

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

Re:)	Case No. 2005-32
Pharmacy License of)	
CLARION COMPOUNDING)	STATEMENT OF CHARGES
PHARMACY INC)	
License No. 1256,)	
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 December 23, 2004, the Board renewed Respondent's general pharmacy license number 1256 with Cory L. Cockburn 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 1256 is current and active until December 31, 2005.
5. Respondent is currently operating a general pharmacy at 212 N. Main Street, Clarion, Iowa 50525, with Cory L. Cockburn 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

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).

B. CIRCUMSTANCES

On or about April 4, 2005 an investigation was commenced, revealing the following:

1. Respondent is compounding inhalation/nebulizer medications for dispensing to patients, pursuant to prescriptions. Respondent is also compounding special strengths or dosages of other medications.
2. One of the inhalation medications compounded by Respondent is a product consisting of two active ingredients, formoterol and budesonide. This combination product is not approved for use by the FDA in the U.S. Although the product is the subject of Phase III clinical trials in the U.S. and has been approved for use in Europe, it is not commercially available in the U.S. at this time.
3. FDA regulations require that inhalation solutions be sterile (21 CFR § 200.51).
4. Preparation of the formoterol and budesonide combination product by Respondent begins with non-sterile ingredients that are mixed in an area that is not aseptic. The final product is not sterilized before it is dispensed to customers.
5. Respondent does not comply with administrative rules relating to sterile product compounding. Among other things, Respondent does not:
 - a. Maintain complete and proper compounding records and documentation.
 - b. Utilize proper aseptic technique.
 - c. Assign lot numbers.
 - d. Affix complete and accurate labeling.
 - e. Follow duly established policies and procedures.
 - f. Conduct adequate testing of products.
 - g. Utilize appropriate recall procedures.
6. As a compounding pharmacy, Respondent does not comply with FDA good manufacturing practices.

7. Due to lack of sterility, inhalation/nebulizer medications prepared by Respondent may be contaminated with life-threatening pathogens. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who have received these products at high risk for injury or disease.

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 26th day of April 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.



Michael J. Seifert, Chairperson
Iowa Board of Pharmacy Examiners
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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. 2005-32
CLARION COMPOUNDING)	
PHARMACY INC.)	EMERGENCY ORDER
License No. 1256,)	
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 Clarion Compounding Pharmacy Inc. possesses pharmacy license number 1256 issued by the Board. A Statement of Charges was filed against Respondent on April 26, 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 December 23, 2004, the Board renewed general pharmacy license number 1256, subject to the laws of the State of Iowa and the rules of the Board.
2. On April 4, 2005, the board commenced an investigation of Respondent which revealed the following facts, which the Board hereby finds:

On or about April 4, 2005 an investigation was commenced, revealing the following:

- a. Respondent is compounding inhalation/nebulizer medications for dispensing to customers, pursuant to prescriptions. Respondent is also compounding special strengths or dosages of other medications.

- b. One of the inhalation/nebulizer medications compounded by Respondent is a product consisting of two active ingredients, formoterol and budesonide. This combination product is not approved for use by the FDA in the U.S. Although the product is the subject of Phase III clinical trials in the U.S. and has been approved for use in Europe, it is not commercially available in the U.S. at this time.
- c. FDA regulations require that inhalation solutions be sterile (21 CFR § 200.51).
- d. Preparation of the formoterol and budesonide combination product by Respondent begins with non-sterile ingredients that are mixed in an area that is not aseptic. The final product is not sterilized before it is dispensed to customers.
- e. Respondent does not comply with administrative rules relating to sterile product compounding. Among other things, Respondent does not:
 - (1) Maintain complete and proper compounding records and documentation.
 - (2) Utilize proper aseptic technique.
 - (3) Assign lot numbers.
 - (4) Affix complete and accurate labeling.
 - (5) Follow duly established policies and procedures.
 - (6) Conduct adequate testing of products.
 - (7) Utilize appropriate recall procedures.
- f. Respondent has failed to comply with Iowa law and Board regulations. Specifically, the following areas of non-compliance were observed by Board compliance officers on or about April 4-5, 2005:
 - (1) The compounding of commercially-available products, such as Neurontin®, in the absence of appropriate documentation from the prescriber that the compounded product is in the best interest of the patient.
 - (2) Lack of documentation of appropriate training of personnel who engage in general compounding and sterile compounding.
 - (3) Lack of a sink in the compounding area.
 - (4) Lack of policies and procedures for cleaning compounding areas.
 - (5) Missing ceiling tiles over the compounding area which resulted in ceiling insulation being exposed.
 - (6) Lack of calibration records for the automated inhalation unit-dose filling machine.
 - (7) Failure of compounding records to indicate all equipment required, or safety equipment for pharmacy personnel.
 - (8) Failure of compounding records to indicate mixing order or procedures.

- (9) Failure to document that all components and bulk drug substances are accurately weighed, measured, or subdivided as appropriate. There is no record of verification of weights with each step in the mixing process.
- (10) Lack of proper documentation of compounding work performed by pharmacy technicians.
- (11) Lack of proper documentation by the pharmacist for some production records.
- (12) Lack of written procedures for product testing.
- (13) Lack of adequate product testing and documentation of testing.
- (14) Lack of appropriate sterilization procedures to prevent microbiological contamination of compound drug products purported to be sterile.
- (15) Lack of adequate labeling on compounded products. Some labels do not provide the quantity or percentages of each active ingredient.
- (16) Lack of appropriate testing to determine if expiration dating assigned to compounded sterile inhalation products is valid.
- (17) Failure of the master formula record to contain a copy of the label.
- (18) Failure of the master formula record to contain detailed compounding instructions, procedures, and specifications.
- (19) Failure of the production record to contain valid lot numbers.
- (20) Lack of quantities on labels of bulk containers of inhalation products and compounded capsules.
- (21) Lack of written policies and procedures and documented on-the-job training for personnel engaging in sterile compounding.
- (22) Lack of a policy for the testing of the clean room for organisms or documentation of changing filters.
- (23) Failure to follow the master formula for formoterol/budesonide inhalation products which indicates that the compounding pharmacy should check with the state board of pharmacy to ensure compliance with state compounding regulations.
- (24) Failure of batch products to list quantity of contents.
- (25) Lack of an auxiliary label on budesonide products indicating that the products should be protected from light.
- (26) Failure to list volume on labels placed on unit dose containers.
- (27) Failure to list an expiration date on unit dose containers.
- (28) Failure to include a code on unit dose containers which would identify the date of preparation and the pharmacist's initials.
- (29) Lack of accurate lot numbers on compounding worksheets.
- (30) Failure to conduct additional testing for pyrogens when using non-sterile chemicals to prepare sterile inhalation products.
- (31) Failure to develop and document quality assurance audits.
- (32) Failure to follow appropriate testing procedures for slow growing fungal contaminants.
- (33) Failure to log aseptic technique test results.

- (34) Failure to revalidate aseptic technique tests every three months.
- (35) The use of outdated drugs and components in compounding.
- (36) Failure to maintain drug invoices on the premises for inspection purposes.
- (37) Failure of pharmacist and technicians to wear identification badges.
- (38) Failure to assign a prescription number to prescriptions for compounded products.
- (39) Lack of proper documentation to determine which products' lot numbers were used to compound prescriptions
- (40) Lack of proper documentation for prescriptions transferred between Clarion Pharmacy and Clarion Compounding Pharmacy.
- (41) Lack of written policies and procedures for the training and utilization of pharmacy technicians.
- (42) Lack of documentation of training for pharmacy technicians.
- (43) Lack of written policies and procedures for the delivery of prescription drugs to patients to ensure accountability, safe delivery, and compliance with temperature requirements.
- (44) Lack of filling information and pharmacist verification on compounded prescriptions.

- g. As a compounding pharmacy, Respondent does not comply with FDA good manufacturing practices.
- h. Due to lack of sterility and the failure to comply with the minimum standards for pharmacy compounding, inhalation/nebulizer medications prepared by Respondent may be contaminated with dangerous or even life-threatening pathogens.
- i. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who have received these products at high risk for injury, disease, or death.

- 3. The Board finds that the evidence assembled during the investigation of Respondent supports the April 26, 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 is engaging in the practice of pharmacy compounding in a manner that renders the compounded products dangerous for human use.
 - b. Respondent is preparing and dispensing an inhalation/nebulizer medication that is not currently approved by the FDA for use in the U.S.
 - c. Respondent is preparing and dispensing non-sterile inhalation/nebulizer medications.
5. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to engage in the practice of pharmacy compounding, 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, especially products purporting to be sterile products, may be 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 engaging in the practice of pharmacy compounding.
 - b. Respondent's license shall remain restricted until satisfactory evidence of Respondent's ability to resume the unrestricted practice of pharmacy has been provided 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 (2003) 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.

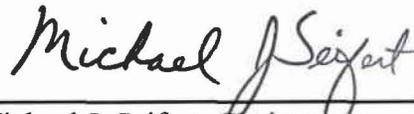
IV. EMERGENCY ORDER

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2003) and 657 Iowa Administrative Code § 35, the pharmacy license of Respondent is hereby restricted to prohibit the preparation and distribution of any and all compounded products. 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 purport to be sterile but were not prepared in a manner assuring sterilization prior to dispensing. The recall shall include all compounded inhalation/nebulizer products and other products that may potentially be contaminated, including the budesonide/formoterol combination product and the albuterol/ipratropium/budesonide combination product which could not be filtered for sterilization. The recall shall include written notification to all patients who have received such products and to all practitioners who prescribed the products. 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 72 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 72 hours of receipt of this Order.

3. Respondent shall surrender to the Board, upon receipt of this Order, all budesonide and budesonide/formoterol combination products in stock, as well as any other products which have been prepared in bulk which have no guarantee of sterility.
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 June 7, 2005. The hearing will commence at 1:00 P.M. and be held at the office of the Iowa Board of Pharmacy Examiners, 400 Southwest 8th Street, Suite E, Des Moines, Iowa 50309.

DATED this 26th day of April 2005.



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