

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NOS. 2013-4075 & 2014-100
Nonresident Pharmacy License of)	
)	NOTICE OF HEARING AND
WEATHERFORD COMPOUNDING)	STATEMENT OF CHARGES
PHARMACY)	
License No. 4075)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Weatherford Compounding Pharmacy ("Respondent"), 2005 Fort Worth Highway #100, Weatherford, Texas 76086, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2015). Respondent's Iowa nonresident pharmacy license number 4075 is currently active and expires on December 31, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on April 28, 2015, before the Board. The hearing shall be held in 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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2015).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I

ADULTERATED DRUGS

Respondent is charged with the introduction or delivery for introduction into commerce of adulterated drugs in violation of Iowa Code sections 126.3 and 155A.23(1)"f", pursuant to Iowa Code section 155A.13A(3) and 657 IAC 36.1(4)"h".

Count II

IMPROPER LABELING

Respondent is charged with failing to have the following information on the label of dispensed compounded sterile preparations: name and quantity of all contents, patient's name, preparer's and reviewing pharmacist's initials or unique identifiers, and stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual, in violation of 657 IAC 13.7(1)"a", "b", "d", and "e", pursuant to Iowa Code section 155A.13A(3) and 657 IAC 36.1(4)"u".

Count III

INCOMPLETE PRODUCTION RECORDS

Respondent is charged with failing to have the following information on the production records of compounded sterile preparations: initials or unique identification of each person involved in each of the compounding steps and the initials or unique identification of each pharmacist verifying each of the compounding steps, in violation of 657 IAC 13.8(1)"c" and "d", pursuant to Iowa Code section 155A.13A(3) and 657 IAC 36.1(4)"u".

Count IV
EXCEEDING APPROPRIATE BEYOND-USE DATES

Respondent is charged with exceeding the appropriate storage period beyond-use date by assigning beyond-use dates exceeding 24 hours for high-risk compounded sterile preparations in the absence of the preparation's passing a sterility test in violation of 13.13(1)"e", pursuant to Iowa Code section 155A.13A(3) and 657 IAC 36.1(4)"u".

Count V
FAILING TO ADHERE TO POLICIES AND PROCEDURES

Respondent is charged with failing to adhere to compounding policies and procedures in violation of 13.6, pursuant to Iowa Code section 155A.13A(3) and 657 IAC 36.1(4)"u".

D. FACTUAL CIRCUMSTANCES

1. In fall of 2013, Respondent shipped herbal compounded preparations containing ginseng and cinnamon to a veterinarian in Iowa to administer to race horses. The preparations were tainted with sildenafil, a banned drug.

2. A review of compounded sterile preparations dispensed by Respondent to the veterinarian in May 2014 revealed the following deficiencies:

a. The labels of compounded sterile preparations did not list the name and quantity of all contents.

b. The labels of compounded sterile preparations did not contain a patient or prescriber name.

c. The labels of compounded sterile preparations did not contain the preparer's and reviewing pharmacist's initials or unique identifiers.

d. The production records of compounded sterile preparations did not contain the initials or unique identification of each person involved in each of the compounding steps.

e. The production records of compounded sterile preparations did not contain the initials or unique identification of each pharmacist verifying each of the compounding steps.

f. The lot numbers on the production records did not match the lot numbers on the labels of compounded sterile preparations.

g. In one instance, the same lot number was assigned to sterile preparations compounded on two different days.

h. The label of one compounded sterile preparation did not contain a lot number.

i. The expiration date on the labels of compounded sterile preparations did not match the beyond-use date or expiration date specified in the production record.

j. The label of one compounded sterile preparation did not contain any expiration date.

k. Respondent assigned beyond-use dates for room temperature high-risk compounded sterile preparations that exceeded 24 hours when the preparations did not undergo sterility testing.

l. Some of the labels of compounded sterile preparations lacked the pharmacy name and the pharmacy address.

3. Respondent's procedure for prescription labels sold directly to veterinarians requires the following to be on the label: the lot number, an expiration date, the pharmacy name, and the pharmacy address.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

On this 10th day of March, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.


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

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

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- | | |
|--|---|
| <input checked="" type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106714610</u> | <input type="checkbox"/> other _____ |

on the 10th day of March, 2015.

I declare that the statements above are true to the best of my information, knowledge and belief.


Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NOS. 2013-4075 & 2014-100
Nonresident Pharmacy License of)	
WEATHERFORD COMPOUNDING)	SETTLEMENT AGREEMENT
PHARMACY)	AND FINAL ORDER
License No. 4075)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Weatherford Compounding Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on March 10, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

9. This Order shall not be binding as to any new complaints received by the Board.
10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.
11. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.
12. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

13. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license effective December 31, 2015, and pay a **CIVIL PENALTY** in the amount of six-thousand dollars (\$6000) no later than November 30, 2015, to resolve this matter.

14. This voluntary surrender has the same force and effect as an order of revocation under 657 IAC 36.15 for purposes of reinstatement. Reinstatement requests are governed by 657 IAC 36.13. Respondent agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

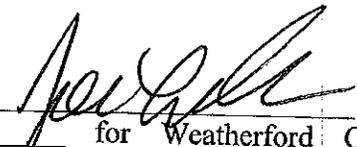
15. The civil penalty and the license should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

16. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

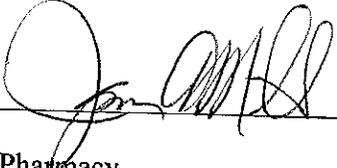
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 21 day of October, 2015.



WEATHERFORD COMPOUNDING
PHARMACY
Respondent

By this signature,  acknowledges s/he is the Agent/owner for Weatherford Compounding Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Weatherford Compounding Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the
4th day of November, 2015.



Chairperson
Iowa Board of Pharmacy

Copies to:

Charles K. Aris
Byrne, Cardenas & Aris, LLP
7557 Rambler Road, Suite 1400
Dallas, TX 75231
ATTORNEY FOR RESPONDENT

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE