



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

October 31, 2001

WARNING LETTER
CIN-02-WL-10838

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Randy J. Winner
Four Star Dairy
14171 Willowdell Road
Yorkshire, Ohio 45388

Dear Mr. Winner:

The U. S. Food and Drug Administration (FDA) was informed by the USDA that tissue from a cow identified with the dealer tag number: 31ZY 3336 and slaughtered on or about August 14, 2001, was found to contain an illegal drug residue. The USDA laboratory's analytical report #429238, shows that the kidney tissue of the referenced animal contained 144.54 ppm Neomycin. The established tolerance level for this drug in cows intended for slaughter as human food is: 7.2 ppm.

This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C) (ii), and 402 (a)(4). On October 31, 2001, an investigation at your dairy operation conducted by an investigator from the Food & Drug Administration and an investigator from the Ohio Department of Agriculture determined that this cow belonged to you. This investigation also documented that you medicate animals with the prescription drug, Neomycin, in violation of Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C 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 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your failure to abide by the withdrawal time specified by [REDACTED] DVM for this drug. A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, i.e., which in this case is the withdrawal time specified by [REDACTED]. Therefore, the drug becomes unsafe for use within the meaning of Section 512(a)(1)(B).

You also falsely provided a "Drug Residue Free" guarantee to the buyer of this animal. Consequently, you caused an animal bearing illegal drug residues, to be slaughtered for food. In addition, on 6/27/01, the Ohio Department of Agriculture inspected your operation due to illegal levels of Neomycin residue in two bob veal calves from your farm that were sent to slaughter for food on or about January 31, 2001 and on or about February 7, 2001.

The FD&C Act is a strict liability statute, which requires anyone in a position of responsibility, with the authority and power to prevent the violation to exercise the necessary care to prevent the violation. It is a felony to intentionally offer misleading information that results in a violation of the FD&C Act. For your information, included with this letter are two (2) notices that many auction markets in the state of Ohio have posted in an effort to prevent violations of the Food Drug and Cosmetic Act. These notices provide information regarding your responsibility under the Food Drug and Cosmetic Act and how you can be held accountable.

You need to 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 caused the adulteration of an animal, which was slaughtered for food, in addition to adulterating a prescription drug after shipment in interstate commerce, is sufficient to hold you responsible for violations of the Act.

You are hereby requested to come to the Cincinnati District Office for an informal meeting. This will provide you the opportunity to present the Food and Drug Administration (FDA) information as to the corrections you have made to prevent future violations of the FD&C Act. Your failure to promptly implement adequate corrections to prevent additional violations of the FD&C Act may result in further regulatory action without additional notice. This action could include seizure and/or injunction.

You should contact Mr. David Radle, Tissue Residue Monitor at the Cincinnati District Office within the next 15 days to schedule a date for this meeting. Mr. Radle can be reached at tel. no. (513) 679-2700 ext: 124 between the hours of 8:00 AM & 4:30 PM Monday through Friday.

Sincerely,


Henry L. Fielden
District Director
Cincinnati District

Enclosure