



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

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April 27, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-51

Kenneth H. Sherwood, President
Alaska Garden and Pet Supply, Inc.
114 N. Orca
Anchorage, Alaska 99501

WARNING LETTER

Dear Mr. Sherwood:

An inspection of your animal feed manufacturing operation Alaska Mill and Feed Company, located at 114 N. Orca, Anchorage, Alaska, conducted by a Food and Drug Administration investigator on April 12, 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, 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.
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 that, your clean out flush does not contain the caution label.

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.

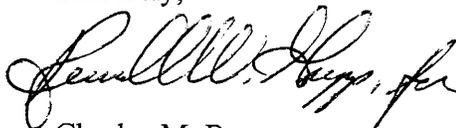
Kenneth H. Sherwood, President
Alaska Garden and Pet Supply, Inc., Anchorage, Alaska
Re: Warning Letter SEA 01-51
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You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure 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 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". The signature is written in a cursive style with a large initial "C".

Charles M. Breen
District Director

Enclosure:
Form FDA 483
Small Entity Compliance Guide