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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 30, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 65

Randal L. Linville
Chief Executive Officer
The Scoular Company
9401 Indian Creek Parkway
Building 40 - Suite 850
Overland Park, KS 55210

Dear Mr. Linville:

On April 16, 17, 23 and May 15, 2001, investigators from the Food and Drug Administration (FDA), inspected your International Proteins Corporation located at 46 East Fourth Street, St. Paul, Minnesota. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, "Animal Proteins Prohibited in Ruminant Feed" (21 CFR 589.2000). 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 this 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 label lamb meal products 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 deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring 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.

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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 and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

During the inspection, John A. Messerich, Managing Director Proteins and Fats, provided copies of letters sent to past purchasers of incorrectly labeled lamb meal. Those letters informed the customers of the labeling error and provided instructions to correct the labeling. We agree with your decision to revise the labeling. That field corrective action will be monitored as a recall by the FDA.

Please provide this office a written update within 15 working days of receipt of this letter with 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. In particular, please describe how you will ensure proper labeling of prohibited animal proteins purchased and sold by your firm in the future. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

TGP/rfk
rfk

Enclosure: FDA Small Entities Compliance Guide, 21 CFR 589.2000

xc: John A. Messerich, Managing Director Proteins and Fats
International Proteins Corporation
46 East Fourth Street
St. Paul, MN 55101

Eric H. Jackson, President
International Proteins Corporation
46 East Fourth Street
St. Paul, MN 55101