



DEPARTMENT OF HEALTH AND HUMAN SERVICE

CFN: 1125712

HFI-35

Public Health Service

M3099M

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

October 25, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. David Rapp, Owner
Rapp's Dairy
P.O. Box 265
Renick, West Virginia 24966

Dear Mr. Rapp:

An investigation of your dairy cow operation located in Renick, West Virginia, was conducted by Food and Drug Administration (FDA) investigators on October 5, 1999. The investigation confirmed that you offered an animal 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). In addition, you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about April 2, 1999, you sold a dairy cow identified with ear tag number 5228 (back tag number 52CG6816) for slaughter as human food at [REDACTED]. You delivered the cow to [REDACTED], on April 1, 1999. [REDACTED] subsequently slaughtered the cow for use as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 0.08 ppm penicillin in the kidneys. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of dairy cows (Title 21, Code of Federal Regulations, Part 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

This is not the first time USDA has detected an illegal drug residue in an animal identified as originating from your dairy farm. On December 23, 1998, USDA reported that their analysis of tissue samples collected from a dairy cow with back tag number 52LG4396 identified the presence of 0.20 ppm penicillin in the liver and 0.06 ppm penicillin in the kidney of this animal. This animal was also offered for sale for slaughter as human food to [REDACTED]. You should have received a letter from USDA dated May 21, 1999 regarding the above residue violations.

Our investigation found that you hold animals under conditions that permit potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; for assuring that medicated animals have been identified; and for assuring that animals medicated by you have been 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 within the meaning of Section 402(a)(4) of the Act.

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In addition, you failed to maintain adequate medication and treatment records and to notify the buyer that animals from your farm were medicated. An FDA-483, Inspectional Observations, was issued to you at the conclusion of the FDA inspection.

You are adulterating the drug penicillin used by your farm on dairy cows within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. Your use of this drug without following the labeled withdrawal period causes the drug to be unsafe.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

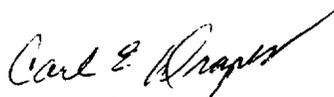
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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 caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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 to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed 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, ext. 14.

Sincerely,



Carl E. Draper
Acting District Director

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cc: USDA/FSIS/FO
5601 Sunnyside Avenue
Suite 1-2288 B
Beltsville, Maryland 20705-5200

West Virginia Department of Agriculture
Meat and Poultry Division
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0170