

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

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Re:

Pharmacy License of

**NUCARA PHARMACY #3**

License No. 882

Respondent

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)  
)  
)

Case No. 2002-882

**STATEMENT OF CHARGES**

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners 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 (2001).
3. Effective February 28, 2002, the Board renewed the Respondent, NuCara Pharmacy #3's license to operate a pharmacy in the State of Iowa subject to the laws of the State of Iowa and the rules of the Board and with Fred Berneking as the pharmacist in charge. Prior to February 23, 2002, Michael Laubach served as the pharmacist in charge.
4. License number 882 is current and active until December 31, 2002.
5. The Respondent operates a pharmacy at 209 East San Marnan, Waterloo, Iowa 50702.

**COUNT I**

The Respondent is charged under Iowa Code § 155A.15 (2001) and 657 Iowa Administrative Code §§ 36.1(4)(i) with intentional or repeated violation of Board rules, including but not limited to rules 6.7 (outdated drugs), 6.8 (DEA form 222 documentation), 8.12 (policies and procedures for shipping and/or delivering prescription drugs), 22.16 (documentation of technician training), 8.32 (expiration dating on emergency containers), 20.11 & 20.12 (compounding records and check by pharmacist), 8.30(1) (reference library), 8.30(4) (policies and procedures for sterile products).

## COUNT II

The Respondent is charged under Iowa Code § 155A.15 (2001) and 657 Iowa Administrative Code §§ 36.1(4)(i) with failing to maintain adequate compounding records as required by 657 Iowa Administrative Code §§ 20.11 & 20.12.

### THE CIRCUMSTANCES

1. While investigating a complaint received about the Respondent, a Board investigator conducted a routine inspection of the Respondent's pharmacy.
2. The inspection revealed numerous violations of the Board's rules including the following:
  - a. IAC 657-6.7 – There were outdated drugs in the compounding area.
  - b. IAC 657-6.8 - Several DEA 222 forms in the files of this pharmacy did not have all of the required documentation concerning date received, quantity received and/or initials of responsible individual.
  - c. IAC 657-8.12 – The pharmacy did not have policies and procedures for shipping and/or delivering medications.
  - d. IAC 657-22.16 – The pharmacy's policies and procedures for the technicians were generic and had not been personalized for this location. Two technicians worked in the compounding area and were primarily responsible for the compounding. One was a certified technician, but the training for the second technician had not been documented.
  - e. IAC 657-8.32 -- The pharmacy provides an emergency container for a local hospice unit. The label on the exterior of the container lacked an expiration date of the supply contained inside the container based upon the earliest expiration date of any drug contained in the supply
  - f. IAC 657-20.11 and 12 - These regulations require that a pharmacist check each stage of a compounding process when the work is done by a technician, and to record the check of each stage. Records in this pharmacy contained the initials of the pharmacist only as to the final check.
  - g. IAC 657-8.30 – The pharmacy did not have a current copy of *American*

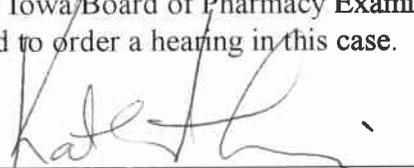
*Hospital Formulary* for use in sterile products preparation.

- h. IAC 657-8.30 – The pharmacy did not have policies and procedures for sterile 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.

  
Lloyd K. Jessen  
Executive Secretary/Director

On this 18 day of June, 2002, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.

  
Katherine A "KAP" Linder, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Shauna Russell Shields  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

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

---

Re:	)	Case No. 2002-882
Pharmacy License of	)	
<b>NUCARA PHARMACY #3</b>	)	<b>STIPULATION</b>
License No. 882	)	<b>AND</b>
Respondent	)	<b>CONSENT ORDER</b>

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COME NOW the Iowa Board of Pharmacy Examiners (“the Board”) and NuCara Pharmacy #3 (“Respondent”) and, pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2001), enter into the following Stipulation and Consent Order settling the contested case currently on file.

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Statement of Charges filed against Respondent on June 18, 2002, shall be resolved without proceeding to hearing, as the parties have agreed to the following Stipulation and Consent Order:

1. That the Respondent’s license to operate a pharmacy was renewed effective February 28, 2002, as evidenced by Pharmacist I license Number 882, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That General Pharmacy License Number 882 issued to and currently held by Respondent is current and in force until December 31, 2002.
3. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on June 18, 2002.
5. This Stipulation and Consent Order is entered into in order to resolve disputed claims and constitutes no admission on the part of the Respondent.
6. Respondent shall pay a civil penalty of \$1,000.00 within 30 days of the date of approval of this Stipulation and Consent Order by the Board. Respondent shall deliver a check made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The check shall be deposited into the general fund of the State of Iowa.
7. Respondent agrees to accept a citation and warning for the alleged violation set forth in the Statement of Charges.
8. Within sixty (60) days of the date of approval of this Stipulation and Consent Order by the Board, the Respondent will provide its *typewritten* policies and procedures for the following:
  - A. Removing outdated drugs from the compounding area;
  - B. Controlled substance record keeping;
  - C. Shipping and delivering medications;
  - D. Training and supervising pharmacy technicians;
  - E. Providing emergency containers for hospice units;
  - F. Pharmacist verification and check of each stage of the compounding process when the work is done by a technician;
  - G. Recording pharmacist verification and check of each stage of the compounding process when the work is done by a technician;

- H. Maintaining a current and up-to-date reference library;
  - I. Use and preparation of sterile products.
9. The typewritten policies and procedures required in paragraph 7, above, shall relate to Respondent's operation of a pharmacy. Following review and approval by the Board, the Respondent agrees to adopt, implement, and adhere to these policies and procedures whenever operating a pharmacy.
  10. Respondent shall fully and promptly comply with all Orders of the Board and the statutes and rules regulating the practice of pharmacy in Iowa. Any violation of the terms of this Order is grounds for further disciplinary action, upon notice and opportunity for hearing, for failure to comply with an Order of the Board, in accordance with Iowa Code § 272C.3(2)(a).
  11. The Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of pharmacy.
  12. Should the Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend the Respondent's Iowa license to operate a pharmacy or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code § 36.1.
  13. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, the Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

14. 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 effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.
15. The Board's approval of this Stipulation and Consent Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

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16. This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 23<sup>rd</sup> day of July, 2002

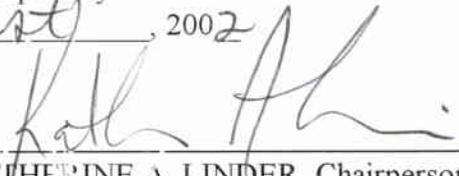
Frederick M. Berneking  
NuCara Pharmacy #3  
Fred Berneking, R.Ph.  
Pharmacist in charge,  
Respondent

Subscribed and sworn to before me by Fred Berneking, who has stated to me that he/she is the pharmacist in charge of NuCara Pharmacy #3 and that he/she is authorized to sign this Stipulation and Consent Order on behalf of said NuCara Pharmacy #3 on this 23 day of July, 2002

Kurt A. Eichelberger  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA



17. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 6<sup>th</sup> day of August, 2002



KATHERINE A. LINDER, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Shauna Russell Shields  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

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

Re:	)	Case No. 2005-96
Pharmacy License of	)	
<b>NU-CARA PHARMACY #3</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 882,	)	
Respondent	)	

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 147, 155A and 272C (2005).
3. Effective May 31, 2005, the Board renewed Respondent's general pharmacy license number 882 with Rex McKee as pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa the rules of the Board.
4. General pharmacy license number 882 is current and active until December 31, 2005.
5. Respondent is currently operating a general pharmacy at 209 East San Marnan, Waterloo, Iowa 50702, with Rex McKee as the pharmacist in charge.

**A. CHARGES**

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

The Respondent is charged with failure to comply with Board rules for pharmacy compounding in violation of Iowa Code §§ 155A.12(1) (2005), 155A.12(4) (2005), and 657 Iowa Administrative Code §§ 8.30, 20.4(2), 20.5, 20.6(1), 20.8, 20.9, 20.10, 20.11, 20.12, 36.1(4)(j), and 36.1(4)(cc).

## COUNT II – LACK OF PROFESSIONAL COMPETENCY BY PHARMACISTS

The Respondent is charged with a lack of professional competency in violation of Iowa Code § 155A.15(2)(c) (2005) and 155A.15(2)(h) (2005) and 657 Iowa Administrative Code § 36.1(4)(b).

## COUNT III – CONTROLLED SUBSTANCE VIOLATION

The Respondent is charged with the destruction of outdated compounded products containing C-III, C-IV and C-V controlled substances in violation of 657 Iowa Administrative Code § 10.18(1).

### B. CIRCUMSTANCES

On or about June 8, 2005 an inspection and investigation was commenced by the Board, revealing the following:

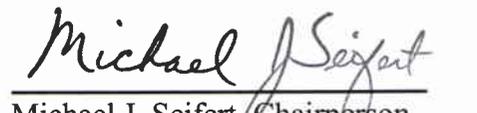
1. Since approximately December 2000, Respondent has compounded inhalation/nebulizer medications for dispensing to patients, pursuant to prescriptions.
2. The inhalation/nebulizer medications which have been compounded by Respondent are products consisting primarily of four active ingredients—albuterol, ipratropium, triamcinolone, and morphine—in various combinations.
3. FDA regulations require that inhalation solutions be sterile (21 CFR § 200.51).
4. Preparation of the albuterol—ipratropium—triamcinolone—morphine combination products by Respondent began with non-sterile ingredients. These products were dispensed in non-sterile containers or vials until approximately July 1, 2005. The products were either not filtered or were inadequately filtered. The final products were not sterilized before they were dispensed to customers. No final products were subjected to proper post-preparation testing for sterility, potency, and pyrogenicity.
5. Respondent did not have a procedure for ensuring that nebulizer vials contained the proper amount of product.
6. Respondent did not have a recall procedure for compounded products.
7. Respondent did not have an acceptable quality assurance program for compounded products.
8. Respondent did not comply with the Board's administrative rules relating to sterile product compounding.

9. Due to lack of sterility, the inhalation/nebulizer medications prepared by Respondent were susceptible to microbial growth and contamination. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that it has placed patients who have received these products at risk for injury or disease.
10. Respondent has dispensed a nebulizer solution of albuterol, ipratropium, and triamcinolone which contained subpotent levels of triamcinolone.
11. Respondent has destroyed outdated compounded products containing C-III, C-IV, and C-V controlled substances without proper authority from either the Board or the U.S. Drug Enforcement Administration (DEA).

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 Secretary/Director

On this 13<sup>th</sup> day of October 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.

  
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Michael J. Seifert, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

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

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

Re:	)	
Pharmacy License of	)	Case No. 2005-96
<b>NU-CARA PHARMACY # 3</b>	)	
License No. 882	)	<b>EMERGENCY ORDER</b>
Respondent	)	

**I. JURISDICTION**

The Iowa Board of Pharmacy Examiners (hereinafter, "Board") has jurisdiction over pharmacy licensees pursuant to Iowa Code Chapters 147, 155A and 272C (2003). Respondent Nu-Cara Pharmacy #3, possesses pharmacy license number 882 issued by the Board. A Statement of Charges was filed against Respondent on October 13, 2005. After receipt and review of the Statement of Charges, and careful review of evidence relating to the Statement of Charges, the Board has adopted the following Findings of Fact and Conclusions of Law and Emergency Order.

**II. FINDINGS OF FACT**

1. On May 31, 2005, the Board renewed general pharmacy license number 882, with Rex N. McKee as pharmacist in charge, subject to the laws of the State of Iowa and the rules of the Board.
2. On June 8, 2005, the board commenced an inspection and investigation of Respondent which revealed the following facts, which the Board hereby finds:
  - a) Since approximately December 2000, Respondent has compounded inhalation/nebulizer medications for dispensing to patients, pursuant to prescriptions.

- b) The inhalation/nebulizer medications which have been compounded by Respondent are products consisting primarily of four active ingredients—albuterol, ipratropium, triamcinolone, and morphine—in various combinations.
  - c) FDA regulations require that inhalation solutions be sterile (21 CFR § 200.51).
  - d) Preparation of the albuterol—ipratropium—triamcinolone—morphine combination products by Respondent began with non-sterile ingredients. These products were dispensed in non-sterile containers or vials until approximately July 1, 2005. The products were either not filtered or were inadequately filtered. The final products were not sterilized before they were dispensed to customers. No final products were subjected to proper post-preparation testing for sterility, potency, and pyrogenicity.
  - e) Respondent did not have a procedure for ensuring that nebulizer vials contained the proper amount of product.
  - f) Respondent did not have a recall procedure for compounded products.
  - g) Respondent did not have an acceptable quality assurance program for compounded products.
  - h) Respondent did not comply with the Board's administrative rules relating to sterile product compounding.
  - i) Due to lack of sterility, the inhalation/nebulizer medications prepared by Respondent were susceptible to microbial growth and contamination. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that it has placed patients who have received these products at risk for injury or disease.
  - j) Respondent has dispensed a nebulizer solution of albuterol, ipratropium, and triamcinolone which contained subpotent levels of triamcinolone.
  - k) Respondent has destroyed outdated compounded products containing C-III, C-IV, and C-V controlled substances without proper authority from either the Board or the U.S. Drug Enforcement Administration (DEA).
3. The Board finds that the evidence assembled during the investigation of Respondent supports the October 13, 2005, Statement of Charges against Respondent. The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 155A and

Chapter 657 of the Iowa Administrative Code in the manner alleged in the Statement of Charges.

4. The Board finds that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:
  - a. Respondent has engaged in the practice of pharmacy compounding in a manner that renders the compounded products dangerous for human use.
  - b. Respondent has prepared and dispensed non-sterile inhalation/nebulizer medications for human use.
5. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to engage in past pharmacy compounding practices, the public health, safety and welfare will be threatened. The public health, safety and welfare would be at risk due to the possibility that compounded products prepared by Respondent which should be sterile when dispensed but are not sterile when dispensed, may be contaminated or may become contaminated with life-threatening pathogens.
6. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:
  - a. Immediate restriction of Respondent's pharmacy license, prohibiting Respondent from further dispensing of compounded products that require sterility but are not sterile.
  - b. Respondent's license shall remain restricted until satisfactory evidence of Respondent's ability to prepare sterile compounded products and validate product sterility has been demonstrated to the Board.

### **III. CONCLUSIONS OF LAW**

1. Respondent's incompetency, as reflected by its failure to comply with rules for pharmacy compounding in Iowa, has rendered it unable to ensure product integrity and patient safety.

2. The provisions of Iowa Code § 17A.18A (2005) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

#### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

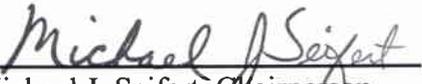
1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2005) and 657 Iowa Administrative Code § 35, the pharmacy license of Respondent is hereby restricted to prohibit the preparation and distribution of compounded products that require sterility but are not sterile. This restriction is effective immediately upon Respondent's receipt of this Order.
2. Respondent shall issue a recall for all compounded inhalation/nebulizer products and other products that should have been sterile but were not prepared in a manner assuring sterility prior to dispensing. The recall shall include all compounded inhalation/nebulizer products and other products that may still be in the possession of patients and may potentially be contaminated, including the albuterol, ipratropium, triamcinolone, and morphine combination products which were either not adequately filtered to ensure sterilization or, if dispensed in non-sterile vials, were not autoclaved to ensure sterilization. The recall shall include written notification to all practitioners who prescribed the products and to all patients who have received such products and may still have them in their possession. The notification shall include the reason for the recall, and

shall reference the fact that the recall is being made pursuant to an order of the Board.

Respondent shall implement this recall within 96 hours of receipt of this Order and shall report to the Board in writing the names and addresses of all patients and all practitioners who have received the recall notice. This report to the Board shall also be made within 96 hours of receipt of this Order.

3. Respondent shall surrender to the Board, upon receipt of this Order, all albuterol, ipratropium, triamcinolone, and morphine combination products in stock, as well as any other compounded products which have been prepared in bulk and have not been validated by appropriate testing as being sterile.
4. Respondent shall be notified of this order as provided in 657 Iowa Administrative Code 35.30(2).
5. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on November 16, 2005. The hearing will commence at 9:00 a.m. and be held at the office of the Iowa Board of Pharmacy Examiners, 400 SW 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309.

**DATED** this 13<sup>th</sup> day of October 2005.

  
\_\_\_\_\_  
Michael J. Seifert, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

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

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

---

Re:  
Pharmacy License of  
**NU-CARA PHARMACY #3**  
License No. 882  
Respondent

Case No. 2005-96

**STIPULATION AND CONSENT ORDER**

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Pursuant to Iowa Code §§ 17A.10, 272C.3(2)(f) (2005) and 657 I.A.C. 36.1(2)(k), the Iowa Board of Pharmacy Examiners (hereinafter, "the Board") and Nu-Cara Pharmacy #3 (hereinafter, "Respondent"), enter into the following Stipulation and Consent Order, settling a licensee disciplinary proceeding currently pending before the Iowa Board of Pharmacy Examiners.

Allegations specified in a Statement of Charges filed against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent's license to operate a pharmacy in Iowa was renewed on January 1, 2007, as evidenced by Pharmacy License Number 882, which is recorded in the permanent records of the Board.
2. The general Iowa Pharmacy License issued to and held by Respondent is active and current until December 31, 2007.
3. A Statement of Charges was filed against Respondent on November 16, 2005.
4. Respondent is currently operating a general pharmacy at 209 East San Marnan, Waterloo, Iowa 50702, with Rex McKee as the pharmacist in charge.
5. The Board has jurisdiction over the parties and jurisdiction over the subject matter of these proceedings.

6. For the purposes of this Stipulation and Consent Order only and without admitting the validity thereof, Respondent does not contest the allegations set forth in the Statement of Charges. Pursuant to 657 I.A.C. § 36.1(2)(k), the parties agree that the Stipulations and Agreements set forth in this Consent Order address and resolve the allegations.

7. As a part of this Stipulation and Consent Order, Respondent agrees that, within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order, it will submit to the Board, in *typewritten*<sup>1</sup> form, its pharmacy policies and procedures regarding (a) compounding of sterile medications, (b) recall of defective products, and (c) destruction of outdated products. Following review and approval by the Board, the Respondent agrees to adhere to these policies and procedures.

8. Should Respondent violate or fail to comply with the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to operate a pharmacy or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code § 36.1.

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

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 effect to either the Board or

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

Respondent. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

11. The Board's approval of this Stipulation and Consent Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 23 day of FEBRUARY 2007.

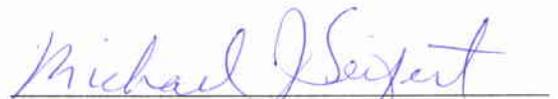
  
Nu-Cara Pharmacy #3  
Pharmacist in Charge  
Respondent

Subscribed and sworn to before me by REX MCKEE, Pharmacist in Charge for Nu-Cara Pharmacy #3, on this 23 day of FEBRUARY 2006.



  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 13 day of March 2007.

  
\_\_\_\_\_, Chairperson  
Iowa Board of Pharmacy Examiners  
400 S.W. Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

Copy to:

Scott M. Galenbeck  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
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