



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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June 23, 2004

WARNING LETTER
CIN-04-21796

FEDERAL EXPRESS

Mr. Mike Loy
669 PD Pyles Road
Columbia, KY 42728

Dear Mr. Loy:

On April 8, 2004, an investigation of your dairy operation conducted by an investigator from the Food & Drug Administration confirmed that you offered for sale a cow for slaughter as food that was adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ("the Act"). The inspection also revealed that you caused animal drugs to be unsafe under Section 512(a) of the Act, and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform to their approved use or to the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations ("CFR"), Part 530).

On or about December 2, 2003, you sold a dairy cow (identified with back tag number: 61TR 7763) for slaughter for human food through _____ The animal was slaughtered on December 5, 2003. The U.S. Department of Agriculture, Food Safety Inspection Service, (USDA, FSIS) sampled the animal and found that it contained illegal drug residues. The USDA laboratory's analytical report, FSIS Sample #415996, shows that the kidney, liver, and muscle tissues of the referenced animal contained violative Gentamicin residue levels of: 106.54 parts-per-million (ppm), 5.00 ppm, and 0.32 ppm, respectively. The muscle tissue was also found to contain a violative Oxytetracycline residue level of 2.94 ppm. There is no established tolerance for Gentamicin in cattle (see 21 CFR Part 556.300); and the established tolerance level for Oxytetracycline in the muscle tissue of dairy cattle is: 2.00 ppm (see 21 CFR Part 556.500). The presence of these drugs at the reported levels in the edible tissues of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Gentamicin is not approved for use in dairy cows. However, the extralabel use of approved veterinary or human drugs is allowed if the use complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that your extralabel use of Gentamicin

failed to comply with these requirements. For example, you administered Gentamicin to the dairy cow with backtag number: 7763, without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a), and your extralabel use resulted in an illegal drug residue, in violation of 21 CFR 530.11(c). Because your extralabel use of Gentamicin was not in compliance with 21 CFR Part 530, the drug was unsafe under Section 512(a) of the Act and your use caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues; and all drug products used on your animals are properly tracked. You also failed to maintain any treatment records for your cows. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that your overall operation and the food you distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in FDA taking regulatory action without further notice to you. Regulatory action may include injunction and/or seizure.

Please notify this office in writing within 15 working days of receiving this letter of the steps you have taken to correct the noted violations and to prevent recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please include copies of any available documentation demonstrating correction.

Please mail your response to: Mr. David Radle, Tissue Residue Monitor, U. S. Food and Drug Administration, 6751 Steger Dr., Cincinnati Ohio, 45237-3097.

Sincerely,

A handwritten signature in black ink, appearing to read "Carol A. Heppe". The signature is fluid and cursive, written over a white background.

Carol A. Heppe
District Director
Cincinnati District