

**BEFORE THE IOWA BOARD OF PHARMACY  
OF THE STATE OF IOWA**

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Re: )	
Pharmacy License of )	Case No. 2011-109
<b>STANGEL COMPOUNDING</b> )	
License No. 1163, )	<b>STATEMENT OF CHARGES</b>
Respondent. )	

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**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).
3. On December 6, 2011, the Board renewed Respondent's general pharmacy license number 1163 for Stangel Compounding (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 1163 is current and active until December 31, 2012.
5. Respondent is currently operating a general pharmacy at 903 Iowa Avenue, Onawa, Iowa 51040, with James W. Stangel as the pharmacist in charge.

**A. CHARGES**

**COUNT I – VIOLATION OF PHARMACY COMPOUNDING RULES**

Respondent is charged pursuant to Iowa Code §§ 155A.15(2)(c), 155A.15(2)(h), and 155A.15(2)(i) (2011) and 657 Iowa Administrative Code 13.3(1), 13.6, 13.24, 13.25, 13.28, 13.29, 13.1, 13.33, 20.3(1), 20.3(4), 20.4, 20.8, 20.10, 20.11, 21.5, and 37.3(2) with failure to comply with Board rules for pharmacy compounding.

**COUNT II – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged pursuant to Iowa Code §§ 155A.15(2)(c) (2011) and 657 Iowa Administrative Code 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa.

### COUNT III – FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged pursuant to Iowa Code §§ 155A.15(4)(h) (2011), and 657 Iowa Administrative Code 36.1(4)(ac) with failure to comply with Board rules for pharmacy compounding recordkeeping.

### COUNT IV – FAILURE TO MEET MINIMUM STANDARDS OF PRACTICE

Respondent is charged pursuant to Iowa Code §§ 155A.15(2)(c), 155A.(2)(d) and 155A.15(2)(h) (2011), and 657 Iowa Administrative 6.2, 8.3(1), 8.4(3), 8.7(1), 8.8, 8.11(1), 8.15(1), 8.15(2), 10.21(1), 10.34(1), 10.34(6) and 10.35(3) with failing to meet the minimum standards of pharmacy practice relating to pharmacy operations, pharmacy staffing, recall of drugs, outdated drugs, delivery of drugs, prescription requirements, recordkeeping and inventory requirements.

### COUNT V – VIOLATION OF CONTROLLED SUBSTANCE LAWS

Respondent is charged pursuant to Iowa Code §§ 124.306, 124.308, 124.401, 124.402, 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(h), and 155A.15(2)(i) (2011) and 657 Iowa Administrative Code 36.1(4)(j) with failing to comply with controlled substance laws.

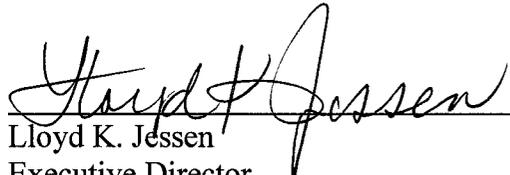
## **B. THE CIRCUMSTANCES**

On October 13, 2011, an investigation commenced which revealed the following:

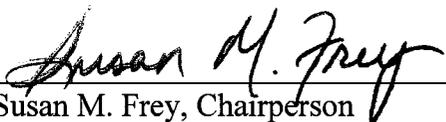
1. At all times material to this statement of charges, Respondent operated a general pharmacy located at 903 Iowa Avenue, Onawa, Iowa.
2. An inspection report dated October 13, 2011 and an investigative report dated November 3, 2011, allege the following:
  - a. Respondent failed to comply with the minimum standards of the operation of a pharmacy when inspected on October 13, 2011.
  - b. Respondent failed to comply with Board rules pertaining to the compounding of high risk sterile products.
  - c. Respondent engaged in the illegal manufacturing of prescription products.
  - d. Respondent failed to comply with Board rules pertaining to the compounding of warfarin capsules.
  - e. Respondent assigned inappropriate expiration dates to several compounded products.
  - f. Respondent compounded methyltestosterone capsules (Schedule III) without proper prescriber authorization.
  - g. Respondent dispensed compounded methyltestosterone capsules to unauthorized recipients.
  - h. Respondent compounded and dispensed methyltestosterone capsules without a proper prescriber/client/pharmacy relationship.
  - i. Respondent failed to maintain proper records for the compounding and dispensing of methyltestosterone capsules.

3. Since November 3, 2011, Respondent has failed to adequately respond to deficiencies reported by Board compliance officers in their report. Respondent has also failed to take necessary corrective action, including recalls of certain compounded products.

**WHEREFORE**, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
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Lloyd K. Jessen  
Executive Director

On this 19<sup>th</sup> day of January 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

  
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Susan M. Frey, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, IA 50319

**BEFORE THE IOWA BOARD OF PHARMACY**

Re:	)	Case No. 2011-109
Pharmacy License of	)	
<b>STANGEL COMPOUNDING,</b>	)	<b>STIPULATED</b>
License No. 1163	)	<b>CITATION AND</b>
Respondent	)	<b>WARNING</b>

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the "Board") and Stangel Compounding (hereinafter, "Respondent") have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on January 19, 2012 shall be resolved without a hearing, as the Board and Respondent stipulate to the following:

1. Respondent's license to operate a general pharmacy in Iowa is evidenced by Pharmacy License Number 1163, which is recorded in the permanent records of the Board.
2. Pharmacy License Number 1163 is current and active until December 31, 2012.
3. The Board has jurisdiction over the parties and the subject matter herein.
4. A Statement of Charges was filed against Respondent on January 19, 2012.
5. Respondent denies the allegations contained in the Statement of Charges, but in the interest of settlement has chosen not to contest the allegations. Respondent acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.
6. Within sixty (60) days after the date of the Board's approval of this Stipulated Citation and Warning, Respondent will submit to the Board

*typewritten*<sup>1</sup> pharmacy policies and procedures for (a) sterile compounding and (b) the secure and appropriate handling and dispensing of controlled substances. Following review and approval by the Board, the Respondent agrees to adopt, implement, and adhere to these policies and procedures.

7. Upon the Board's approval of this Stipulated Citation and Warning, Respondent shall be assessed a civil penalty in the amount of \$2,500. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulated Citation and Warning. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulated Citation and Warning, the Board may initiate further action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

9. This Stipulated Citation and Warning is the resolution of a contested case. By entering into this Stipulated Citation and Warning, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulated Citation and Warning.

10. This proposed settlement 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

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<sup>1</sup> For the purposes of this order, "*typewritten*" policies may be generated on computer word-processing equipment.

effect to either party. If the Board approves this Stipulated Citation and Warning, it shall be the full and final resolution of this matter.

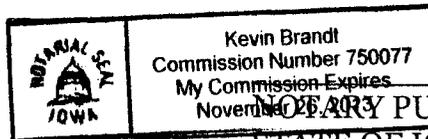
11. The State's counsel may present this Stipulated Citation and Warning to the Board.

12. The Board's approval of this Stipulated Citation and Warning shall constitute a FINAL ORDER of the Board in a disciplinary proceeding.

This Stipulated Citation and Warning is voluntarily submitted by Stangel Compounding to the Iowa Board of Pharmacy for its consideration on this 19<sup>th</sup> day of JUNE 2012.

STANGEL COMPOUNDING  
Respondent  
By James W. Stangel R.Ph.  
Pharmacist In Charge

Subscribed and sworn to before me by James Stangel, who has stated to me that he/she is the pharmacist in charge of Stangel Compounding and is authorized to sign this Stipulated Citation and Warning on behalf of Stangel Compounding on this 19 day of June 2012.



Kevin Brandt  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA

This Stipulated Citation and Warning is accepted by the Iowa Board of Pharmacy on this 26<sup>th</sup> day of June 2012.

Susan M. Frey  
SUSAN M. FREY, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688