

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

Re:)	Case No. 2005-32
Pharmacy License of)	
NATION-MED PHARMACY INC.)	STATEMENT OF CHARGES
License No. 1255,)	
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 1255 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 1255 is current and active until December 31, 2005.
5. Respondent is currently operating a general pharmacy at 210 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).

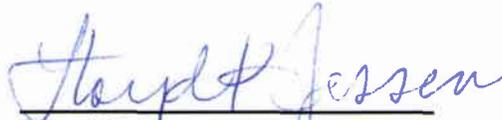
B. CIRCUMSTANCES

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.

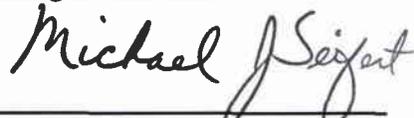
7. Due to lack of sterility, inhalation/nebulizer medications prepared by Respondent may be contaminated with life-threatening pathogens. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who 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
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cc: Scott M. Galenbeck
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