



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

d19826

PHILADELPHIA DISTRICT

WARNING LETTER

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

Telephone: 215-597-4390

August 11, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-PHI-28

Samuel A. Stoltzfus
RR #1
P.O. Box 342
Homer City, Pennsylvania 15748

Dear Mr. Stoltzfus:

On June 30, 1998 Food and Drug Administration (FDA) Investigator Robert T. Vaughn conducted an inspection of your dairy farm located on RR #1 in Homer City, 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 the slaughterhouse, [REDACTED]; and [REDACTED];

[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 #7051, for slaughter as human food at [REDACTED]. The subject cow was purchased by [REDACTED] on April 9, 1998 and was slaughtered for food on April 10, 1998. USDA testing revealed the presence of tilmicosin in the edible tissues of your animal at the following levels: kidney tissue, 21.80 ppm (parts per million); liver tissue, 15.20 ppm; and muscle tissue, 2.98 ppm. No tolerance has been established for tilmicosin in bovine kidney or muscle tissue. A tolerance of 1.2 ppm has been established for tilmicosin in the liver tissue of cattle (Title 21, Code of Federal Regulations, Part 556.735). The presence of tilmicosin in the edible tissues from your animal at the concentration levels 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 [REDACTED]

[REDACTED]

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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.

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,

Marquerte E. Eagan

Marquerite E. Eagan
Acting District Director
Philadelphia District

jci