



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 17, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-50

Reid Kooch, President
Wallowa County Grain Growers, Inc.
911 S. River
Enterprise, Oregon 97828

WARNING LETTER

Dear Mr. Kooch:

An inspection of your animal feed manufacturing operation located at 804 Depot, Enterprise, Oregon, conducted by a Food and Drug Administration investigator on March 29, and 30, 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 at this facility to be adulterated within the meaning of Section 402(a)(2)(C) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found a failure to separate the receipt, processing, and storage of the product containing prohibited material from non-prohibited material; failure to establish a written system, including clean-out, and flushing procedures, to avoid commingling and cross-contamination of common equipment; failure to maintain records sufficient to track the materials throughout the receipt, processing, and distribution of your products.

The above is not intended to be an all-inclusive list of deviation 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 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

Reid Kooch, President
Wallowa County Grain Growers, Inc. Enterprise, Oregon
Re: Warning Letter SEA 01-50
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You should notify this office in writing within fifteen (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 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.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long, sweeping horizontal stroke extending to the right.

Charles M. Breen
District Director

Cc: James L. Butner, General Manager

Enclosure:
Form FDA 483
Small Entity Compliance Guide