



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

448

PHILADELPHIA DISTRICT

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

10/1/97

WARNING LETTER

September 22, 1997

97-PHI-43

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

John D. Whiting, Owner  
New Wilmington Slaughterhouse  
RD #4  
P.O. Box 404  
New Wilmington, PA 16142

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>9/24/97</u>
Reviewed by: <u>[Signature]</u>	

Dear Mr. Whiting:

On August 8, 1997, your firm, New Wilmington Slaughterhouse, located on RD #4 in New Wilmington, Pennsylvania was visited by Food and Drug Administration (FDA) investigator Robert Vaughn in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow you delivered and offered for slaughter for human food at your facility. Additional investigation by the FDA at producer, [REDACTED], has revealed serious violation of Section 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 18, 1997, you picked up an down cow, ear tagged 23VSZ9676, at the [REDACTED] and delivered and offered the animal for slaughter for human food at your firm New Wilmington Slaughterhouse, New Wilmington, Pennsylvania. The subject animal was slaughtered at your facility on or about March 19, 1997. United States Department of Agriculture (USDA) analysis of tissues from this cow revealed the presence of 0.41 parts per million (ppm) and 0.09 ppm penicillin in the kidney and liver tissues respectively. The tolerance for penicillin in edible portions of bovine tissue is 0.05 ppm. The presence of penicillin in edible tissues from your animal causes the food obtained from the animal to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

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New Wilmington Slaughterhouse

Inspection at the [REDACTED] revealed [REDACTED] informed you that the subject down cow was medicated. According to [REDACTED] you told him that since the cow had been medicated, it would only be good for hide. You, however, offered the subject cow for slaughter for human food. [REDACTED] received no payment from you for the cow even though USDA's records indicate that the subject cow's carcass passed USDA inspection. [REDACTED] signed affidavits attesting to the above information.

The violation listed above is not intended to be all inclusive. It is your responsibility to assure that your operations are in compliance with the law. As a dealer or purchaser of animal, you are frequently the individual who introduces or offers for introduction into interstate commerce, an adulterated animal. As such, you share responsibility for violating the Federal, Food, Drug, and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

- 1) implementing a system to identify the animals you purchase with records to establish the traceability to the source of the animal;
- 2) implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,
- 3) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal then it should not be offered for human food, and be clearly identified and sold as a medicated animal.

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.

As a the owner of a facility where livestock is slaughtered for human food, it is your responsibility to assure that the animals you offer for slaughter have not been treated with unapproved veterinary drugs, or if the drugs are approved, that the levels do not exceed established limits. Animals treated with medications must be withheld from slaughter for the appropriate time period.

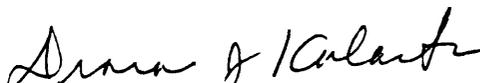
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It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused adulterated (medicated) animals to be offered for slaughter for human food at a slaughterhouse 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

jci

cc: Dr. Max A. Van Buskirk, Director  
PA State Bureau of Animal Industry  
Agriculture Building  
2301 North Cameron Street  
Harrisburg, PA 171

cc: Food Safety and Inspection Service (FSIS)  
106 South 15th Street  
Suite 904  
Omaha, Nebraska 68102  
Attention: Residue Staff

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