



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

1141 Central Parkway
Cincinnati, OH 45202-1097

October 15, 1997

WARNING LETTER
CIN-WL 98-17

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Rodney W. Royer
11000 Lautenschlager Rd.
Apple Creek, Ohio 44408

Dear Mr. Royer:

The Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow identified with the back tag number: 451, and slaughtered on or around 7/10/97, was found to contain an illegal drug residue. The USDA laboratory's analytical report #280257, shows that the liver and kidney tissues of the referenced animal contained Penicillin at levels of 0.27 and 1.20 ppm, respectively. The tolerance established for this drug is: 0.05 ppm. This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(D), and 402 (a)(4) and Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). An investigation at your dairy operation conducted by our investigator on September 10-24, 1997, determined that this cow belonged to you.

A food is adulterated under Section 402 (a)(2)(D) 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 lack of records for animals which you medicate. Consequently, you failed to assure that animals to which you have administered medication such as Penicillin have been withheld from slaughter for an appropriate period of time sufficient to deplete any potentially hazardous residue of the drug. As a result, a medicated animal bearing possibly harmful drug residues was likely to enter the food supply.

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, thereby making it unsafe within the meaning of Section 512(a)(1)(B). In this case, you failed to follow procedures adequate to assure that the drug, Penicillin, was used according to the directions contained in the drug's labeling.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods which you distribute, are in compliance with the law. For your reference, we have enclosed a booklet addressing residue prevention.

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Please notify this office within fifteen (15) working days from the receipt of this letter of the specific steps that you have taken to correct the noted violations. We also request that you include in this notification, an explanation of each step being taken to prevent the recurrence of similar violations in the future. If your corrective action can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Failure to promptly implement adequate corrections may result in further regulatory action such as injunction, without additional notice.

Your response should be directed to the U.S. Food and Drug Administration, Cincinnati District Office, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

A handwritten signature in black ink, appearing to read "Diana J. Kolaitis". The signature is stylized with large, flowing loops and a prominent initial "D".

Diana J. Kolaitis
District Director
Cincinnati District

Enclosure