



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91282d

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-01-7705

May 22, 2001

Karl T. Kule
Co-Owner
Valley Feed Mill, Inc
18 West Main Street
Orwell, OH 44076

Dear Mr. Kule:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on April 11 and 13, 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 investigation found your procedures to prevent cross contamination are inadequate in that:

- There are no written procedures for cleaning out or flushing equipment after mixing feeds containing prohibited material.

You should establish adequate procedures and verify that the flush/clean-out method you use cleans out the remainder of preceding batches containing prohibited materials. If you flush with feed ingredients, or sequence with non-ruminant feed, you must label these products with the required cautionary statement "Do not feed to Cattle or Other Ruminants". (Your April 23, 2001 letter states you will use 500 pounds of shelled corn to flush and the flushed material will be labeled: "Shelled Corn for Use in Poultry Feed Only". It is acceptable to use the flush for poultry feed, but the label should also include the cautionary statement.)

- There are no processing records or records documenting that the system was cleaned or flushed in accordance with your approved procedures.

Customer records are not adequate to track products that contain, or may contain, prohibited material.

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 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. Include copies of any available documentation demonstrating that corrections have been made. 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

