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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue  
New Orleans, LA 70122-3896 D1315B  
Telephone (504) 589-7166  
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January 28, 1998

**WARNING LETTER NO. 98-NOL-16**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Bruce Rohde, CEO, President  
ConAgra Corporation  
1 ConAgra Drive  
Omaha, Nebraska 68102-5005

Dear Mr. Rohde:

An inspection of your medicated feed mill, located at ConAgra Frozen Foods Feed Mill, 220 McDonald Road, Many, Louisiana 71449, conducted by a Food and Drug Administration investigator, on January 6-8, 12, 1998, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title, Code of Federal Regulations, Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found failure to validate the automated feed mill batch control mixing system; failure to flush or otherwise clean mixing equipment, following the batch production of Category II medicated feed, immediately prior to the production of finishing feeds; failure to have written manufacturing instructions for the specified formula of each Category II medicated feed, including mixing steps and mixing times; failure to document batch production records have been reviewed by a responsible individual; failure to indicate a lot or control number, date of manufacture or other suitable identification on the distribution records for Category II medicated feeds; failure to document visual examination of incoming shipments of Category II drugs for damage; and failure to follow the drug receiving procedure, the medicated feed distribution procedure and the flushing procedure.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but

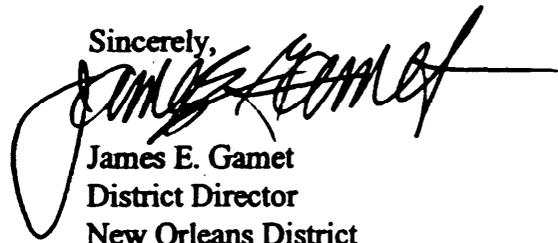
are not limited to, seizure and/or injunction. This letter constitutes official notice of CGMP violations as required under Section 512 (m)(4)(B)(ii) of the Federal Food Drug and Cosmetic Act. Based on the result of the January 6-8, 12, 1998 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

You should notify this office in writing, within thirty (30) working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within thirty (30) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Carolyn W. White, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA-483

cc: Mr. J. Thomas Culotta, General Manager  
ConAgra Frozen Foods Feed Mill  
Hwy 1 Bypass South  
P.O. Box 1008  
Natchitoches, Louisiana 71458-1008

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