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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

September 11, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John M. Hargenrader, Partner
Terry F. Hargenrader, Partner
William Hargenrader, Partner
Thomas Hargenrader, Partner
Hargenrader Farms
Route 1
P.O. Box 57
Marble, PA 16334

Gentlemen:

On August 19, 1998 Food and Drug Administration (FDA) Investigator Robert T. Vaughn conducted an inspection of your dairy farm located on Route #1 in Marble, Pennsylvania, in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow you offered for sale and slaughter for human food. Additional investigation by the FDA at [redacted], has revealed serious violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about April 8, 1998, you offered a cow, back tag #3957, for slaughter as human food at [redacted] The subject cow was purchased by [redacted] on April 8, 1998 and was slaughtered for food on April 9, 1998. USDA testing revealed the presence of 6.90 parts per million gentamicin in the kidney tissue of the animal. 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 edible tissues from your animal renders the food from the animal to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

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 for assuring that animals have been treated with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring 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.

Our inspection also determined the subject animal was treated by you with [redacted] (gentamicin) for mastitis without veterinary oversee. Additionally, you had no instruction from a veterinarian regarding the withhold time for slaughter. Use of gentamicin to treat mastitis in dairy cows constitutes "extra-label use" of the product. "Extra-label use" refers to the actual or intended use of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug labeling.

Under the Act, use of a drug in a manner different from that set forth in the approved labeling would cause the drug to be adulterated. Until recently, FDA would permit the extra-label use of approved drugs in food-producing animals under very specific criteria as a discretionary policy. That policy required an extra-label use decision to be made by a veterinarian based on a valid veterinarian/client/patient relationship and other factors, and could not result in a residue in edible animal tissue. The Animal Medicinal Drug Use Clarification Act (AMDUCA) passed by Congress in October of 1994 and the implementing regulations which were effective December 9, 1996, permit the extra-label use of approved human and veterinary drugs in food-producing animals only under very specific criteria as a matter of law rather as a discretionary policy. Under AMDUCA, extra-label use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and that use may not result in any residue which may present a risk to the public health. The decision to use a product in an extra-label manner may not be done by a layperson.

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 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 violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

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

Sincerely,

Marquerite E Eagan

Marquerite E. Eagan
Acting District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
PA State Bureau of Animal Industry
Agriculture Building
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