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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE



Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000  
FACSIMILE: 303-236-3551

April 2, 1998

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Daniel L. Wright, General Partner  
Wright Dairy Management, Inc.  
9521 South 5600 West  
Payson, UT 84651

**PURGED**

Ref - DEN-98-09

Dear Mr. Wright:

An investigation at your dairy and beef cattle operation located in Payson, Utah, was conducted by Consumer Safety Officer Margaret Annes on January 6 through 12, 1998. The inspection confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

On or about October 8, 1997, you offered a Holstein cow, identified with back tag [X] for slaughter as human food at [XXXXXXXXXX]. The Holstein cow was then sold to [XX] [XXXXXXXXXX]. USDA analysis of muscle tissue samples collected from this animal identified the presence of penicillin. A tolerance of .05 ppm had been established for residues of penicillin in the edible tissues of Holstein cows in Title 21 Code of Federal Regulations Part 556.510 (21 CFR 556.510) at the time the analysis was conducted. The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(D) of the Act.

Our investigation also found that you hold animals under conditions which are inadequate so that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals treated with drugs which have been approved for use in those species; 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 within the meaning of section 402(a)(4) of the Act.

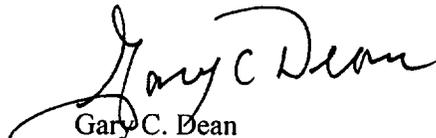
You are adulterating the drug [XXXX] brand of [XXXX] that your firm uses on Holstein cows within the meaning of section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. Your use of the drug in Holstein cows without following labeled withdrawal periods causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

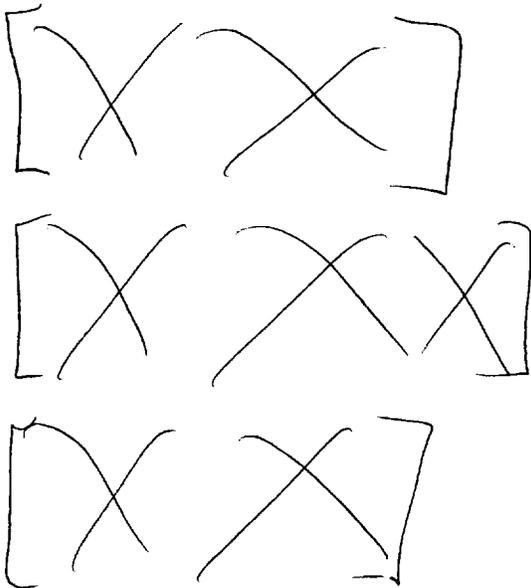
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

We are in receipt of your letter post marked February 17, 1998. Your letter indicates that in the future you will keep a permanent record of drug use on all animals which may be sold for human food. Your prompt action should keep drug residues in foods from entering distribution. Should another inspection become necessary, we will evaluate the adequacy of your changes.

Sincerely,

  
Gary C. Dean  
District Director

cc:



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