



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

m2307A

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

January 4, 1999

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Sam Knevelbaard, Partner  
Knevelbaard Dairies  
6485 Harrison Ave.  
Corona, CA 91720

WL 18-9

Dear Mr. Knevelbaard,

An investigation at your dairy operation located at 6485 Harrison Ave., Corona, California, conducted by our investigator on December 7-8, 1998, confirmed that you offered animals for sale for slaughter as food in violation of Section 402(a)(2)(ii)(C), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

On or about August 7, 1998, you sold a culled dairy cow identified by USDA report #373498 for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the liver at 0.38 ppm and in the muscle at 0.31 ppm. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack the conditions of an adequate system for assuring that animals have been treated only 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 the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The following new animal drugs found on your premises, are adulterated under Section 501(a)(5) of the Act, when they are used, as was indicated to our investigator, in a manner contrary to their approved labeling:

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1. Injectable penicillin G procaine is labeled for a dosage of 1 cc/100 lbs with a maximum of 10 ccs per injection site. Your use of 20 ccs at a single site is greater than labeled.
2. [REDACTED] boluses are labeled for administration of 2 boluses on the first day and 1 bolus per day for the following 3 days. Your administration of 2 boluses per day for 3 days is greater than labeled.

The above is not intended to be an all-inclusive list of violation. 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 the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as injunction.

Please note that 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 that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

We acknowledge the response submitted by your manager. The FAX indicates that you have modified your computerized data system. Any record-keeping system must assure that drugs used in the treatment of your animals are administered according to labeled directions. Our investigator found that you are using drugs in an extra-label manner without written directions for such use from a licensed veterinarian. The response submitted fails to address this issue.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

Your response should be directed to:

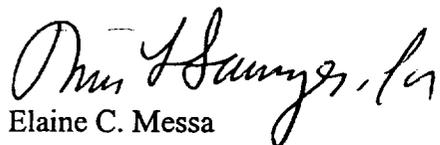
Barbara J. Rincon  
Consumer Safety Officer  
U.S. Food & Drug Administration  
1990 MacArthur Blvd., Ste. 300  
Irvine, CA 92612

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Sincerely,



Elaine C. Messa

District Director

Los Angeles District

cc: Steve Wong, Branch Chief  
State of California  
Department of Food & Agriculture  
P.O. Box 942871  
Sacramento, CA 94271-0001