

MAHAN



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

March 3, 1999

99-PHI-17

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Douglas J. Hillegass, Owner
Debra A. Hillegass, Owner
Mountain View Farm
9198 Glades Pike
Berlin, PA 15530

GEN.	SPEC.
RELEASE	
F# _____	DATE 3/4/99
Reviewed by: <i>[Signature]</i>	

Dear Mr. and Mrs. Hillegass:

On January 12, 1999 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your dairy farm located in Berlin, Pennsylvania, 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 December 3, 1998, you offered a cow, back tag [redacted] for sale for slaughter as human food at [redacted]. The subject cow was purchased by [redacted] and was slaughtered for food on or about December 4, 1998. United States Department of Agriculture (USDA) testing revealed the presence of 99.0 ppm (parts per million) neomycin in the kidney tissue of the animal. This is considered to be a violative tissue residue since the tolerance for neomycin in edible bovine kidney tissue is 7.2 ppm [Title 21 CFR Part 556.430 (copy attached)]. The presence of neomycin 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 for assuring that animals have been treated with drugs which have been approved for use in those species; for

Page 2

Warning Letter: Mountain View Farm

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.

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 violation 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 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

Page 3

Warning Letter: Mountain View Farm

Enclosure: 21 CFR Part 556.430

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