



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

m2269n

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

Telephone: 215-597-4390

WARNING LETTER

December 22, 1998

99-PHI-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ruby J. McNichol, Owner
McNichol's Dead and Crippled Livestock
P.O. Box 88
1193 Perry Highway
Portersville, Pennsylvania 16051

Dear Ms. McNichol:

On November 10, 1998 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your livestock hauling operation located in Portersville, 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 FDA at [REDACTED] has revealed serious violation of Sections 402(a)(2)(C)(i)(i) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about September 25, 1998, your husband, Robert McNichol delivered a down cow with suspect ear tag #M154 and bang ear tag #23DXT3731 for sale for slaughter as human food at [REDACTED]. The subject cow was slaughtered for human food at this facility on or about the September 25, 1998. USDA testing revealed the presence of 0.07 parts per million (ppm) penicillin in the kidney tissue of your animal. The tolerance for penicillin in edible bovine tissue is 0.05 ppm. The presence of penicillin in the kidney 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 that permit those bearing potentially harmful drug residues 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

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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.

Our inspection revealed that you have no process in place to maintain the identification and medication status of animals delivered for slaughter for human food. As a result, animals with violative drug residues cannot be traced to their source. Additionally, you do not determine the medication status of animals you deliver for slaughter.

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 or hauler of an 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 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 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 knowingly purchased a medicated cow and subsequently sold the animal to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you

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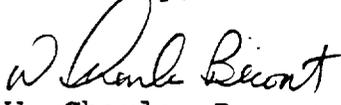
responsible for a violation of the Act.

The FDA has sent your firm letters in the past regarding other medicated animals which your firm has delivered for slaughter for human food. These letters are enclosed for your information and review.

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,


W. Charles Becoat
Acting District Director
Philadelphia District

jci

Enclosures:

- (1) Letter dated 8/10/98
- (2) Letter dated 7/11/95

cc: Dr. John I. Enck, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

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