



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HPI-35

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER CIN-WL-6723-01**

March 21, 2001

Jerry and Helen Stewart  
Owners  
Stewart's Farm Supply  
309 Frankfort Street  
Brookville, KY 41004

Dear Mr. and Mrs. Stewart:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on February 13-15, 2001. 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 distributed by your facility to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

The articles are adulterated within the meaning of Section 402(a)(4) because there are no records to document that the feed mixing system was cleaned or flushed in accordance with your approved procedures.

Crushed corn used to flush equipment after mixing products containing prohibited material is misbranded within the meaning of Section 403(f) because it is not labeled 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.

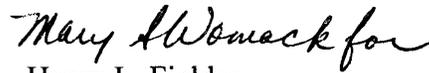
You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 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 Deborah Grelle, Director of Compliance, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (513) 679-2700 extension 160.

Sincerely yours,



Henry L. Fielden  
District Director

Enclosure: Small Entity Compliance Guide

Cc Eli Miller  
University of Kentucky  
Division of Regulatory Service  
103 Regulatory Service Building  
Lexington, KY 40546-0275