



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN 1125547

Public Health Service

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Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

March 22, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Danny Ritchie
Rt. 1, Box 224
Broadway, Virginia 22815

Re: Case No. 98-0365-VA

Dear Mr. Ritchie:

A representative of the State of Virginia, under an agreement with the Food and Drug Administration (FDA), conducted an investigation of your operation located in Broadway, Virginia on December 3, 10 and 28, 1998. The investigation confirmed that you offered a cow for sale for slaughter as human food that contained an illegal drug residue. This causes such food to be adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about October 9, 1998, you sold a cow identified as originating from your premises, for slaughter as human food, at [REDACTED]. Analysis by the United States Department of Agriculture's (USDA) of tissue collected from that animal disclosed the presence of 0.17 parts per million (ppm) penicillin in the kidney. The limit established for residues of penicillin in edible tissues of cattle is 0.05 ppm (Title 21, Code of Federal Regulations, Section 556.510). The presence of this drug in edible tissues from this animal causes the food to be adulterated. You should have received a letter dated November 12, 1998 from the USDA concerning this matter.

The above violation is your fourth residue violation in calendar year 1998. The USDA has reported illegal residues in three other cows offered for slaughter for human food that were identified as originating from your premises. USDA analysis of tissues collected from these animals disclosed the presence of the following drug residues:

- 0.12 ppm penicillin in the kidney from a cow you sold for slaughter as human food at [REDACTED] on or about September 30, 1998;
- 1.10 ppm gentamicin in the kidney of a cow you sold for slaughter as human food at [REDACTED], on or about May 5, 1998; and

- 0.84 ppm gentamicin in the kidney of a cow you sold for slaughter as human food at [REDACTED], on or about April 28, 1998. No tolerance has been established for residues of gentamicin in the edible tissues of cattle.

You should have received letters dated June 10, 1998 and October 13, 1998 from the USDA concerning these violations.

The State's investigation found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack documentation to show that animals have been treated, and you lack an adequate system to assure that medicated animals have been identified and withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, injunction, and/or prosecution.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers the adulterated animal for introduction into interstate commerce. As such, you share the responsibility for violating the Act. To avoid future illegal tissue violations, you should take precautions such as:

1. implementing a system of records to identify the animals you purchase to establish 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 drugs from edible tissue. If you chose not to hold the medicated animal, then it should not be offered for human food, and should clearly be identified and sold as a medicated animal.

You should notify this office in writing within 15 working 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 reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Mr. Danny Ritchie
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Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

cc: USDA/FSIS
Northeastern Region
Mellon Independence Center
701 Market St., 2-B South
Philadelphia, PA 19106-1576

cc: Virginia Department of Agriculture and Consumer Services
Division of Consumer Protection
Office of Meat & Poultry Services
P.O. Box 1163
Richmond, VA 23218