

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1204 B

Refer to:

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

February 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. Denham Crum
Crumland Farm
7612 Willow Road
Frederick, Maryland 21702

Dear Mr. Crum:

An investigation at your dairy operation located in Frederick, Maryland was conducted by a representative of the State of Maryland under contract to the Food and Drug Administration on January 8, 1997. The investigation confirmed that you offered a dairy cow for sale for slaughter as human food that was adulterated within the meaning of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as the cow contained an illegal drug residue, and you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about November 19, 1996, you sold a cow identified as originating from your premises, for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 8.00 parts per million (ppm) Sulfadimethoxine in the liver tissue and 1.60 ppm in the muscle tissue. A tolerance of 0.10 ppm has been established for residues of Sulfadimethoxine in the edible tissue of cattle (Title 21, Code of Federal Regulations, Section 556.640). The presence of this drug in edible tissues from this animal causes the food to be adulterated. You should have received a letter dated January 8, 1997, from USDA concerning this matter.

The investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system to assure that drugs are used in accordance with labeled directions and that medicated animals have been withheld from slaughter for appropriate periods of time to deplete drug residues from edible tissues. Foods from animals held under such conditions are adulterated.

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You adulterated the drug Sulfadimethoxine in dairy cows within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Failure to follow the labeled withdrawal period causes the drug to be unsafe.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for violations 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.

The aforementioned violations are not intended to be an all-inclusive list. 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 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.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken and/or plan to take to prevent further violations. 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.

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.

Sincerely,



George R. Brubaker, Ph.D.
Acting Director, Baltimore District

Mr. J. Denham Crum

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

cc: Maryland Department of Agriculture
Animal Health
50 Harry S. Truman Parkway
Annapolis, Maryland 20742