



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

October 24, 2001

In reply refer to Warning Letter SEA 02-06

Kenneth Roy Tufly, Owner
Dixon Feeds, Inc.
HC 77 Box 93
Dixon, Montana 59831

WARNING LETTER

Dear Mr. Tufly:

An inspection of your animal feed manufacturing operation Dixon Feeds, Inc., HC 77 Box 93, Dixon, Montana, conducted by a Food and Drug Administration (FDA) investigator on September 27, 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).

1. 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, 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.
2. Our investigation found a failure to label your 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. In addition the other animal feeds manufactured by your firm contain no labeling, including the "Do Not Feed to Cattle or Other Ruminants", or ingredient statements, firm name, address

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or other required information. This becomes even more critical since customers can pick up products, which are unlabeled, without anyone present at the firm. According to the information you provided to our investigator, customers fill out the invoice and leave a check. In at least one case you did not know the customer and were unable to locate him through local telephone directories. Since the products picked up by the customers are unlabeled, and the instructions are for them to label the products, the probability of them making an error or not labeling the products is high.

In addition to the BSE problems noted above, our investigator also found deviations which can be considered violations of the Good Manufacturing Practices regulations for medicated feeds. These observations include, but are not limited to the following:

- A. The spring scale, used for weighing out Category I drugs, has not been calibrated to assure that the correct amount of drug is weighed to assure that it meets the labeled amount of active drug ingredient.
- B. The mixer was found to have a buildup of materials on the mixing surfaces, the source of which could not be determined since you are not maintaining production and cleaning records. This buildup material may consist of prohibited materials or category I drugs either of which could cross-contaminate feeds, including ruminant feeds, or non-medicated feeds.

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 the FDA's Small Entity Compliance Guide to assist you in 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.

We are in receipt of your response letter dated October 10, 2001. Your corrective actions in response to the FDA 483 dated September 27, 2001, appears to adequately address FDA 483 items #1, 3, 4 & 5. However, you failed to address what corrective actions you have taken, or plan to take for products manufactured prior to and during the inspection, which may still be in storage, that contain prohibited materials, but were not labeled with the warning statement, "**Do Not Feed to Cattle and other Ruminants.**"

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

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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,



Charles M. Breen
District Director

Enclosure:
Form FDA 483
Small Entity Compliance Guide