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

In the Matter of the Accusation Against: **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.	Case No. 4308

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

KAMALA D. HARRIS
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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **FRANCK'S COMPOUNDING PHARMACY** **1210 A SW 33 Ave.** **Ocala, Florida 34474** **Non-Resident Pharmacy License No. NRP 674** **Non-Resident Sterile Compounding Pharmacy License No. NSC 99297** Respondent.	Case No. 4308 **STIPULATED SURRENDER OF LICENSE(S) AND ORDER**

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

PARTIES

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

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

3. On or about September 23, 2005, the Board of Pharmacy issued Non-Resident Pharmacy License No. NRP 674 to Franck's Lab, Inc. dba Franck's Compounding Pharmacy (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.

4. On or about November 29, 2005, the Board of Pharmacy issued Non-Resident Sterile 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

5. Accusation No. 4308 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on September 14, 2012. Respondent timely filed a Notice of Defense contesting the Accusation. A copy of Accusation No. 4308 is attached as exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges/allegations in Accusation No. 4308. Respondent also has carefully read, fully discussed with counsel, and understands the effects of, this Stipulated Surrender of License and Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at its own expense; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands that the charges and allegations in Accusation No. 4308, if proven, constitute cause for discipline. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at hearing, Complainant could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges. Respondent hereby surrenders its Non-Resident Pharmacy License No. NRP 674, and its Non-Resident Sterile Compounding License No. NSC 99297, for the Board's formal acceptance. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its licenses without further process.

RESERVATION

10. Admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement.

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

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

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

ORDER

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

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

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

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

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

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

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

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

7. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 4308 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

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

DATED: 10/9/2012

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

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

DATED: 10/10/2012

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

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

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Attorneys for Complainant

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

In the Matter of the Accusation Against: **FRANCK'S COMPOUNDING PHARMACY** **1210 A SW 33 Ave.** **Ocala, Florida 34474** **Non-Resident Pharmacy License No. NRP 674** **Non-Resident Sterile Compounding** **Pharmacy License No. NSC 99297** Respondent.	Case No. 4308 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about September 23, 2005, the Board of Pharmacy issued Non-Resident Pharmacy License No. NRP 674 to Franck's Lab, Inc. dba Franck's Compounding Pharmacy, Paul W. Franck, President (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.

3. On or about November 29, 2005, the Board of Pharmacy issued Non-Resident Sterile 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

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

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

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

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

STATUTORY AND REGULATORY PROVISIONS

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

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

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

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

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

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

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

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

FACTUAL BACKGROUND

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

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

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

FIRST CAUSE FOR DISCIPLINE

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

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

SECOND CAUSE FOR DISCIPLINE

(License discipline by another state)

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

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

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

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

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:

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

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

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

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

DATED: 9/14/12

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

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