 PARTIES

23 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.  
24 She brought this action solely in her official capacity and is represented in this matter by Kamala  
25 D. Harris, Attorney General of the State of California, by Kent D. Harris, Supervising Deputy  
26 Attorney General.  
27  
28





1 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,  
2 and the Board shall not be disqualified from further action by having considered this matter.

3 13. The parties understand and agree that Portable Document Format (PDF) and facsimile  
4 copies of this Stipulated Surrender of License and Order, including Portable Document Format  
5 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

6 14. This Stipulated Surrender of License and Order is intended by the parties to be an  
7 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
8 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
9 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order  
10 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing  
11 executed by an authorized representative of each of the parties.

12 15. In consideration of the foregoing admissions and stipulations, the parties agree that  
13 the Board may, without further notice or formal proceeding, issue and enter the following Order:

14 **ORDER**

15 IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit No. NRP 701, issued to  
16 Respondent The Compounding Shop Corporation dba The Compounding Shop, Michael Haulsee,  
17 President and Pharmacist-in-Charge, is surrendered and accepted by the Board of Pharmacy.

18 1. The surrender of Respondent's Non-Resident Pharmacy Permit and the acceptance of  
19 the surrendered license by the Board shall constitute the imposition of discipline against  
20 Respondent. This stipulation constitutes a record of the discipline and shall become a part of  
21 Respondent's license history with the Board of Pharmacy.

22 2. Respondent shall lose all rights and privileges as a Non-Resident Pharmacy in  
23 California as of the effective date of the Board's Decision and Order.

24 3. Respondent shall cause to be delivered to the Board its pocket license and, if one was  
25 issued, its wall certificate on or before the effective date of the Decision and Order.

26 4. If respondent ever applies for licensure or petitions for reinstatement in the State of  
27 California, the Board shall treat it as a new application for licensure. Respondent must comply  
28 with all the laws, regulations and procedures for licensure in effect at the time the application or

1 petition is filed, and all of the charges and allegations contained in Accusation No. 5138 shall be  
2 deemed to be true, correct and admitted by Respondent when the Board determines whether to  
3 grant or deny the application or petition.

4 5. Respondent shall pay the agency its costs of investigation and enforcement in the  
5 amount of \$2,829.00 prior to issuance of a new or reinstated license.

6 6. If Respondent should ever apply or reapply for a new license or certification, or  
7 petition for reinstatement of a license, by any other health care licensing agency in the State of  
8 California, all of the charges and allegations contained in Accusation, No. 5138 shall be deemed  
9 to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any  
10 other proceeding seeking to deny or restrict licensure.

11 ACCEPTANCE

12 I have carefully read the above Stipulated Surrender of License and Order and have fully  
13 discussed it with my attorney, Brian A Kahan. I understand the stipulation and the effect it will  
14 have on my Non-Resident Pharmacy Permit. I enter into this Stipulated Surrender of License and  
15 Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order  
16 of the Board of Pharmacy.

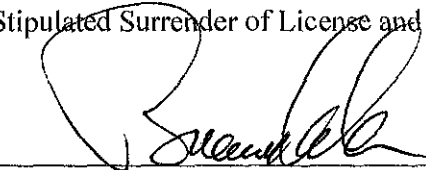
17  
18 DATED: 12/12/14



MICHAEL HAULSEE, PRES./PIC  
THE COMPOUNDING SHOP CORPORATION  
DBA THE COMPOUNDING SHOP  
Respondent

21 I have read and fully discussed with Respondent The Compounding Shop Corporation dba  
22 The Compounding Shop, Michael Haulsee, President and Pharmacist-in-Charge the terms and  
23 conditions and other matters contained in this Stipulated Surrender of License and Order. I  
24 approve its form and content.

25 DATED: 12/16/14

  
BRIAN A KAHAN  
Attorney for Respondent

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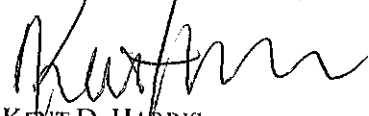
ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 12/16/14

Respectfully submitted,

KAMALA D. HARRIS  
Attorney General of California  
LINDA SCHNEIDER  
Senior Assistant Attorney General



KENT D. HARRIS  
Supervising Deputy Attorney General  
*Attorneys for Complainant*

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Stipulated Surrender The Compounding Shop Draft2.doc

**Exhibit A**

**Accusation No. 5138**



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2 KENT D. HARRIS  
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7 *Attorneys for Complainant*

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15 **REBECCA BRADLEY, V.P.**  
16 **4000 Park Street North**  
17 **St. Petersburg, FL 33709**

**ACCUSATION**

18 **Original Non-Resident Pharmacy Permit No. NRP 701**

19 **Respondent.**

20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about February 14, 2006, the Board issued Original Non-Resident Pharmacy  
25 Permit Number NRP 701 to The Compounding Shop Corporation ("Respondent"), doing business  
26 as The Compounding Shop, with Michael Haulsee as president and pharmacist-in-charge and  
27 Rebecca Bradley as vice president. The non-resident pharmacy permit was in full force and  
28 effect at all times relevant to the charges brought herein and will expire on February 1, 2015,  
unless renewed.

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1 7. Code section 4303, subdivision (b), states:

2 The board may cancel, deny, revoke, or suspend a nonresident pharmacy  
3 registration, issue a citation or letter of admonishment to a nonresident pharmacy, or  
4 take any other action against a nonresident pharmacy that the board may take against  
5 a resident pharmacy license, on any of the same grounds upon which such action  
6 might be taken against a resident pharmacy, provided that the grounds for the action  
7 are also grounds for action in the state in which the nonresident pharmacy is  
8 permanently located.

9 8. Code section 477, subdivision (b), states that a "license" includes "certificate",  
10 "registration" or other means to engage in a business or profession.

11 9. Code section 4022 states:

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

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

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

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

22 10. Code section 4112 states, in pertinent part:

23 (a) Any pharmacy located outside this state that ships, mails, or delivers,  
24 in any manner, controlled substances, dangerous drugs, or dangerous devices into this  
25 state shall be considered a nonresident pharmacy.

26 (b) A person may not act as a nonresident pharmacy unless he or she has  
27 obtained a license from the board. The board may register a nonresident pharmacy  
28 that is organized as a limited liability company in the state in which it is licensed.

29 . . . .

30 (d) All nonresident pharmacies shall comply with all lawful directions  
31 and requests for information from the regulatory or licensing agency of the state in  
32 which it is licensed as well as with all requests for information made by the board  
33 pursuant to this section . . .

34 11. Code section 4127.2, subdivision (a), states that "[a] nonresident pharmacy shall not  
35 compound injectable sterile drug products for shipment into the State of California without a  
36 license issued by the board pursuant to this section. The license shall be renewed annually and  
37 shall not be transferable".

1 12. Code section 4127.3, subdivision (a), states:

2 Whenever the board has a reasonable belief, based on information  
3 obtained during an inspection or investigation by the board, that a pharmacy  
4 compounding injectable sterile drug products poses an immediate threat to the public  
5 health or safety, the executive officer of the board may issue an order to the pharmacy  
6 to immediately cease and desist from compounding injectable sterile drug products.  
7 The cease and desist order shall remain in effect for no more than 30 days or the date  
8 of a hearing seeking an interim suspension order, whichever is earlier.

6 13. Health and Safety Code section 109970 states:

7 "Manufacture" means the preparation, compounding, propagation,  
8 processing, or fabrication of any food, drug, device, or cosmetic. The term  
9 "manufacture" includes repackaging or otherwise changing the container, wrapper, or  
10 labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the  
11 food, drug, device, or cosmetic. The term "manufacture" does not include  
12 repackaging from a bulk container by a retailer at the time of sale to its ultimate  
13 consumer.

11 14. Health and Safety Code section 111250 states that "[a]ny drug or device is  
12 adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

13 15. Health and Safety Code section 111295 states that "[i]t is unlawful for any person to  
14 manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

15 **FLORIDA STATUTES**

16 16. Florida Statutes section 465.016 states, in pertinent part:

17 (1) The following acts constitute grounds for denial of a license or  
18 disciplinary action . . .

19 . . . .

20 (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal  
21 Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the  
22 Comprehensive Drug Abuse Prevention and Control Act; or chapter 893 . . .

22 17. Florida Statutes, section 499.005, states, in pertinent part:

23 It is unlawful for a person to perform or cause the performance of any of  
24 the following acts in this state:

25 (1) The manufacture, repackaging, sale, delivery, or holding or offering  
26 for sale of any drug, device, or cosmetic that is adulterated or misbranded or has  
27 otherwise been rendered unfit for human or animal use . . .

27 ///

28 ///

1 18. Florida Statutes, section 499.006, states, in pertinent part:

2 A drug or device is adulterated:

3 (1) If it consists in whole or in part of any filthy, putrid, or decomposed  
4 substance . . .

5 **COST RECOVERY**

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

10 **DRUG CLASSIFICATIONS**

11 20. "Rhinocort", a brand of budesonide, is indicated for the treatment of nasal congestion.  
12 Rhinocort is a dangerous drug within the meaning of Code section 4022 in that it requires a  
13 prescription under federal law.

14 **BACKGROUND**

15 21. On and between March 18, 2013, and March 22, 2013, the Food and Drug  
16 Administration ("FDA") inspected Respondent's pharmacy, The Compounding Shop.

17 22. On or about March 22, 2013, the FDA posted a Form 483 Inspection Report, listing  
18 12 observations made by FDA representatives during the inspection as to The Compounding  
19 Shop's sterile processing (the FDA posted an amended Form 483 Inspection Report pertaining to  
20 the inspection on March 25, 2013).

21 23. On or about May 8, 2013, the FDA posted a news release alerting the public that the  
22 FDA's preliminary findings of practices at The Compounding Shop of St. Petersburg, Florida,  
23 raised concerns about a lack of sterility assurance for sterile drugs produced at and distributed  
24 from the pharmacy. The FDA stated that they had advised The Compounding Shop it was in the  
25 best interest of public health to take action to remove all sterile products from the market. The  
26 Compounding Shop informed the FDA that it was recalling sterile products and was in the  
27 process of notifying customers.

28 ///

1           24. On or about June 25, 2013, the Board's inspector issued a Cease and Desist Order to  
2 The Compounding Shop, informing them that the Board had no record of licensure or  
3 accreditation that would authorize the pharmacy to ship compounded sterile drug product into  
4 California to patients, prescribers, or other recipients. The inspector ordered The Compounding  
5 Shop to cease and desist such shipments absent appropriate licensure. The inspector requested  
6 that The Compounding Shop provide the Board with, among other things, documentation of all  
7 compounded sterile injectable products they had shipped into California since January 1, 2012,  
8 and a list of all patients, prescribers or other recipients in California to whom any of The  
9 Compounding Shops' recalled or otherwise suspect products were shipped.

10           25. On or about July 2, 2013, The Compounding Shop's legal representative sent an  
11 email to the inspector stating that the pharmacy had voluntarily suspended preparation of any  
12 sterile compounded products and that no compounded sterile products were being shipped into  
13 California.

14           26. On or about July 10, 2013, the inspector received various documents from The  
15 Compounding Shop's legal representative, including a 14 page Log of Scripts for medications the  
16 pharmacy had shipped into California. The log indicated that The Compounding Shop had  
17 shipped over 170 prescriptions of compounded sterile injectable medications into California  
18 between January 1, 2012, and July 1, 2013.

19           27. On or about September 3, 2013, the FDA published a Form 483 Inspection Report  
20 documenting sterility issues with compounded budesonide that they observed during an  
21 inspection of The Compounding Shop. The inspection was conducted between August 23, 2013,  
22 and September 3, 2013.

23           28. On or about September 27, 2013, the FDA published a Safety Alert, warning patients  
24 and health care providers that budesonide solution from The Compounding Shop may be  
25 contaminated and should not be used or administered to patients. The FDA stated that they had  
26 observed a bottle of budesonide solution from The Compounding Shop that contained a visible,  
27 white, floating material. The FDA identified the material as a fungus. The FDA expressed their  
28 concern that contamination may be present in other budesonide solution products from The

1 Compounding Shop that may currently be on the market. The FDA explained that drug products  
2 that are for oral inhalation, such as the budesonide solution from The Compounding Shop, which  
3 is labeled “for inhalation only”, are required to be sterile, and that contaminated drug products,  
4 whether used by inhalation or otherwise, put patients at risk for infection.

5 29. That same day (September 27, 2013), the inspector sent a letter to The Compounding  
6 Shop, requesting that they halt shipping sterile compounded products, such as budesonide  
7 solution for inhalation/irrigation, into California until the sterility issues have been resolved. The  
8 inspector also requested documentation of all compounded sterile products that had been shipped  
9 to California since January 1, 2013.

10 30. On or about October 9, 2013, pharmacist-in-charge, Michael Haulsee, sent dispensing  
11 information for compounded medications The Compounding Shop had shipped into California  
12 between January 1, 2013, and October 4, 2013. The documentation showed that The  
13 Compounding Shop had not shipped any medication to California subsequent to April 25, 2013.

14 **CAUSE FOR DISCIPLINE**

15 **(Violations of the Pharmacy Law or of Applicable State Laws Governing Pharmacy)**

16 31. Respondent is subject to disciplinary action pursuant to Code section 4301,  
17 subdivision (o), for unprofessional conduct, in that Respondent violated or attempted to violate,  
18 directly or indirectly, a provision or term of the Pharmacy Law (Bus. & Prof. Code § 4300, et  
19 seq.) or of the applicable state laws governing pharmacy, as follows:

20 a. On and between January 1, 2012, and April 15, 2013, Respondent shipped over 170  
21 prescriptions of compounded sterile injectable medications, including Nandrolone Decanoate 200  
22 mg/ml injectable, Testosterone Cyp (Sesame) 200 mg/ml injectable, Nandrolone Decanoate 100  
23 mg/ml injectable, Nandrolone Decanoate 250 mg/ml injectable, Folic Acid/B-12 5mg/100  
24 mcg/ml injectable, and/or Test Cyp/Test Prop Blend 60/60 mg/ml, into the State of California  
25 without a sterile compounding license issued by the Board, in violation of Code section 4127.2,  
26 subdivision (a).

27 b. On and between August 23, 2013, and September 3, 2013, Respondent manufactured,  
28 sold, delivered, held and/or offered for sale a drug, specifically, budesonide solution, that was

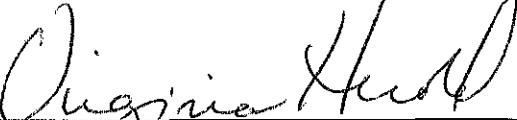
1 adulterated, as set forth in paragraphs 27 and 28 above, in violation of Health and Safety Code  
2 section 111295. Respondent's acts and/or omissions alleged above would constitute grounds for  
3 disciplinary action against Respondent in the State of Florida, where Respondent's nonresident  
4 pharmacy is permanently located, pursuant to Florida Statutes, section 465.016, subdivision  
5 (1)(e), by virtue of Respondent's violation of Florida Statute, section 499.005, subdivision (1).

6 **PRAYER**

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

- 9 1. Revoking or suspending Original Non-Resident Pharmacy Permit Number NRP 701,  
10 issued to The Compounding Shop Corporation, doing business as The Compounding Shop;  
11 2. Ordering The Compounding Shop Corporation, doing business as The Compounding  
12 Shop, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of  
13 this case, pursuant to Business and Professions Code section 125.3;  
14 3. Taking such other and further action as deemed necessary and proper.

15  
16 DATED: 7/28/14

  
17 VIRGINIA HEROLD  
18 Executive Officer  
19 Board of Pharmacy  
20 Department of Consumer Affairs  
21 State of California  
22 Complainant

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