



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M3200N

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

Telephone: 215-597-4390

WARNING LETTER

May 2, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Larry R. Frederick, Owner/Partner
Richard J. Frederick, Partner
Rich Lou Farm
RD #2
P.O. Box 243
Martinsburg, PA 16662

Dear Messrs. Frederick:

Food and Drug Administration investigations at Rich Lou Farm, Martinsburg, PA on February 16, 2000 and March 7, 2000 and at [REDACTED] on March 17, 2000 in response to United States Department of Agriculture (USDA) reports, confirmed that you have offered three (3) cows with violative drug residues for slaughter for human food during the past year. Additional investigation by the FDA at [REDACTED] revealed serious violations of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection determined that since May 1999 you have sold the following medicated cows to [REDACTED] without informing the firm regarding their medication status. As a result these animals were purchased by the [REDACTED] and were slaughtered for human food.

<u>Back Tag</u>	<u>Slaughter Date</u>	<u>Slaughterhouse</u>	<u>Residue (ppm)</u>	<u>Tolerance (ppm)</u>
[REDACTED]	3/14/00	[REDACTED]	Penicillin: 0.07 (K)	0.05
[REDACTED]	6/22/99	[REDACTED]	Tilmicosin: 7.10 (L) Tilmicosin: 3.80 (K) Tilmicosin: 0.38 (M)	1.2 none none
[REDACTED]	5/25/99	[REDACTED]	Neomycin: 11.00 (L)	3.6

(K)=kidney tissue; (L)=liver tissue; (M)=muscle

United States Department of Agriculture (USDA) testing of the referenced animals revealed the presence of violative levels of penicillin, tilmicosin, and neomycin residues in the edible tissues of your animals. The tolerance for penicillin in edible bovine tissue is 0.05 parts per million (ppm); the tolerance for tilmicosin in edible bovine liver tissue is 1.2 ppm (no tolerance has been established for tilmicosin in kidney and muscle tissue); and, the tolerance for neomycin in bovine liver tissue is 3.6 ppm. The presence of penicillin, tilmicosin, and neomycin in the edible tissues of your animals at the concentration levels found renders the food from the animals adulterated [Section 402(a)(2)(C)(ii)].

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, that drugs are not used in a manner contrary to the directions contained in the labeling, and 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 [Section 402(a)(4)].

Our inspection revealed that you medicate your animals without veterinary oversight and that medication records and animal identification records are not maintained.

As a matter of law the extra-label use of approved human and veterinary drugs in food-producing animals is permitted only under very specific criteria, i.e., 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 made by a layperson.

The FDA is also aware of another medicated cow, tag [REDACTED] which was offered for slaughter for human food at [REDACTED]. The cow was slaughtered on or about November 3, 1998 and subsequent USDA testing revealed 0.27 ppm and 0.37 ppm sulfadimethoxine in its liver and muscle tissues, respectively. The tolerance for sulfadimethoxine in edible bovine tissue is 0.1 ppm, and, as a result, these residues render the food from this animal adulterated.

The above is not intended as an all-inclusive list of violations.

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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.

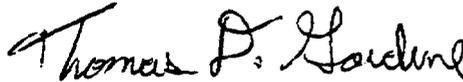
You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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 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

Enclosure: Title 21 Code of Federal Regulations, Part 530,
Extra Label Drug Use in Animals