



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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M2808n

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

Warning Letter

April 8, 1999

D. Michael Hoover, Owner
Michael Hoover Dairy Farm
RD #1
P.O. Box 433
Tyrone, PA 16686

Dear Mr. Hoover:

On March 17, 1999 Food and Drug Administration (FDA) Investigator Robert T. Vaughn conducted an inspection of your dairy farm located in Tyrone, PA, in response to a United States Department of Agriculture (USDA) report regarding a violative drug residue in a cow you offered for sale for slaughter for human food. Additional investigation by the FDA at [REDACTED] and at [REDACTED] has revealed serious violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about September 20, 1998, you offered a cow, back tag #23MO5871, ear tag #23VWR8342, for sale for slaughter as human food at [REDACTED]. The subject cow was purchased by [REDACTED] on or about September 23, 1998 and was slaughtered for food on the same date. United States Department of Agriculture (USDA) testing revealed the presence of 3.70 ppm (parts per million) streptomycin in the kidney tissue of the animal. This is considered to be a violative tissue residue since the tolerance for streptomycin in edible bovine tissue is 2.0 ppm. The presence of streptomycin in the edible kidney tissue from your animal at the concentration level detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system to assure that animals have been treated with drugs which have been approved for use in those species; to assure that drugs are used in a manner not contrary to the directions contained in the labeling; and to assure that 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. Food from animals held under such conditions is adulterated.

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Our investigation revealed that you did not inform the hauler, James Clark, of the medication status of your cow which was offered for sale for slaughter for human food at Morrison Cove Livestock Auction. The offering of animals for slaughter for human consumption which contain illegal drug residues is a violation of the Act. Part of your responsibility is to assure that all animals offered for slaughter for human food from your facility are free of drugs to prevent tissue residues.

A person who causes an animal with an illegal drug residue to be sold for human food may be subject to regulatory action. This applies to anyone in the chain of handling an animal including the producer, dealer, hauler, auctionhouse, and the slaughterhouse. It is important that the consumer be protected from excessive intake of drug residues in the food supply.

The FDA is aware of another medicated cow which you delivered for sale for slaughter for food at Belleville Livestock Market, Belleville, PA, on or about March 18, 1998. This cow, back tag #3046, was slaughtered for human food at Taylor Packing Company on or about March 19, 1998 and subsequent USDA testing revealed the presence of 1.2 ppm gentamicin in the animal's kidney tissue. Gentamicin is not approved for oral or injectable use in cattle, and therefore, there is no tolerance for the presence of this drug in edible bovine tissue. The presence of gentamicin in the kidney tissue of this animal renders the food from the animal to be adulterated. During the Pennsylvania Department of Agriculture (PDA) inspection of your farm on March 18, 1998 regarding this violative tissue residue you signed an affidavit indicating that you did not inform Belleville Livestock Market of the medication status of the subject cow.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a

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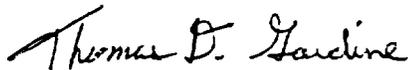
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slaughterhouse that ships beef in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 days 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 violation and prevent its recurrence.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
PA Department of Agriculture
Bureau of Animal Health and Diagnostic Services (BAHDS)
2301 North Cameron Street
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)
106 South 15th Street
Suite 904
Omaha, Nebraska 68102
Attention: Residue Staff