



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to FEI: 1000512356

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Food and Drug Administration  
Baltimore District Office  
Central Region  
6000 Metro Drive  
Suite 101  
Baltimore, MD 21216  
Telephone: (410) 779-5454  
FAX: (410) 779-5705

03-BLT-24

July 30, 2003

**WARNING LETTER**

**Via Certified Mail**  
**Return Receipt Requested**

Mr. Carl L. Diller, Owner  
Carl L. Diller Dairy Farm  
14634 Smithburg Pike  
Hagerstown, Maryland 21742

Dear Mr. Diller:

The Food and Drug Administration (FDA) conducted an investigation at your dairy operation located at the above address from April 17-25, 2003 and confirmed that you offered an animal for sale as slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), and that you have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 22, 2002, you sold a dairy cow, identified by back number 23XX2618, for slaughter to Zullinger Packing Co., Waynesboro, Pennsylvania. U.S. Department of Agriculture analysis of kidney tissue samples collected from that animal identified the presence of 0.15 parts-per-million (ppm) of penicillin. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible uncooked tissues of dairy cows per Title 21, Code of Federal Regulations, Section 556.510(a). The presence of this drug in edible tissue from the animal in question causes that food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. In addition, you do not maintain adequate treatment records. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You also failed to adhere to the 10-day withdrawal time for the Agri-Cillin brand of penicillin that your firm used to treat dairy cow number 23XX2618. By not using this drug in conformance with its approved labeling, or the regulations for Extralabel Drug Use in Animals contained in 21 CFR Part 530, you caused the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

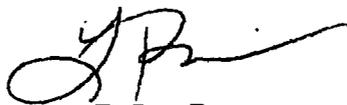
It is your responsibility to assure that your operations are in compliance with the law. It is not necessary for you to personally ship an adulterated food or drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of food or a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct these violations and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. Possible actions include, but are not limited to, seizure, injunction and/or criminal prosecution.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Branch Director, at the letterhead address above. If you have questions regarding any issue in this letter, please contact Mr. Sooter at (410) 779-5412.

Sincerely,



R. Lee Bowers  
Director, Baltimore District