DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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September 30, 2004

WARNING LETTER CIN-WL-04-22854
Sent Via Federal Express

Dean E. Zimmer, Owner
Zimmer View Dairy
700 Zimmer Road
Marietta, OH 45750

Dear Mr. Zimmer:

On July 8, 9, and 19, 2004, U.S. Food and Drug Administration investigators conducted an inspection of your operations at 700 Zimmer Road, Marietta, Ohio. The inspection confirmed that you offered an animal for sale for food that was adulterated within the meaning of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Food, Drug and Cosmetic Act (the Act). A food is adulterated under section 402(a)(2)(C)(ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of section 512(a) of the Act.

On or about March 16, 2004, you sold a cow, dealer back tag #[redacted], to [redacted], a cattle dealer. [redacted] sold this cow through [redacted] to [redacted]. [redacted] took this cow to [redacted], [redacted] for slaughter on March 18, 2004. The USDA laboratory's analytical report #437336 for the cow with dealer back tag [redacted] shows that the kidney tissue of the referenced animal contained 21.22 ppm Oxytetracycline and the liver tissue contained 6.10 ppm Oxytetracycline. The established tolerance levels for this drug in cattle intended for slaughter as human food in the kidney tissue is 12 ppm and in the liver tissue is 6 ppm (Title 21, Code of Federal Regulations, Section 556.500b). The lab report also shows that the muscle tissue of the referenced animal contained 2.55 ppm Sulfadimethoxine, and the liver tissue contained 4.33 ppm Sulfadimethoxine. The established tolerance level for this drug in is 0.1 ppm (Title 21, Code of Federal Regulations, Section 556.640). The presence of this drug in excess of the established tolerance causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our inspection also revealed that you hold animals under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. Food from animals held under such conditions are adulterated under section 402(a)(4) of the Act. For example our investigator noted the following conditions at your farm:

1. You lack an adequate system for assuring that the medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

2. You lack a system for tracking the medication given to the animals.

3. You lack an inventory system for determining the quantities of drugs used to medicate your livestock.

This letter may not list all the deviations at your 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 be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to violate the Food Drug & Cosmetic Act. The fact that you offered an adulterated animal for sale, which was slaughtered and held for sale in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations. Failure to promptly correct these deficiencies may result in regulatory action being initiated by the Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Please notify this office within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Gina M. Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District