



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91289d

Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER CIN-WL-01-7667**

May 24, 2001

Thomas Bostic  
General Manager  
Central Ohio Farmers Cooperative, Inc.  
1477 State Route 294  
Marion, OH 43302

Dear Mr. Bostic:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on April 5 and 27, 2001. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found your firm fails to label feeds which contain, or may contain, prohibited materials with the required cautionary statement "**Do not feed to Cattle or Other Ruminants**". We suggest this statement be distinguished by different type size or color or other means of highlighting the statement so it is easily noticed by the purchaser.

Our investigator was verbally told that you have separate processing equipment for products containing prohibited materials, but the equipment is not identified and there are no written procedures to address separation of the products which contain, or may contain, prohibited material. It is risky to assume your employees will know what to do in the future just because you have always done it that way in the past.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

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You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of 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 violations, and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed.

Your reply should be directed to Deborah Grelle, Director of Compliance, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (513) 679-2700 extension 160.

Sincerely yours,

  
Henry L. Fielden  
District Director

Enclosure: Small Entity Compliance Guide

Cc: David Schleich, Chief Plant Industry Division  
Ohio Department of Agriculture  
8995 East Main Street  
Reynoldsburg, OH 43068-3399

Charles H. Grau  
Branch Manager  
Central Ohio Farmers Cooperative, Inc.  
1477 State Route 294  
Marion, OH 43302