

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

In the Matter of the Accusation Against:

Case No. 4308

FRANCK'S COMPOUNDING PHARMACY
1210 A SW 33 Avenue
Ocala, FL 34474

Non-Resident Pharmacy License No. NRP 674
Non-Resident Sterile Compounding
Pharmacy License No. NSC 99297

Respondent.

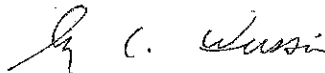
DECISION AND ORDER

The attached Stipulated Surrender of License 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 December 28, 2012.

It is so ORDERED on November 28, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
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Attorneys for Complainant

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STATE OF CALIFORNIA

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12 **1210 A SW 33 Ave.**
13 **Ocala, Florida 34474**

**STIPULATED SURRENDER OF
LICENSE(S) AND ORDER**

14 **Non-Resident Pharmacy License No. NRP 674**
15 **Non-Resident Sterile Compounding**
16 **Pharmacy License No. NSC 99297**

Respondent.

17 In the interest of a prompt and speedy resolution of this matter, consistent with the public
18 interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the
19 parties hereby agree to the following Stipulated Surrender of License(s) and Order to submit to
20 the Board for approval and adoption as the final disposition of the Accusation in this case.

21
22 PARTIES

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

26 2. Franck's Lab, Inc. dba Franck's Compounding Pharmacy (Respondent) is represented
27 in this proceeding by attorney Ned Milenkovich, of McDonald Hopkins LLC, 300 North LaSalle
28 Street, Suite 2100, Chicago, IL 60654.

1 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
2 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order
3 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
4 executed by an authorized representative of each of the parties.

5 13. The parties understand and agree that facsimile copies of this stipulation, including
6 facsimile signatures thereto, shall have the same force and effect as the originals.

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

9
10 **ORDER**

11 IT IS HEREBY ORDERED that Non-Resident Pharmacy License No. NRP 674, and its
12 Non-Resident Sterile Compounding License No. NSC 99297, issued to Respondent, are each and
13 severally surrendered and accepted by the Board of Pharmacy.

14 1. The surrender of Respondent's Non-Resident Pharmacy License and Non-Resident
15 Sterile Compounding License and the acceptance of the surrendered license(s) by the Board shall
16 constitute the imposition of discipline against Respondent. This stipulation constitutes a record of
17 the discipline and shall become a part of Respondent's license history with the Board.

18 2. Respondent shall lose all rights and privileges as a Non-Resident Pharmacy and a
19 Non-Resident Sterile Compounding Pharmacy in California as of the effective date of the Board's
20 Decision and Order.

21 3. Respondent shall cause to be delivered to the Board its pocket license(s) and, if one or
22 more was issued, its wall certificate(s), on or before the effective date of the Decision and Order.

23 4. Respondent may not apply, reapply, or petition for any licensure or registration of the
24 Board for three (3) years from the effective date of the Decision and Order.

25 5. If Respondent ever applies for licensure or petitions for reinstatement in the State of
26 California, the Board shall treat it as a new application for licensure. Respondent must comply
27 with all the laws, regulations and procedures for licensure in effect at the time the application or
28 petition is filed, and all of the charges and allegations contained in Accusation No. 4308 shall be

1 deemed to be true, correct and admitted by Respondent when the Board determines whether to
2 grant or deny the application or petition.

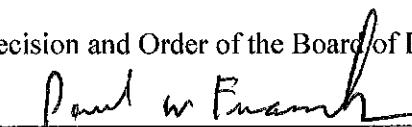
3 6. If Respondent ever applies or petitions for a new or reinstated license, Respondent
4 shall pay the Board its costs of investigation and enforcement in the amount of \$19,619.00 prior
5 to issuance of the new or reinstated license.

6 7. 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. 4308 shall be deemed to
9 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
12 ACCEPTANCE

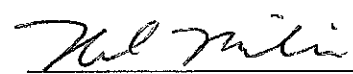
13 I have carefully read the above Stipulated Surrender of License and Order and have fully
14 discussed it with my attorney, Ned Milenkovich. I understand the stipulation and the effect it will
15 have on my Non-Resident Pharmacy License, and Non-Resident Sterile Compounding License. I
16 enter into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

18 DATED: 10/9/2012


Paul W. Franck, R.Ph., FIACP, President, for
FRANCK'S LAB, INC dba
FRANCK'S COMPOUNDING PHARMACY
Respondent

19
20
21
22 I have read and fully discussed with Respondent Franck's Lab, Inc. dba Franck's
23 Compounding Pharmacy the terms and conditions and other matters contained in this Stipulated
24 Surrender of License and Order. I approve its form and content.

25 DATED: 10/10/2012


NED MILENKOVICH, PharmD, JD
McDonald Hopkins LLC
Attorneys for Respondent

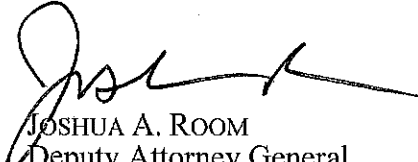
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ENDORSEMENT

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: 10/19/2012

Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General


JOSHUA A. ROOM
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4308

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
3 JOSHUA A. ROOM
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A C C U S A T I O N

16 **Non-Resident Pharmacy License No. NRP 674**
17 **Non-Resident Sterile Compounding**
18 **Pharmacy License No. NSC 99297**

Respondent.

19 Complainant alleges:

20 PARTIES

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

23 2. On or about September 23, 2005, the Board of Pharmacy issued Non-Resident
24 Pharmacy License No. NRP 674 to Franck's Lab, Inc. dba Franck's Compounding Pharmacy,
25 Paul W. Franck, President (Respondent). The License was in full force and effect at all times
26 relevant herein. It expired on September 1, 2012, and has not been renewed.

27 3. On or about November 29, 2005, the Board of Pharmacy issued Non-Resident Sterile
28 Compounding License No. NSC 99297 to Respondent. The License was in full force and effect
at all times relevant herein. It expired on September 1, 2012, and has not been renewed.

JURISDICTION

1
2 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
3 Consumer Affairs, under the authority of the following laws. All section references are to the
4 Business and Professions Code (Code) unless otherwise indicated.

5 5. Section 4011 of the Code provides that the Board shall administer and enforce both
6 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
7 Act [Health & Safety Code, § 11000 et seq.].

8 6. Section 4300(a) of the Code provides that every license issued by the Board may be
9 suspended or revoked.

10 7. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration,
11 surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a
12 disciplinary action during the period within which the license may be renewed, restored, reissued
13 or reinstated. Section 4402(e) of the Code provides that any non-pharmacist license issued by the
14 Board may be canceled by the Board if not renewed within 60 days after its expiration, and any
15 license canceled in this fashion may not be reissued but will instead require a new application.

STATUTORY AND REGULATORY PROVISIONS

16
17
18 8. Section 4301 of the Code provides, in pertinent part, that the Board shall take action
19 against any holder of a license who is guilty of "unprofessional conduct," defined to include, but
20 not be limited to, any of the following:

21 (j) The violation of any of the statutes of this state, of any other state, or of the United
22 States regulating controlled substances and dangerous drugs.

23 (n) The revocation, suspension, or other discipline by another state of a license to practice
24 pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

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

1 9. Health and Safety Code section 109970, in pertinent part, defines "manufacture" to
2 mean "the preparation, compounding, propagation, processing, or fabrication of any food, drug,
3 device, or cosmetic."

4 10. Health and Safety Code section 111255 provides that a drug or device is adulterated if
5 it has been produced, prepared, packed, or held under conditions whereby it may have been
6 contaminated with filth, or whereby it may have been rendered injurious to health.

7 11. Health and Safety Code section 111295 provides that it is unlawful for any person to
8 manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

9 12. 21 U.S.C. § 331 prohibits, in pertinent part, the introduction or delivery for
10 introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that
11 is adulterated or misbranded, the adulteration or misbranding of any food, drug, device, tobacco
12 product, or cosmetic in interstate commerce, and the receipt in interstate commerce of any food,
13 drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or
14 proffered delivery thereof for pay or otherwise.

15 13. 21 U.S.C. § 351(a) provides, in pertinent part, that a drug or device shall be deemed
16 to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance;
17 or if it has been prepared, packed, or held under insanitary conditions whereby it may have been
18 contaminated with filth, or whereby it may have been rendered injurious to health.

19
20 FACTUAL BACKGROUND

21 14. For an unknown period of at least several years until at least in or about April 2012,
22 Respondent compounded sterile injectable drug products or preparations, shipping those products
23 from its compounding facilities in Florida to California and other states. Among the compounded
24 products prepared by Respondent were two products intended for injection into the human eye
25 (intraocular or intravitreal injection) during or in connection with eye surgery: (1) a dye product
26 called Brilliant Blue G (BBG); and (2) an anti-inflammatory product containing triamcinolone
27 acetone (TMC). Both are dangerous drug (prescription-only) sterile injectable drug products.

28 ///

1 15. After reports prior to and/or in March 2012 of outbreaks of fungal endophthalmitis
2 (inflammation due to fungal infection) in surgical patients to whom BBG or TMC products that
3 were compounded by Respondent had been administered, on or about March 9, 2012, Respondent
4 issued an "Urgent Product Recall" identifying four (4) lots of BBG that were suspected of fungal
5 contamination and seeking to recall all unexpended lots of BBG compounded by Respondent. On
6 or about March 19, 2012, the federal Food and Drug Administration (FDA) posted a confirming
7 "Recall of Unapproved Drug" pertaining to all BBG products compounded by Respondent, that
8 referenced an ongoing multi-agency investigation of fungal endophthalmitis (eye infections) in
9 patients given BBG. This was followed by several further warnings and/or notices by the FDA
10 regarding BBG products compounded by Respondent. On or about March 29, 2012, Respondent
11 issued a second recall notice identifying one lot of TMC suspected of fungal contamination, and
12 seeking recall of that one lot. On or about April 20, 2012, the FDA updated its recall notice(s),
13 warning letter(s) and/or other notice(s) to issue a second warning regarding reports received of
14 eye infections in patients given TMC injections compounded by Respondent.

15 16. A contemporaneous multi-agency investigation involving, among others, the Board,
16 other California state and local agencies, the Florida Board of Pharmacy and/or Department of
17 Health, state or local agencies from other states, and the federal Food and Drug Administration
18 (FDA) and Centers for Disease Control (CDC), confirmed fungal contamination of both BBG and
19 TMC drug products that had been compounded by Respondent in or between in or about August
20 2011 and April 2012. The contaminants confirmed in the BBG drug products compounded by
21 Respondent included the mold *Fusarium incarnatum-equiseti* species complex, as well as other
22 bacterial and fungal species including *Rhodotorula*, *Bullera*, *Pseudomonas*, and *Enterobacter*. In
23 the TMC drug products compounded by Respondent, confirmed contaminants included the mold
24 species *Bipolaris hawaiiensis*. The total number of doses, prescriptions, and/or patients affected
25 is not known, but at least twenty (20) confirmed and probable cases (7 confirmed, 13 probable) of
26 fungal infection resulting from BBG compounded by Respondent, and at least thirteen (13) such
27 cases (11 confirmed, 2 probable) of infection resulting from TMC compounded by Respondent,
28 were identified in seven (7) states. Up to seventeen (17) of these cases were in California.

1 FIRST CAUSE FOR DISCIPLINE

2 (Manufacturing, Compounding and/or Dispensing Adulterated Drug Product(s))

3 17. Respondent is subject to disciplinary action under section(s) 4301(j) and/or (o) of the
4 Code, by reference to Health and Safety Code section(s) 109970, 111255, and/or 111295, and/or
5 21 U.S.C. §§ 331 and/or 351(a), in that, as described above in paragraphs 14 to 16, Respondent
6 manufactured, compounded, and/or dispensed, caused to be manufactured, compounded, and/or
7 dispensed, attempted to manufacture, compound, and/or dispense, assisted or abetted in the
8 manufacture, compounding, and/or dispensing, and/or conspired to manufacture, compound,
9 and/or dispense, in interstate commerce, preparations or drugs that were adulterated.

10 SECOND CAUSE FOR DISCIPLINE

11 (License discipline by another state)

12 18. Respondent is subject to disciplinary action under section 4301(n) of the Code, in that
13 effective May 11, 2010, Respondent's license to act as a pharmacy issued by the State of Florida
14 (License No. PH 19761) was subjected to discipline within that state, as follows:

15 a. On or about July 29, 2009, an Administrative Complaint was filed in Case No.
16 2009-09413 before the State of Florida, Department of Health, against Respondent, that alleged
17 four counts (causes for discipline) against Respondent's license issued by that state, arising out of
18 factual allegations that during 2009 Respondent had: (1) compounded an injectable drug solution
19 for horses (pursuant to a formula based on a drug with the brand name Biodyl, not available in the
20 United States) for a veterinarian; (2) had miscalculated the amount of a component drug (sodium
21 selenite) to be included in the furnished solution, including 100 times the intended amount; (3) by
22 so doing deviated from the prescription; (4) engaged in unlawful wholesale distribution; and (5)
23 mislabeled the prepared solution with the name of the clinic rather than the name of the patient.

24 b. On or about November 16, 2009, a Settlement Agreement was presented to the
25 State of Florida, Department of Health, wherein Respondent agreed to a settlement including: the
26 dismissal of the third count; an administrative fine of \$9,250.00; investigation and prosecution
27 costs of \$6,000.00; a reprimand on Respondent's permit to operate a pharmacy; a probation of 18
28 months on Respondent's permit to operate a pharmacy; and targeted continuing education.

1 c. On or about May 11, 2010, the Settlement Agreement came before the State of
2 Florida, Board of Pharmacy, in Case No. 2009-09413. The Board rejected/amended the terms of
3 the Settlement Agreement to reduce the costs to \$5,137.21 and to delete the probation term, but
4 otherwise adopted the amended agreement, effective May 11, 2010.

5
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:

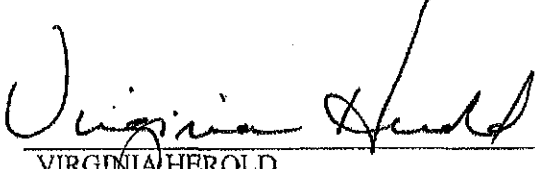
9 1. Revoking or suspending Non-Resident Pharmacy License No. NRP 674, issued to
10 Franck's Lab, Inc. dba Franck's Compounding Pharmacy, Paul W. Franck, President
11 (Respondent);

12 2. Revoking or suspending Non Non-Resident Sterile Compounding License No. NSC
13 99297, issued to Respondent;

14 3. Ordering Respondent to pay the Board the reasonable costs of the investigation and
15 enforcement of this case, pursuant to Business and Professions Code section 125.3;

16 4. Taking such other and further action as is deemed necessary and proper.

17
18 DATED: 9/14/12


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

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