



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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g1083d

March 27, 2001

WARNING LETTER

PURGED

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Terry D. Viktorin
Co-Owner
Z&W Mill, Inc.
P.O. Box 236
Torrington, Wyoming 82240

Ref. #: DEN-01-25

Dear Mr. Viktorin:

An inspection of your animal feed manufacturing operation located at Torrington, Wyoming, conducted by a Food and Drug Administration Investigator on February 12 & 13, 2001, 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 Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by 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 a failure to label your product, Hen Ration, 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. I would like to point out that the corrected label which you provided the Investigator during the inspection (copy attached) is almost illegible and as such serves little value in notifying the purchaser of this important requirement.

The above is not intended to be an all-inclusive list of violations. 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 regulations.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Although you corrected the label of the Hen Ration during the inspection, we are disturbed to have found this violation since you were previously informed of the requirements during an earlier inspection in May, 1999. Failure to make immediate and lasting corrections may result in regulatory action without further notice such as seizure, and/or injunction.

Page 2 - Z & W Mill, Inc.
March 27, 2001

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,


Thomas A. Allison
District Director

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Enclosure: "Small Entity Compliance Guide"
Revised Label - Hen Ration