



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M3313n

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

Telephone: 215-597-4390

WARNING LETTER

December 8, 1999

00-PHI-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marlin S. Irwin
1620 May Post Office Road
Quarryville, PA 17566

Dear Mr. Irwin:

On August 27, 1999, your livestock dealing/hauling business, located at 1620 May Post Office Road in Quarryville, PA, was visited by Food and Drug Administration (FDA) Investigator Michael R. Talley 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 FDA confirmed you offered for slaughter for food a dairy cow, back tag number [REDACTED] which was adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the edible kidney tissue contained 0.12 ppm (parts per million) penicillin.

On or about April 21, 1999, your employee, [REDACTED], a truck driver, picked up a down cow, back tag number [REDACTED] at [REDACTED] dairy farm located in [REDACTED] [REDACTED] delivered the subject down cow for slaughter as human food to [REDACTED] [REDACTED]. The cow was subsequently slaughtered and condemned on April 21, 1999. USDA testing of the animal revealed the presence of 0.12 ppm penicillin in the kidney tissue. The tolerance for penicillin in edible bovine tissue is 0.05 ppm, and the presence of this drug at this level renders the food from the animal adulterated under Section 402(a)(2)(C)(ii) of the Act.

FDA's investigation revealed the producer of the cow contacted you on or about April 21, 1999, when the subject cow went down, and sold you the cow. At that time, the producer verbally informed you that the cow had been medicated within the past three or four days.

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, purchaser, or hauler of an animal, you are frequently the individual who introduces or delivers for introduction into interstate commerce an adulterated animal. As such, you share responsibility for violating the Act. To avoid future illegal residue violations, you should take precautions such as:

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- 1) implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s) and
- 2) 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 you should not offer the animal for human food.

As a cattle dealer/hauler, 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.

We remind you that, on November 29, 1995, FDA issued you a Warning Letter regarding a similar incident in which you knowingly delivered a medicated cow for slaughter for human food. A copy of this letter is enclosed for your information. You also received a letter dated January 4, 1999 regarding an additional incident in which you knowingly delivered a medicated cow for slaughter for human food.

FDA policy continues to be that all persons in the chain of handling an animal, including the producer, livestock dealer/hauler, auctionhouse, and slaughterhouse, are responsible to assure that adulterated animals (including medicated animals) are not delivered to the slaughterhouse to be slaughtered and sold for human consumption. FDA considers these violations to be very serious. Illegal drug residues represent a real potential for harm to people consuming the edible tissues from these animals.

You should take prompt action to correct the above violation 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 knowingly purchased a medicated cow and subsequently sold the animal 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 15 working days, state the reasons for the delay and the timeframe in which correction will be achieved.

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Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the address listed on the letterhead.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Enclosure

cc: Dr. John I. Enck, Director
Bureau of Animal Health Diagnostic Services
PA Department of Agriculture
2301 North Cameron Street
Harrisburg, PA 17120

cc: Manzoor H. Chaudry, DVM, Branch Chief
Residue Staff
FSIS/FO/Technical Service Center
United States Department of Agriculture
Federal Building, Suite 904
106 S. 15th Street
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