



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9 1779d  
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-7703-01**  
**September 20, 2001**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

William P. Herrington, President  
Buckeye Feed Mills, Inc.  
(dba) Buckeye Nutrition  
330 East Schultz Avenue  
Dalton, OH 44618

Dear Mr. Herrington:

Food and Drug Administration (FDA) investigators conducted an inspection of your feed mill from April 5-24, 2001. The inspection found significant and serious 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). These deviations caused products manufactured by your firm to be adulterated and misbranded.

The violations are as follows:

Our investigators documented that you did not flush or sequence the incoming receiving pit conveyor systems and ingredient storage bins after the receipt of ruminant meat and bone meal to avoid contamination of ingredients that were used in ruminant feeds.

Further, the investigators found that 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**".

There are no written procedures for cleaning out or flushing the receiving pit conveyor system and ingredient storage bins. Additionally, you do not have records documenting that the system was cleaned or flushed in accordance with any written procedures.

Your procedure for sequencing/flushing of the *mixers* (MOP-004 rev. date 2/2/98) allows for feeds containing ruminant meat and bone meal to be followed by horse and rabbit feeds that should bear the cautionary statement but do not.

The deviations from regulations as noted above caused 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).

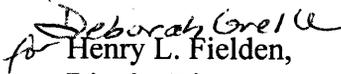
You should establish adequate procedures and verify that the flush/clean-out method you use cleans out the remainder of preceding batches containing prohibited materials. Note: If you flush with feed ingredients, or sequence with non-ruminant feed, you must also label these products with the required cautionary statement "Do not feed to Cattle or Other Ruminants".

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. We are aware of some of the corrective actions you have taken to date. It is critical that you establish a system to prevent future violations. **Failure to correct these violations promptly and adequately may result in regulatory action, such as seizure and/or injunction, without further notice.**

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 Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (5 13) 679-2700 extension 167.

Sincerely,

  
for Henry L. Fielden,  
District Director

Enclosure: Small Entity Compliance Guide