



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

PHILADELPHIA DISTRICT

94450d

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

Telephone: 215-597-4390

## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

04-PHI-01

December 23, 2003

Donna Williams, Owner/President  
H.B. Williams, Inc.  
RR #2  
P.O. Box 188  
Kingsley, PA 18826

Dear Ms. Williams:

The U.S. Food and Drug Administration (FDA) Investigator Eric S. Mysokowski conducted an inspection of your dairy farm operation located at RR 2 Box 188, Kingsley, Pennsylvania on August 7-8, 2003. The inspection confirmed that you offered an animal with illegal drug residues for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

Our inspection determined that on or about July 10, 2003 you delivered a bob veal calf identified with back tagged 241, to Wyalusing Livestock Market for sale for slaughter for human food without informing the firm of the medication status of this animal. This animal was slaughtered for human food at Nicholas Meat Packing Company in Loganton, Pennsylvania. U.S. Department of Agriculture (USDA) analysis of kidney tissue samples collected from the animal identified the presence of 22.10 parts per million (ppm) of neomycin. This violation resulted in a USDA Residue Violation Letter issued to you on July 28, 2003.

Neomycin is not approved for use in veal calves intended for processing into veal, and therefore, there is no tolerance for the presence of this drug in edible veal tissue. The presence of neomycin in the kidney from your animal renders the food from the animal adulterated under Section 402(a)(2)(C)(ii) of the Act since the food contains a drug residue that is unsafe within the meaning of Section 512 of the Act.

A food is adulterated under Section 402(a)(4) of the Act “if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health.” As it applies in this case, “insanitary conditions” means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. The insanitary conditions observed at your dairy operation included:

- You lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species, or otherwise in compliance with the extra label use provisions in 21 C.F.R. Part 530.
- You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling, or otherwise in compliance with the extra label use provisions in 21 C.F.R. Part 530.
- You lack an adequate system 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.

You are also adulterating the drug Biosol ® Liquid, a brand of neomycin sulfate, within the meaning of Section 501(a)(5) of the Act in that it is new animal drug under Section 201(v), and is unsafe within the meaning of Section 512 of the Act because the drug was not used in conformance with the approved labeling for such drugs. The manufacturer’s labeling for Biosol ® Liquid states, “Do not use in calves to be processed for veal.” The use of this drug to treat calves intended for processing into veal is contrary to the labeling of this product.

This is your second residue violation within a three month period of operation, the first of which resulted in a USDA Residue Violation Letter issued to you on June 3, 2003. On or about April 28, 2003 you delivered a bob veal calf identified with back tagged 997, to Wyalusing Livestock Market for sale for slaughter for human food without informing the firm of the medication status of this animal. This animal was slaughtered for human food at Nicholas Meat Packing Company in Loganton, Pennsylvania. USDA analysis of kidney tissue samples collected from the animal identified the presence of 117.48 ppm of neomycin and 0.07 ppm of penicillin. Neomycin is not approved for use in veal calves intended for processing into veal, and therefore, there is no tolerance for the presence of this drug in edible veal tissue. In accordance

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with Title 21, Code of Federal Regulations, Part 556.510 (21 CFR 556.510), the tolerance for penicillin in edible bovine tissue is 0.05 ppm.

The above is not intended as an all inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt correction may result in enforcement action without further notice, including seizure and/or injunction. Please notify this office in writing within 15 working days of receipt of this letter 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,

A handwritten signature in cursive script that reads "Thomas D. Gardine". The signature is written in black ink and is positioned above the printed name.

Thomas D. Gardine  
District Director  
Philadelphia District

jci