



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT  
g1175d

April 9, 2001

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

01-PHI-12

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Brian J. Raymond, Owner  
Sandy Lake Mills  
26 Mill Street  
P.O. Box 117  
Sandy Lake, PA 16145

Dear Mr. Raymond:

Food and Drug Administration Investigator Gregory E. Beichner conducted an inspection of your animal feed manufacturing operation, located in Sandy Lake, Pennsylvania, on March 23, 2001, and determined that your firm manufactures animal feeds including feeds containing prohibited materials. The 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. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured at this facility to be misbranded within the meaning of Section 403(f), of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found failure to label your swine feed with the required cautionary statement "Do Not Feed to Cattle or other Ruminants". The FDA suggests that 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.

In addition, we note that you are using approximately 140 pounds of cracked corn to flush your [REDACTED] mixer used in the manufacture of animal feeds containing prohibited material. This flushed material is fed to wild game including deer, a ruminant animal. Feed material which may potentially contain prohibited material should not be fed to ruminant animals which may become part of the food chain.

The above is not intended to be an all-inclusive list of deviations from the regulations. 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 FDA's Small Entity Compliance Guide to assist you with

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complying with the regulation.

We acknowledge your efforts to advise customers to whom you have shipped feeds containing prohibited materials. You may be hearing further from Philadelphia District Office on this matter.

You should take whatever additional action may be appropriate 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 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 reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above-referenced address.

Sincerely yours,

Handwritten signature of Thomas D. Gardine in cursive script.

Thomas D. Gardine  
District Director  
Philadelphia District

jci

Enclosure: FDA 483 dated 3/23/01