



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

HFI-35  
PURGED

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One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 279-1675  
FAX: (781) 279-1742

WARNING LETTER  
NWE-37-00W

VIA FEDERAL EXPRESS

September 5, 2000

Mr. Andy Davis, Owner  
Davis Dairy Farm  
261 River Road  
Sterling, CT 06377

Dear Mr. Davis:

An investigation of your dairy farm located in Sterling, CT was conducted by our investigators on May 2, 2000. This investigation confirmed that you offered an animal for sale for slaughter as food in violation of sections 402 (a) (2) (C) (ii) and 402 (a) (4) of the Federal Food, Drug, and Cosmetic Act, and that you may have caused animal drugs to become adulterated within the meaning of Section 501 (a) (5).

In late January 2000, you sold a dairy cow, identified by farm tag 199 Amber and back tag 16CA/9398 for slaughter as human food to animal dealer Joseph Mancini of Putnam, CT. Mr. Mancini subsequently transported this animal for slaughter to Taylor Packing, Co., Wyalusing, PA. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the liver of the animal at a level of 3 ppm and in the kidney at a level of 8 ppm. Gentamicin is not approved for use in cattle therefore there is no established tolerance for residues of gentamicin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal cause the food to be adulterated.

Our investigation also found that you hold animals under conditions which are inadequate to ensure that diseased animals and/ or medicated animals bearing potentially harmful drug residues are prevented from entering the food supply. Specifically, you fail to keep medication records that identify the amount of drug administered and that allow you to document and adhere to the proper withdrawal time to permit depletion of potentially hazardous residues from the edible tissues. You also fail to maintain drug inventory records and you store and use drugs beyond their expiration date. Food from animals held under these conditions is adulterated.

You are adulterating the drug gentamicin that your firm uses on dairy cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with the approved conditions of use. Gentamicin is not approved for use in dairy cattle. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision

based on a valid veterinarian/client/patient relationship, no residue occurs, and other conditions, described fully in 21 Code of Federal Regulations Part 530, have been met. In addition, this drug product has a 1998 expiration date. The potency, safety and reliability of drug products cannot be assured after it expires. Use of the drug well past the expiration date is also contrary to the approved conditions of use.

This letter is not intended to be 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 food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure or/ and injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse engaged in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should promptly notify this office in writing describing the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrections cannot be completed promptly, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to David K. Elder, Director of Compliance, at the address noted above. If you have any questions concerning this matter, please contact Mr. Elder at (781) 279-1675, Extension 1790.

Sincerely,



Gail T. Costello  
District Director  
New England District Office