DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN 1125205
FEI 3001236266

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Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3591x143
FAX: (410) 962-2307

01-BLT-34

June 22, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. Richard A. Edwards, President
Oakland View Farms
14545 Oakland Road
Ridgely, Maryland 21660

Dear Mr. Edwards:

An investigation of your dairy cow operation located at 14545 Oakland Road, Ridgely, Maryland, conducted by a Food and Drug Administration (FDA) investigator on May 30-31, 2001, confirmed that you offered veal calves for sale for slaughter as human food that were treated with Neomycin (Biosol). Neomycin is not approved for use in veal calves. The presence of neomycin in the edible tissues of the calves renders the food from the animals adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), because the edible tissues contain a new animal drug that is unsafe within the meaning of Section 512 of the FD&C Act.

On or about October 18, 2000 and January 24, 2001, you sold for slaughter as human food, two veal calves at the [redacted] and/or [redacted] U.S. Department of Agriculture (USDA) analysis of tissue samples collected from the two calves revealed the presence of Neomycin residues in the kidney tissues of the slaughtered calves of 21.24 ppm and 16.16 ppm, respectively. The use of Neomycin in the treatment of veal calves is not allowed, per Title 21, Code of Federal Regulations (21 CFR), Part 520.1485. The presence of this drug in edible tissue of the calves causes the food to be adulterated within the meaning of Section 402(a)(2(C)(ii) of the FD&C Act. A copy of Part 520.1485 is enclosed for your review.

Our investigation also found that your operation is conducted in a manner that may allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example:

- You do not identify treated animals to assure they are not sold for slaughter unless all the appropriate conditions for sale are met;
- You do not maintain medication/treatment records which identify the animal, the date of medication, the drug use, the dosage administered, and the time period to withhold from sale;
- Labeling directions are not followed to assure that veal calves are being treated by an approved method. For example, the medicated feed and Biosol are labeled "DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL;"

- You do not have a system in effect for the review of records to assure that medicated animals do not enter the market place unless the acceptable time frame for withdrawal has been met.

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 Act.

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

The above violations are not intended to be an all-inclusive list of violations observed at your dairy farm. 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.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to bring your dairy operations into compliance with the law. Your response should be addressed 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,

Lee Bowers
Director, Baltimore District

Enclosures