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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

May 4, 2001

WARNING LETTER
CHI-30-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerry M. Behimer, President
Material Resources, LLC – Gateway Co-Packing Company
901 Kingshighway
Washington Park, IL 62204

Dear Mr. Behimer:

On March 4, 5 and 10, 2001, the Food & Drug Administration (FDA) conducted an inspection at your feed mill, which operates as a contract manufacturer for [REDACTED] a Division of the [REDACTED]. 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). Such deviations cause products being manufactured by your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found the following violations during the inspection:

- Your firm does not provide adequate measures to avoid commingling or cross-contamination of prohibited and non-prohibited protein material.
- Your firm has no written procedures that document measures that have been adopted to prevent commingling or cross-contamination, between feeds that contain prohibited protein with feeds that contain non-prohibited materials.
- Your firm lacks adequate records to track products that contain, or may contain, prohibited material throughout their receipt and processing.

The above is not intended to be an all-inclusive list of violations. While your animal feed labeling and distribution operations for manufactured product are directed, through contract arrangement, by the above-mentioned [REDACTED], your firm, as a manufacturer of materials intended for animal feed use, is responsible for controlling your manufacturing operation to ensure that the products you manufacture are in

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compliance with the law. At the conclusion of the inspection, our investigator issued an FDA 483 (Inspectional Observations) to Mr. Stacy D. Thomason, your Plant Manager. (A copy of the FDA 483 is enclosed.) These observations represent his evaluation of your firm's performance regarding various aspects of your firm's operations.

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

Please provide this office within 15 working days of receipt of this letter the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations, and prevent their recurrence. 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. Include copies of any available documentation, demonstrating that corrections have been made.

Your reply should be directed to James T. Karpus, Compliance Officer, at the above address.

Sincerely,

\s\

Raymond V. Mlecko
District Director

cc with enclosures: Mr. Stacy D. Thomason, Plant Manager
Material Resources, LLC-Gateway Co-Packing Company
901 Kingshighway
Washington Park, IL 62204

cc with enclosures

