



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

April 7, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas W. Moreland, Dairy Program Manager
University of Maryland
Clarksville Facility
4240 Folly Quarter Road
Ellicott City, Maryland 21042

Dear Mr. Moreland:

An investigation of your dairy operation located in Ellicott City, Maryland, conducted by our investigators on March 16 & 24, 2000, confirmed that you offered an animal for sale for slaughter as human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On or about October 5, 1999, you sold for slaughter as human food, a dairy cow identified with back tag number 4332, at the [REDACTED] where it was purchased by the [REDACTED] and slaughtered for use as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 0.20 ppmv/Penicillin and 4.20 ppmv/Gentamicin in the kidney tissues.

Our investigation also found that you hold animals under conditions that may allow diseased animals and/or medicated animals bearing potentially harmful drug residues to enter the food supply. For example:

1. Records are not maintained showing the treatment of a dairy cow (back tag #4332) with Gentamicin, the date of the medication, the dosage administered, and drug pre-slaughter withdrawal times.
2. Label directions were not followed for the treatment of a dairy cow (back tag #4332) with Penicillin G Procaine, which was administered in excess of the recommended dosage level.
3. A system is not in place for the review of treatment records prior to offering an animal for slaughter as human food, to assure that drugs have been used only as directed and the appropriate withdrawal times have been observed.

Food from animals held under conditions such as those listed above are adulterated within the meaning of the FD&C Act. An FDA-483, Inspectional Observations, was issued to you at the conclusion of the FDA inspection. A copy is enclosed for your information. This 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 FD&C Act.

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 FD&C 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 FD&C Act.

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You should notify this office in writing, within 15 working days of receipt of this letter, 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 timeframe within which the correction will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Ms. Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, telephone number (410) 962-3591, extension 143.

Sincerely,



Roberta F. Wagner
Acting District Director

Enclosure: FDA-483

Cc: Dr. Thomas Fritz
Dean of the College of Agriculture
1106 Symons Hall
College Park, Maryland 20742