



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M31461

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

Telephone: 215-697-4390

Warning Letter

November 12, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John M. Ochs, Corporate Treasurer/Owner
Red Bank Mills, Inc.
234 Liberty Street
New Bethlehem, PA 16242

Dear Mr. Ochs:

An inspection of your animal feed manufacturing operation, Red Bank Mills, Inc., located in New Bethlehem, Pennsylvania, conducted by Food and Drug Administration Investigator Gregory E. Beichner on June 3 and 8, 1999, 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 transmissible spongiform encephalopathies (TSE's). 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 product 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.

Our inspection also revealed objectionable conditions regarding the repackaging and distribution of [REDACTED], as addressed on the FDA-483 dated June 8, 1999 (copy attached). We have noted your intention to discontinue the repackaging and and distribution of medicated articles.

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 complying with the regulation.

Page 2

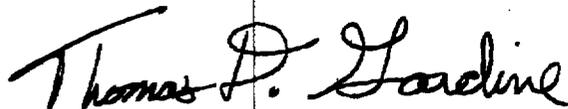
Warning Letter: Red Bank Mills, New Bethlehem, PA

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 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,



Thomas D. Gardine
District Director
Philadelphia District

jci

Enclosures: FDA-483 dated 6/8/99
Small Entity Compliance Guide