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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 **ACCUSATION**

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 infections 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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