



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

M 990N

4/23/97

PHILADELPHIA DISTRICT

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

Telephone: 215-897-4390

WARNING LETTER

June 11, 1997

97-PHI-29

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

| | |
|---|---------------------|
| GEN. | SPEC. |
| RELEASE | |
| F# _____ | DATE <u>6/13/97</u> |
| Reviewed by: <u>Jane M. [Signature]</u> | |

Terry A. Weyandt
P.O. Box 238
Claysburg, Pennsylvania 16625

Dear Mr. Weyandt:

On February 19, 1997, June 28, 1996, and December 15, 1995, your livestock dealing/hauling business, located in Claysburg, Pennsylvania was visited by Food and Drug Administration (FDA) investigator Robert T. Vaughn in response to a United States Department of Agriculture (USDA) reports regarding illegal drug residues in calves you offered for sale and slaughter for human food. During each inspection Mr. Vaughn met with and spoke with you regarding each violative drug residue. Mr. Vaughn also conducted inspections at the respective slaughterhouses involved in these violative tissue residues, [REDACTED], and [REDACTED], to determine their handling and identification of the subject calves. Our inspections have revealed serious violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Food and Drug Administration inspections have determined that since August 16, 1995 you have delivered ten (10) calves for slaughter for human food. The inspections have documented that you cannot determine with any certainty the producers of these animals. United States Department of Agriculture (USDA) analytical testing has revealed violative drug residues in the edible tissues of the

subject animals as follows:

| <u>USDA Sample #</u> | <u>ID</u> | <u>Slaughter Date</u> | <u>Drug Residue/tissue (ppm)</u> |
|--------------------------|-----------|---------------------------|--|
| 284100 | no tag | 8/22/96 [REDACTED] | 0.33 ppm sulfamethoxazole/liver 1.70 ppm sulfamethoxazole/muscle |
| 328612 | 23MO3333 | 8/21/96 [REDACTED] | 5.70 ppm gentamicin/kidney |
| 328601 | no tag | 7/18/96 [REDACTED] | 0.21 ppm gentamicin/liver 1.09 ppm gentamicin/kidney |
| 328602 | no tag | 7/18/96 [REDACTED] | 0.52 ppm penicillin/liver 0.63 ppm penicillin/kidney 0.07 ppm gentamicin/liver 0.49 ppm gentamicin/kidney |
| 328603 | no tag | 7/18/96 [REDACTED] | 2.54 ppm penicillin/liver 5.62 ppm penicillin/kidney |
| 335292 | 23KS5158 | 7/8/96 [REDACTED] | 4.02 ppm streptomycin/kidney |
| 335281 | no tag | 2/13/96 [REDACTED] | 88.9 ppm chlortetracycline/kidney 67.2 ppm chlortetracycline/liver 8.97 ppm chlortetracycline/muscle |
| 759752 | 23MO6002 | 8/16/95 [REDACTED] | 0.50 ppm penicillin/kidney 0.43 ppm penicillin/liver |
| 759753 | 23MO6003 | 8/16/95 [REDACTED] | 0.06 ppm penicillin/liver |
| 759754 | 23MO6004 | 8/16/95 [REDACTED] | 0.24 ppm penicillin/kidney |
| 759758 | 23MO5849 | 8/16/95 [REDACTED] | 0.96 ppm penicillin/kidney 0.11 ppm penicillin/liver |

[REDACTED]

Gentamicin is not approved for use in dairy cattle, and therefore, there is no tolerance for the presence of this drug edible bovine

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tissue. The tolerance for presence of the other drugs listed above in edible bovine tissue are as follows: penicillin, 0.05 ppm; sulfamethoxazole, 0.1 ppm; streptomycin, 2.0 ppm; and chlortetracycline, 12.0 ppm kidney, 6.0 ppm liver, 2.0 ppm muscle, for the tetracycline class of drugs which includes chlortetracycline. The presence of these drugs in the edible tissues from your animals at the concentration levels detected renders the food from the animals 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.

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 you deliver for slaughter for human food have been withheld from slaughter for 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.

The violations 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

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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 obtained medicated calves and delivered and subsequently sold the animals 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.

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 17120

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