



Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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PURGED

April 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mat Geib
Owner
Greeley Elevator Company
700 6th Street
Greeley, Colorado 80631

Ref. #: DEN-01-26

Dear Mr. Geib:

An inspection of your animal feed manufacturing operation located at Greeley, Colorado, conducted by Colorado Department of Agriculture Inspectors on February 20, 2001, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or 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).

The inspection found that your procedures to prevent cross-contamination are inadequate in that:

You do not have written procedures specifying the clean-out procedures for your feed mixer.

You do not maintain records sufficient to track materials containing meat and bone meal throughout their receipt, processing, and distribution.

Our investigation also found that you fail to label your product, Greeco Lay Mash with meat and bone meal, with the required cautionary statement **"Do Not Feed to Cattle or Other Ruminants"**. The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

The above is not intended to be an all-inclusive list of violations. 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 regulations.

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March 27, 2001

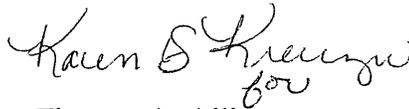
We find it quite disturbing that the above violations still exist considering you have been advised on at least 2 occasions of these requirements. In fact, during the previous inspection of April, 2000, you advised the Inspector you no longer use meat and bone meal. At the beginning of the current inspection the Inspector was again told by the firm's agronomist that no meat and bone meal was being used. On inspection of the mixing area and the basement storage area, the Inspector found both labeled and unlabeled bags of meat and bone meal and was told by an employee that it was used in the Grecco Lay Mash formula.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections will result in regulatory action without further notice including seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

Handwritten signature of Karen S. Krausz in cursive script.

Thomas A. Allison
District Director

Enclosure: "Small Entity Compliance Guide"

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