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Food and Drug Administration  
Baltimore District Office  
Central Region  
6000 Metro Drive, Suite 101  
Baltimore, MD 21215  
Telephone: (410) 779-5454  
FAX: (410) 779-5707

03-BLT-07

January 10, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Robert S. Wilcom, Owner  
3940 Tabler Road  
Frederick, Maryland 21701

Dear Mr. Wilcom:

An investigation of your dairy farm located at 3940 Tabler Road, Frederick, Maryland, by a Food and Drug Administration (FDA) investigator on November 13 & 26, 2002 confirmed that you offered a cow for sale for slaughter as food, in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On or about June 12, 2002, you sold a cow identified with back tag number 51FS1103 to [REDACTED], where it was subsequently sold to [REDACTED]. The cow was then slaughtered for use as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from the cow confirmed the presence of 1.00 ppm Sulfadimethoxine in the liver tissue of the cow, and 0.70 ppm Sulfadimethoxine in the muscle tissue. A tolerance of 0.1 parts per million (ppm) has been established for residues of Sulfadimethoxine in the uncooked edible tissues of cattle per Title 21, Code of Federal Regulations, Part 556.640. The presence of this drug in excess of established tolerance levels in the edible tissues of cattle causes the food to be adulterated.

In addition, an inspection conducted by the State of Maryland on December 18, 2001 revealed another cow treated on your farm and subsequently sold for slaughter for use as human food (Tag #146791) contained levels of Sulfadimethoxine in the liver tissue (1.09 ppm) and in the muscle tissue (1.84 ppm).

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

- You do not maintain medication/treatment records that identify the animal, the date of treatment, the drug used, dosage administered, and the drug withdrawal times.
- You do not have a system in effect for the review of treatment records to assure that drugs have been used as directed in the labeling and that the appropriate withdrawal times have been observed.
- Terramycin (Oxytetracycline HCl) observed in the drug storage are on your farm, and used in the treatment of cattle, was past the expiration date of April 2001.

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An FDA 483, Inspectional Observations, was issued to you at the conclusion of the inspection listing the objectionable conditions observed during the inspection.

The above is not intended to be an all-inclusive list of the violations that may be occurring at your farm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the food 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 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.

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 documentation demonstrating that corrections have been made.

Your response should be directed to Ms. Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, telephone number (410) 779-5417.

Sincerely,



Lee Bowers  
Director, Baltimore District