



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Certified/Return Receipt Requested

March 1, 1999

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Melvin Laughery
110 West Washington
Box 187
Fontanelle, IA 50846

KAN #99-015

Dear Mr. Laughery:

We are writing to you because on October 5 & 6, 1998, an inspector from the Iowa Department of Agriculture collected information that revealed a serious regulatory problem concerning your offering of a beef heifer for sale for slaughter as food, which contained residues of a new animal drug that is unsafe.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this heifer is food, which is defined as "articles used for food or drink for man or other animals." In legal terms, the food is adulterated under Section 402(a)(2)(C)(ii) of the Act. The food is adulterated because it bears or contains a new animal drug, which is unsafe within the meaning of Section 512 of the Act.

On/about August 4, 1998, a beef heifer owned by you was delivered by C Bar D Cattle Company, Gravity, Iowa, to [REDACTED] (no ID number). USDA analysis (Lab Report #341989) of tissue samples collected from this animal identified the presence of Tilimicosin ranging from 0.42 ppm to 10.6 ppm. The allowable tolerance for Tilimicosin is 1.2 ppm in the liver.

In addition, the USDA has reported the finding of illegal residues in two beef heifers sold by you on October 23, 1997, and offered for slaughter for human food (carcass numbers 6472 and 6473, respectively). Tissue samples were found to contain Gentamicin at 0.25 ppm to 1.00 ppm. There is no allowable tolerance for Gentamicin in the edible tissue of cattle.

The above is not intended to be an all-inclusive list of violations. As a buyer/dealer of food animals and the last owner of record, and the marketing of these animals for sale for slaughter as food, it is your responsibility to make sure your operations are in compliance with the law.

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As a dealer or purchaser of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Act. To avoid future illegal residue violations you should take precautions such as:

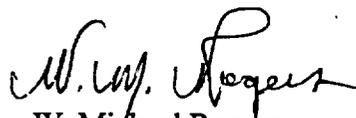
- implementing a system to identify the animals you purchase with records to establish the traceability to the source of the animal;
- implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,
- if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal then it should not be offered for human food, and should be clearly identified and sold as a medicated animal.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your food-producing animals.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District