



September 18, 1997

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

WARNING LETTER
CHI-49-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert Hilby
4742 N. Menominee Road
East Dubuque, IL 61025

Dear Mr. Hilby:

An investigation of your cattle raising and shipping operation, conducted by Investigator Darrell E. Luedtke on August 19, 1997, confirmed that you offered a dairy cow for sale for slaughter as human food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

On or about July 8, 1997, you sold a dairy cow for slaughter as human food to [redacted]. USDA analysis of tissue samples collected from the animal identified the presence of 0.79 parts per million (ppm) penicillin in kidney tissue. The established Regulatory Action levels for penicillin in cattle is 0.05 ppm. The presence of this drug in the edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(D) of the Act.

A food is also deemed to be adulterated under Section 402(a)(4) if it has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possible harmful drug residues are likely to enter the food supply. Our investigation found that you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling. You also lack adequate maintenance of drug treatment records to assure that animals medicated by you have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drug from edible tissues.

The above is not intended as an all-inclusive list of violations. A List of Observations (FDA-483) was issued to you at the conclusion of the inspection. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

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You should take prompt action to correct these violations and establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes official notification under the law.

Please advise 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 each step 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 directed to Paul A. Boehmer, Compliance Officer.

Sincerely,

Raymond V. Mlecko
District Director

cc: Judd Giezentanner, DVM
North Central Region
FSIS Inspection Operations
United States Department of Agriculture
11338 Aurora Ave.
Des Moines, IA 50322

cc: Richard Hull, DVM
Chief Veterinarian
Bureau of Animal Health
Division of Animal Industries
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281

cc: Mark Ringler
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