



DEPARTMENT OF HEALTH & HUMAN SERVICES

MORLOCK

HFI-35

5/8/97  
e/f

Public Health Service  
Food and Drug Administration  
CINCINNATI DISTRICT OFFICE

1141 Central Parkway  
Cincinnati, OH 45202-1097

April 22, 1997

WARNING LETTER  
CIN-WL 97-327

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Thomas Morlock  
10436 Jeffery Rd.  
West Salem, Ohio 44287

Dear Mr. Morlock:

The Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow identified with the back tag number: 23SE0877, and slaughtered on or around 1/17/97, was found to contain an illegal drug residue. The USDA laboratory's analytical report #284009, shows that the kidney tissue of the referenced animal contained 1.30 ppm Gentamycin. There is no tolerance established for this drug in cows intended for slaughter as human food. 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 March 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 held an animal which was ultimately offered for sale for food, under conditions which are so inadequate that 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). Gentamycin has not been approved for use in cattle, therefore, you adulterated the drug through its use on this animal.

The above is not intended to be an all inclusive list of violations. This is also the second time that you have been warned about the inappropriate use of Gentamycin and your lack of records for the animals you medicate. The FDA previously notified you that these acts were in violation of the Food Drug and Cosmetic Act in a warning letter dated December 22, 1995. The fact that the previous violation occurred in a calf, does not exonerate you from this violation.

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As the owner of Morlock Farms, you are responsible for assuring that your operation and the foods you distribute, will not be adulterated with illegal drug residues. For your reference, we have enclosed a booklet addressing residue prevention.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in 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 without such as seizure and/or 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 "John R. Marzilli", with a stylized flourish at the end.

John R. Marzilli  
District Director  
Cincinnati District

Enclosure