



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
FAX: 303-236-3100

June 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Scott Nelson, Owner
Integral Fish Foods, Inc.
715 South 7th Street
Grand Junction, CO 81501

Ref. #: DEN-01-35

Dear Mr. Nelson:

An inspection of your fish feed manufacturing operation located at Grand Junction, Colorado, conducted by a Colorado Department of Agriculture Inspector on March 20, 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 your facility to be adulterated within the meaning of section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection found that your procedures to prevent cross-contamination are inadequate in that:

You do not have written procedures specifying the clean-out procedures for your feed mixer.

Our investigation also found that you fail to label your products, Fat Cat Catfish Fingerling Feed and Gold Nugget Trout Fry Feed #2 Crumble, each containing meat and bone meal, 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.

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.

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We find it quite disturbing that the above violations still exist considering you have been advised on 2 previous occasions of these requirements, including April 7, 1999 and March 6, 2000.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections will result in regulatory action without further notice including seizure, and/or injunction.

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

Enclosure: "Small Entity Compliance Guide"

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