



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

g1197d

60 8th Street, N.E.
Atlanta, Georgia 30309

March 30, 2001

VIA FEDERAL EXPRESS

D. W. Knight
President
Farmers Mill & Elevator Company
265 Main Street
Dexter, Georgia 31019

WARNING LETTER
(01-ATL-39)

Dear Mr. Knight:

An inspection of your feed mill located at 1342 1st Street in Dudley, Georgia, was conducted on March 12 & 13, 2001 by Investigator B. Douglas Brogden. 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/or distributed by your facility to be adulterated within the meaning of 402(a)(2)(C) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found that you had failed to establish written procedures covering the flushing or cleaning out of equipment to prevent cross contamination or commingling of non-prohibited materials with prohibited materials. This equipment would include your mixer, bag out bin, load out auger, and bulk feed delivery truck. Production records are not maintained and there was no documentation available indicating that common equipment had been flushed or cleaned out as claimed by your employees. Common equipment is used to manufacture swine feed, containing meat and bone meal, and cattle feed. Meat and bone meal was also noted on pallets of cattle feed stored at your facility.

Further investigation revealed that you had failed to label all of your products with the required cautionary statement "Do Not Feed to Cattle or Other Ruminants". Flush material used to clean out your mixing equipment prior to making cattle feed had been bagged and sold as animal feed. No caution statement was placed on the labels attached to these bags. Failure to meet the required labeling provisions for this product caused the feed to be misbranded under 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. The above deviations were included on the Inspectional Observations (FDA 483) which was issued to and discussed with David M. Nichols, Manager, at the conclusion of the inspection. A copy of the FDA 483 is enclosed for your review. We have also enclosed a copy the FDA Small Entities Compliance Guide to assist you with complying with the regulation.

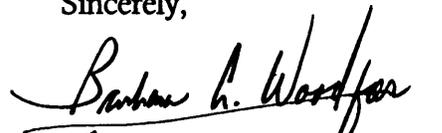
Of particular concern is that these same violations were pointed out during the previous inspection of this facility on October 21, 1998. That inspection was conducted by the Georgia Department of Agriculture. The two violations noted were the failure to establish flush procedures for the use of prohibited materials and feed labels not including the cautionary statement.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur at the Dudley mill or any similar facilities you own and operate. 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 fifteen (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 describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. You should include copies of any available documentation demonstrating that corrections have been made.

Your reply should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,


Ballard H. Graham, Director
Atlanta District

Enclosures

