



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT  
M. 21320

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106  
Telephone: 215-597-4390

WARNING LETTER

October 23, 1998

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Randall P. Meabon, Owner  
Green Meadow Farm  
11023 Half Moon Road  
Wattsburg, PA 16442

Dear Mr. Meabon:

On October 6, 1998 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your dairy farm in response to a United States Department of Agriculture (USDA) report regarding illegal drug residues in two (2) cows you offered for sale and slaughter for human food. Our investigation has revealed serious violation of Sections 402(a)(2)(C)(ii), 402(a)(4), and 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about June 23, 1998, you offered 2 cows, back tags [redacted] and [redacted], for slaughter as human food at [redacted] Pennsylvania. The cows were slaughtered at this establishment on or about the same date. USDA testing of the edible tissues of your animals revealed the following violative drug residues.

<u>Back Tag</u>	<u>Tissue/Drug Residue (ppm)</u>	<u>Tolerance</u>
[redacted]	Kidney/Gentamicin.....0.79 ppm	0.00
	Liver/Sulfamethazine...23.00 ppm	0.10 ppm
	Muscle/Sulfamethazine..11.00 ppm	0.10 ppm
[redacted]	Liver/Sulfamethazine...39.00 ppm	0.10 ppm
	Muscle/Sulfamethazine..17.00 ppm	0.10 ppm

These drug residues are considered violative because (1) the tolerance for sulfamethazine in edible bovine tissue is 0.10 ppm, and (2) gentamicin is not approved for oral or injectable use

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in cattle, and therefore, there is no tolerance for the presence of gentamicin in edible bovine tissue. The presence of sulfamethazine in edible tissue from your animals at the concentration levels detected renders the food from your animals adulterated under Section 402(a)(2)(C)(ii) of the Act because the food contains a new animal drug that is unsafe within the meaning of Section 512. The presence of gentamicin in edible tissue from your animal [REDACTED] also renders the food from your animal adulterated under Section 402(a)(2)(C)(ii) of the Act because the food 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 that you treated the subject cows with [REDACTED] (gentamicin) and [REDACTED]. The [REDACTED] you used was labeled by your veterinarian, [REDACTED], with a [REDACTED] withdrawal time for slaughter. [REDACTED] is labeled with an [REDACTED] withdrawal time for slaughter. During our inspection, you admitted that you failed to follow the labeled withdrawal times for slaughter for these drug products. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of the violative levels of sulfamethazine and gentamicin in the edible tissues of the cows you offered for slaughter for food. As a result, [REDACTED] and [REDACTED] to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling.

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, permits the extra-label use of approved human and veterinary drugs in food-producing animals only under very specific criteria as a matter of law

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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 within 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,

*Margaret E. Egan*

Roberta F. Wagner  
Acting District Director  
Philadelphia District

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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