



DEPARTMENT OF HEALTH AND HUMAN SERVICES

41876

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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March 24, 2003

Warning Letter
CIN-WL-03-16954

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael A. Hatcher, Owner
PO Box 517
307 Holmes Bend Road
Columbia, KY 42728

Dear Mr. Hatcher:

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 originated from your cattle farm or one of the farms that raise cattle for you. An investigation of your operations conducted by our investigator on 2/19/03 confirmed that you offered an animal for sale for slaughter as food in violation of section 402(a)(2)(C)(ii) and 402(a)(4) of the Food, Drug and Cosmetic Act (the Act).

A food is adulterated under section 402(a)(2)(C)(ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of section 512. A food is adulterated under Section 402(a)(4) of the Act if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions," refers to your lack of records for animals which you or your employees or contractors medicate.

On or about November 12, 2002, you sold a cow, dealer back tag #61TR6945 to [REDACTED]. That cow was then taken for slaughter on November 13, 2002, to [REDACTED]. The USDA laboratory's analytic report #436450 for the cow with dealer back tag # 61TR6945 shows that the liver tissue of the referenced animal contained 49.13 ppm Sulfamethazine and the muscle tissue contained 48.46 ppm Sulfamethazine. The established tolerance levels for this drug in cattle intended for slaughter as human food is 0.1 ppm (Title 21, Code of Federal Regulations, Section 556.640). The lab report also shows that the kidney tissue of the referenced animal contained 1.9 ppm Penicillin and the liver tissue contained 0.8 ppm Penicillin. The established tolerance level for this drug in cattle intended for slaughter as human food is 0.05 ppm (Title 21, Code of Federal Regulations, Section 556.510). Our investigation confirmed that the cow identified with the dealer tag number 61TR6945 and slaughtered on or around 11/13/02 belonged to you. You failed to inform the auction house of the medicated status of the animal and you neglected to take reasonable steps to insure that the animal was properly disposed of. Consequently, an animal bearing possibly harmful drug residues was slaughtered for food.

Statements made by you to the FDA investigator indicate you hold animals under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that the

medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Consequently, you held an animal, which was ultimately offered for sale for human food, under conditions which are so inadequate that a medicated animal bearing potentially harmful drug residues entered the food supply.

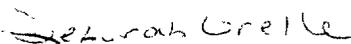
You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to violate the Food Drug & Cosmetic Act. The fact that you offered an adulterated animal for sale, which was slaughtered and held for sale in interstate commerce, is sufficient 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 receipt of 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 reoccurrence 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,


for Carol A. Hepe
District Director
Cincinnati District