



Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

July 12, 2004

WARNING LETTER
CHI-16-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Donald E. Hamilton, President/Owner
Illini Feeds, Inc.
P.O. Box 86, 1145 State Hwy. 94
Aledo, Illinois 61231

Dear Mr. Hamilton:

On February 19 and 20, 2004, the Food and Drug Administration (FDA) conducted an inspection of your animal feed handling facility located at 1145 State Highway 94, Aledo, Illinois. The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 (21 CFR 589.2000) – **Animal Proteins Prohibited in Ruminant Feed**. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). The deviations cause the swine feed manufactured by your facility to be misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found that salvaged pet food containing prohibited material was added as an ingredient to the swine products manufactured at your facility. During the inspection, our investigator found that you failed to label your non-ruminant products with the required caution statement – “**Do not feed to cattle or other ruminants.**” [21 CFR 589.2000(d)(1)]

The above is not intended to be an all-inclusive list of violations. As a manufacturer of materials intended for use in animal feed, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

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

Page 2

During the inspection, you told the investigator that you would put the required cautionary statement on your products that contain prohibited material, and maintain tracking documents for all incoming ingredients, including animal proteins prohibited in ruminant feed. Please notify this office in writing within 15 working days of receiving this letter of any further steps you have taken to assure that your firm is in compliance with the law. Your response should also include an explanation of each step taken to correct the violations, and prevent their recurrence. Please include copies of any available documentation such as written procedures, corrected labeling, etc., demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott J. MacIntire". The signature is written in a cursive style with a large, sweeping initial "S".

Scott J. MacIntire
District Director