



June 22, 2004

Warning Letter
CIN-WL-04-21791

VIA FEDEX

Dr. Kenneth Deputy, Owner
Mammoth Cave Dairy Auction, Inc.
PO Box 129
Intersection I-65 & US 65
Smiths Grove, KY 42171-0129

Dear Dr. Deputy:

A tissue report received by the U.S. Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in a cow that was sold at your auction house. An investigation of your operations conducted by our investigator on April 7, 2004 confirmed that you offered an animal for sale for slaughter as food in violation of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). Food is adulterated under section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of section 512. In this case, the new animal drugs are unsafe because the producer failed to adhere to the withdrawal times contained in these drugs' labeled directions. As set forth below, the producer's failure to follow the labeled withdrawal times resulted in above-tolerance tissue residues.

On or about December 2, 2003, you sold a cow, dealer back tag #61TR7763 to [REDACTED]. That cow was then taken for slaughter on December 2, 2003, to [REDACTED]. The USDA laboratory's analytic report #415996, for this cow shows that the kidney tissue contained 106.54 parts-per-million (ppm) Gentamicin, the liver tissue contained 5 ppm Gentamicin, and the muscle tissue contained 0.32 ppm Gentamicin and 2.94 ppm Oxytetracycline. There is no established tolerance for Gentamicin in cattle, and the established tolerance for Oxytetracycline in the muscle of cattle is 2 ppm (Title 21, Code of Federal Regulations, Section 556.500). Our investigation confirmed that the cow identified with the dealer back tag #61TR7763 and slaughtered on or around December 5, 2003 was sold through your auction house. You failed to obtain the medicated status of the animal from the producer. Consequently, an animal bearing above-tolerance tissue residues was slaughtered for human food.

In addition, food is adulterated under section 402(a)(4) of the Act, "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." As it applies to this case, insanitary conditions means that you hold animals, which are ultimately offered for sale for slaughter as food, under conditions that may allow medicated animals bearing possibly harmful drug residues to enter the food supply.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to violate the Act. The fact that you offered an adulterated animal for sale, which was slaughtered and held for sale in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations. Failure to promptly correct these deficiencies may result in regulatory action being initiated by the Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Please notify this office within fifteen (15) working days of receiving this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your response to this Warning Letter should be sent to Gina M. Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carol A. Heppe".

Carol A. Heppe
District Director
Cincinnati District