



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER

WL-CIN-9099-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 16, 2001

Charles A. Holdren, CEO/President
Agri-Mark Farmers Co-op, Inc.
813 Clark Avenue
Ashland, OH 44805

Dear Mr. Holdren:

On 7/10,12-13/2001 two Food and Drug Administration investigators conducted an inspection of your medicated feed mill located at 6800 Chestnut Street, Sterling, OH. The inspection revealed 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).

Our inspection found your firm failed to label feeds that 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.

It also revealed that your customer records are not sufficient to track the distribution of products that contain, or may contain, prohibited material

The deviations from the BSE regulations, as noted above, 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 Act.

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

Our investigators also found that you mixed and distributed a cattle feed containing Lincomycin, a drug not indicated for use in cattle. Further, you did not flush the mixer, storage bins, and bulk truck used in the manufacture of the feed containing Lincomycin. The failure to adequately flush this equipment immediately following this feed caused the subsequent cross-contamination of the cattle feed, dairy cow feed and calf feeds that were handled in this equipment after the original product. You should implement procedures and/or practices to prevent the recurrence of this type of violation.

You should notify this office in writing within fifteen (15) 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 15 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 Stephen J. Rabe, Compliance Officer at the address listed above.

Sincerely,



Henry L. Felden
District Director
Cincinnati District

Attachment: Small Entity Compliance Guide

Cc: Scott A. Crossen, Branch Manager
Agri-Mark Farmers Co-op, Inc.
6800 Chestnut Street
Sterling, OH 44276