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Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127-2601

Telephone: 504-253-4500  
Facsimile: 504-253-4560

March 7, 2001

**WARNING LETTER NO. 2001-NOL-13**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. Sam C. Shields, Owner  
Shields Feed and Supply Company  
164 Legion Street  
Coffeeville, Alabama 36524

Dear Mr. Shields:

An inspection of your animal feed operation, located at 164 Legion Street, Coffeeville, Alabama, conducted by a U.S. Food and Drug Administration (FDA) investigator on February 1, 2001, found significant deviations from the requirements set forth in Title 21, *Code of Federal Regulations*, Part 589.2000 (21 CFR, 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 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. Our investigation found:

- Your procedures to prevent cross-contamination are inadequate in that your firm has no written procedures specifying appropriate clean-out of your feed mixer, and the corn used for clean out is not labeled and quarantined;
- Your firm does not maintain records to cover the mixing and distribution of your feed products; and,
- Your firm fails to label your finished product 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 deviations from the regulations. As a manufacturer of materials intended for feed, 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.

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 fifteen (15) working days of the 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 within fifteen (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 Nicole F. Hardin, Compliance Officer, at the above address.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosures: FDA Form 483  
FDA's Small Entity Compliance Guide