



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT  
m778m

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

Telephone: 215-597-4390

WARNING LETTER

July 26, 1999

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Reed A. Luce  
RD #2  
Rockwood, Pennsylvania 15557

Dear Mr. Luce:

On March 3 and 12, 1999, your livestock dealing/hauling business was visited by Food and Drug Administration (FDA) Investigator Gregory E. Beichner 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 at the slaughterhouse, [REDACTED] and [REDACTED] has revealed serious violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about January 4, 1999 you delivered a cow, back tagged [REDACTED] for sale for slaughter for human food at [REDACTED]. The subject cow was slaughtered on January 5, 1999. USDA analysis of tissue samples collected from the animal identified the presence of 25.00 ppm (parts per million) sulfamethazine in the kidney tissue and 9.10 ppm sulfamethazine in the muscle tissue. This is considered a violative tissue residue since the tolerance for sulfamethazine in edible bovine tissue is 0.10 ppm. The presence of sulfamethazine in edible tissue from your animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act because it contains a new animal drug that is unsafe within the meaning of Section 512.

Our investigation at [REDACTED] revealed that there were at least two metal ear tags on the subject cow which you identified with back tag [REDACTED]. Neither of these two metal ear tags were found on the subject cow with back tag #460 by USDA at [REDACTED].

██████████ Our investigation at your facility determined that there is the potential for misidentification of animals that your firm picks up for delivery for slaughter. You provided the following information regarding your firm's procedures and practices for identifying animals:

Cows are back tagged either at the farm where they are picked up or upon arrival at your facility.

It is commonplace to make several stops to pick up cows and have commingled loads upon final delivery to your facility.

There is no policy in place to document tags or markings that are already present on cows which are picked up by your firm.

You are the only individual permitted to assign and attach back tags to cows sent to slaughter for human food to ensure proper identification. As a result, when cows are picked up by someone other than you, back tags may not be assigned to commingled cows until arrival at your facility.

Our inspection determined that the subject ██████████ cow may not have been assigned back tag ██████████ until its arrival at your facility commingled with other cows.

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 animals, 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 accurate 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

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drugs from edible tissues. If you do not want to hold the medicated animal, then it should not be offered 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.

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 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 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.

Sincerely,



Thomas D. Gardine  
District Director  
Philadelphia District

jci