



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 7, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-46

Mr. Philip C. Anderson, General Manager
Darling International, Inc.
2041 Marc Avenue
Tacoma, Washington 98401

WARNING LETTER

Dear Mr. Anderson:

An inspection of your rendering operation conducted by Investigator Donald B. McKechnie, on February 22 and 26, 2002, found a significant deviation 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 deviation causes products being manufactured and/or distributed by your 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 consistently label your meat and bone meal product shipped to [REDACTED] with the required cautionary statement "Do Not Feed to Cattle or Other Ruminants". The meat and bone meal contains beef offal along with other ingredients including chicken, fish, and pork. 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.

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 with complying with the regulation.

You should take prompt action to correct this violation, and you should establish a system whereby such violation does not recur. Failure to promptly correct this violation may result in regulatory action without further notice, such as seizure and/or injunction.

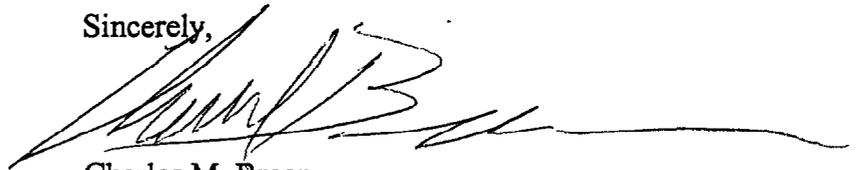
You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violation, and to prevent its

Philip C. Anderson, General Manager
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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.

Please send your reply to the Food and Drug Administration, Attention: Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Piekarski at (425) 483-4975.

Sincerely,

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

Charles M. Breen
District Director

Cc:
Mr. Dennis Taura, Chief Executive Officer
Darling International, Inc.
251 O'Connor Ridge Boulevard, Suite 300
Irving, Texas 75038

Enclosure:
Small Entity Compliance Guide