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5/8/97  
[Signature]



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

PHILADELPHIA DISTRICT

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

WARNING LETTER

April 1, 1997

97-PHI-21

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Robert H. Rohrer & Sons  
Robert L. Rohrer Jr. (Owner/Partner)  
Robert H. Rohrer (Owner/Partner)  
Michael T. Rohrer (Owner/Partner)  
123 Charleston Road  
Washington Boro, PA 17592

GEN.	SPEC.
RELEASE	
FN _____	DATE <u>4/3/97</u>
Reviewed by: <u>[Signature]</u>	

Dear Mr. Rohrer:

On February 23, 1997 Food and Drug Administration (FDA) investigator Gregory E. Beichner conducted an inspection of your dairy farm located on 123 Charleston Road in Washington Boro, 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 Food and Drug Administration at the slaughterhouse, [redacted], [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 2, 1996, you sold a cow, back tag #310, for slaughter as human food at [redacted]. United States Department of Agriculture (USDA) testing revealed the presence of 0.95 ppm sulfadimethoxine in the liver and 0.88 ppm sulfadimethoxine in the muscle tissues of the animal. This is considered to be an illegal tissue residue since the tolerance for sulfadimethoxin in edible bovine tissue is 0.10 ppm. The presence of sulfadimethoxin in the edible 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 which are inadequate such that diseased animals and/or medicated animals bearing potentially harmful drug residues are

Warning Letter: Robert H. Rohrer & Sons

likely 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.

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 fifteen (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.

Very Truly Yours,



Diana J. Kolaitis  
District Director  
Philadelphia District

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cc: Dr. Max A. Van Buskirk, Director  
PA State Bureau of Animal Industry  
Agriculture Building  
2301 North Cameron Street  
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa  
USDA Northeast Regional Office  
701 Market Street  
2B South  
Mellon Independence Center  
Philadelphia, PA 19102-1516