

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2012-97
Nonresident Pharmacy License of)	
FRANCK'S COMPOUNDING)	STATEMENT OF CHARGES
PHARMACY)	& NOTICE OF HEARING
License No. 3385,)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent was issued Iowa nonresident pharmacy license #3385. Respondent's license was active until July 25, 2012, when the entity which purchased Respondent's pharmacy applied to the Board for a name change and was assigned the same license number.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on August 27, 2013, before the Iowa Board of Pharmacy. The hearing shall be held during the afternoon session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover State Office Building
Des Moines, Iowa 50319.

Ms. Gavin can also be reached by phone at (515) 281-6736 or at Meghan.Gavin@iowa.gov.

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistant Attorney General Meghan Gavin at (515) 281-6736.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2013).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148C, and 272C (2011) and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

C. CHARGES

COUNT I FAILURE TO COMPLY WITH IOWA PHARMACY RULES AND COMPOUNDING REQUIREMENTS

Respondent is charged with failing to comply with Iowa pharmacy rules and compounding requirements in violation of Iowa Code sections 155A.13A(3) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.3, 19.10, 20.1, 20.3, 20.10, and 36.1(4)(j).

COUNT II FAILURE TO PROVIDE NOTICE OF PHARMACY CLOSING

Respondent is charged with failing to provide notification of the closing of its pharmacy, in violation of Iowa Code sections 155A.13A(3) and 155A.15(2)(c) and 657 Iowa Administrative Code 8.35(7).

D. FACTUAL CIRCUMSTANCES

1. Respondent held Iowa nonresident pharmacy license #3385. Respondent closed for business July 5, 2012. Respondent's license was active until July 25, 2012, when the entity

which purchased Respondent's pharmacy applied to the Board for a name change, and was assigned the same license number.

2. At all times material to the charges, Respondent operated a nonresident pharmacy at 1210 A SW 33rd Ave., Ocala, FL 34474.

3. On May 25, 2012, Respondent issued a user and physician level recall of all the sterile products it compounded between November 21, 2011, and May 21, 2012.

4. This recall was due to:

- a. A report from the Food and Drug Administration (FDA) that microorganisms and fungal growth were present in a sample taken from the pharmacy's sterile compounding lab; and
- b. Information from the Centers for Disease Control and Prevention (CDC) of 33 cases of fungal eye infections linked to the use of ophthalmic dye Brilliant Blue-G and intravitreal Triamcinolone injections compounded by Respondent.

5. Respondent dispensed 25 compounded sterile products to the offices of three physicians and two veterinarians in Iowa between November 21, 2011, and May 21, 2012. Respondent advised the Board that no adverse events were reported by any Iowa customers who received these products. The Board contacted the five Iowa providers and confirmed with three physicians and one veterinarian that no adverse events occurred from the use of these products.

6. Respondent closed for business on July 5, 2012. The entity which purchased Respondent applied to the Board for a name change on July 25, 2012, and was assigned the same license number. Respondent failed to notify the Board that the pharmacy was being sold, as required by 657 IAC 8.35.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this 20th day of June, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2012-97
Nonresident Pharmacy License of)	
FRANCK'S COMPOUNDING)	SETTLEMENT AGREEMENT AND
PHARMACY)	FINAL ORDER
License No. 3385,)	
Respondent.)	

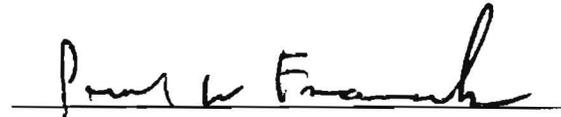
Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy (Board) and Franck's Compounding Pharmacy (Respondent), enter into this Settlement Agreement and Final order to settle the licensee disciplinary proceeding currently pending before the Board.

The allegations contained in the Statement of Charges and Notice of Hearing against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued Nonresident Pharmacy License No. 3385 for the pharmacy located at 1210 SW 33rd Avenue, Ocala, FL 34474.
2. On May 25, 2012, Respondent issued a user and physician level recall of all sterile products it compounded between November 21, 2011, and May 21, 2012.
3. This recall was due to:
 - a. A report from the Food and Drug Administration that microorganisms and fungal growth were present in a sample taken from the pharmacy's sterile compounding lab, and
 - b. Information from the Centers for Disease Control and Prevention that 33 cases of fungal eye infections were linked to the use of Brilliant Blue-G ophthalmic dye and Triamcinolone intravitreal injections compounded by Respondent.
4. On or around July 5, 2012, Respondent ceased doing business.
5. Respondent sent a letter to the Board dated September 20, 2012, indicating it had ceased doing business, had surrendered its Florida license, and had no plans to dispense or distribute prescription drugs in Iowa.
6. The Board filed a Statement of Charges and Notice of Hearing on June 26, 2013, alleging the Respondent violated Iowa pharmacy rules and compounding requirements and failed to provide adequate notification of the closing of its pharmacy.

7. The Board has jurisdiction over the parties and the subject matter of these proceedings.
8. Respondent has chosen not to contest the allegations in the Statement of Charges and Notice of Hearing. The parties agree that these allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
9. Upon the Board's approval of this Settlement Agreement and Final Order, Respondent is hereby CITED for violating Iowa pharmacy rules and compounding requirements and for failing to provide adequate notification of the closing of its pharmacy and WARNED that future violations could lead to further disciplinary action.
10. Respondent agrees to voluntarily surrender its nonresident license, which is treated as a revocation under 657 Iowa Administrative Code rule 36.15.
11. Respondent agrees not to apply for reinstatement of its Iowa nonresident license or for a new Iowa nonresident license for a minimum of ten (10) years.
12. Respondent agrees to pay a civil penalty in the amount of \$250. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within thirty (30) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.
13. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges and Notice of Hearing, and waives any objections to this Final Order.
14. Respondent acknowledges that it had an opportunity to consult with legal counsel regarding this matter prior to signing this Settlement Agreement and Final Order.
15. The State's legal counsel may present this Settlement Agreement and Final Order *ex parte* to the Board.
16. This Settlement Agreement and Final Order is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.
17. The Board's approval of this Settlement Agreement and Final Order shall constitute a FINAL ORDER of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 26th day of July, 2013.



For Respondent

By this signature, Paul Franck acknowledges s/he is the CEO for Franck's Compounding Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Franck's Compounding Pharmacy.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 28th day of August, 2013.



Edward Maier, Chairperson
Iowa Board of Pharmacy
400 SW Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Cathelyn
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

Paul Franck
Trinity Care Solutions
202 SW 17th St.
Ocala, FL 34471