



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Baltimore District Office  
Central Region  
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Baltimore, MD 21215  
Telephone: (410) 779-5454  
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04-BLT-18

April 22, 2004

**WARNING LETTER**

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

Mr. William M. Brinsfield, Jr., Owner  
Udder Delight Dairy  
12885 Church Lane  
Cordova, Maryland 21625-2001

Dear Mr. Brinsfield,

An investigation at your dairy operation, doing business as Udder Delight Dairy, located at 12885 Church Lane, Cordova, MD, conducted by our investigators John Dan and Heath Harley, on January 12-30, 2004, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 301(a), 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and that you have either caused a new animal drug to become adulterated within the meaning of Section 501(a)(5) of the FD&C Act or caused a medicated feed to become adulterated within the meaning of Section 501(a)(6) of the FD&C Act .

On or about October 3, 2003, you sold a bob veal calf, identified with back tag #356, for slaughter as human food to [REDACTED]. The United States Department of Agriculture (USDA) analysis of kidney tissue samples collected from that animal identified the presence of 2.50 parts per million (ppm) of neomycin. In accordance with Title 21, Code of Federal Regulations (CFR), Parts 558.364 and 556.430, there is no established tolerance level for neomycin sulfate in the edible tissues of veal calves. The presence of this drug in the kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the FD&C Act. This violation resulted in a USDA Residue Violation Letter issued to you on November 12, 2003.

A food is adulterated within the meaning of Section 402(a)(4) of the FD&C Act, "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health". Our investigation found that you hold animals under insanitary conditions whereby diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. Insanitary conditions exist in that you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those animals; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and 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. Foods from animals held under such conditions are adulterated.

The insanitary conditions observed at your dairy operation included:

- you fail to have a system to control the administration of drug treatments to your animals;
- you fail to maintain drug treatment records for all medicated animals; and
- you fail to systemically review treatment records prior to offering an animal for slaughter for human food to assure that drugs have been used only as directed and that appropriate withdrawal times have been observed. If you chose not to hold the medicated animal, then it should not be offered for human food, and should clearly be identified and sold as a medicated animal.

As indicated by the affidavit signed by William Brinsfield, III, the bull calf in question was probably given neomycin oral solution mixed with drinking water, normally given to heifer calves. The affidavit also acknowledges that it is possible that the calf could have been accidentally fed medicated milk replacer that contains neomycin and oxytetracycline. Therefore, you either adulterated the new animal drug within the meaning of Section 501(a)(5) or adulterated the medicated milk replacer, normally fed to heifer calves, within the meaning of Section 501(a)(6) of the FD&C Act .

This is your third tissue residue violation within a sixteen month period of operation. On or about January 24, 2003, you sold a bob veal calf (back tag #360) for slaughter to [REDACTED]. USDA analysis of liver tissue samples collected from that animal identified the presence of 0.65 ppm of gentamicin. Additionally, on or about June 7, 2002, you sold a dairy cow (back tag #23NH9491) for slaughter to [REDACTED]. USDA analysis of the kidney tissue samples collected from that animal identified the presence of 0.61 ppm of gentamicin. There is no established tolerance level for gentamicin in edible tissues of cattle [21 CFR 556.300]. The presence of this drug in the kidney and liver tissues of those animals caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the FD&C Act. As a result of these residue violations, you received an FDA Untitled Letter, dated December 9, 2003, and USDA Residue Violation Letters, dated March 20, 2003 and June 19, 2002. No response to the December Untitled Letter has been received from you by this office.

This letter may not list all of the violations at your dairy operation. It is your responsibility to ensure that all requirements of the FD&C Act and applicable regulations are met. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these 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 corrections will be completed. Your response should address each discrepancy brought to your attention during the investigation and in this letter, and should include copies of any documentation demonstrating that corrections have been made.

Page 3 - Mr. William M. Brinsfield, Jr., Owner, Udder Delight Dairy  
April 22, 2004

Please direct your reply to Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. B.', with a long horizontal stroke extending to the right.

Lee Bowers  
Director, Baltimore District

Cc: Julie A. Cornett, D.V.M  
Branch Chief, Standards and Procedures  
USDA/FSIS/Technical Service Center  
Landmark Center, Suite 300  
1299 Farnam Street  
Omaha, Nebraska 68102