



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

93697d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 1000135351

November 18, 2002

Steve X. Simas, Managing Partner  
Lu-Ar Dairy  
6017 13<sup>th</sup> Avenue  
Hanford, CA 93230

**WARNING LETTER**

Dear Mr. Simas:

A tissue residue report from the United States Department of Agriculture (USDA) and an inspection of your dairy farm located at 6121 15th Avenue, Hanford, CA 93230, on October 7, 8, and 11, 2002, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon, 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 (the Act), and that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On August 29, 2002, you sold a cull dairy cow, identified as animal #4384, back tag #804, retain tag #0958 (last 4 digits), USDA/FSIS Case #02-0013-CA, Form #440124, for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 6.21 ppm (parts per million). Presently, there is no tolerance for gentamicin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

Our inspection 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 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 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 under Section 402(a)(4) of the Act.

The introduction or delivery for introduction into interstate commerce of any adulterated food is prohibited under Section 301(a) of the Act. 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.

The drug GentaMax 100 (Gentamicin Sulfate Solution) that your firm used on the animal in question is adulterated within the meaning of Section 501(a)(5) since you failed to use it in conformance with its approved labeling. The drug is only approved for use in horses. Although a veterinarian prescribed the drug to your dairy for extra label use, specifically for heifer calves less than 30 days of age and for calf diarrhea, this case involved the treatment of an older animal for pneumonia. Furthermore, the veterinarian established a withdrawal time of 18 months from the time of administration of the drug to the time of slaughter to minimize the chance for a residue in meat. The manner in which you used the drug causes it to be unsafe within the meaning of Section 512 of the Act.

A Form FDA 483, Inspectional Observations, was issued to you at the conclusion of the inspection.

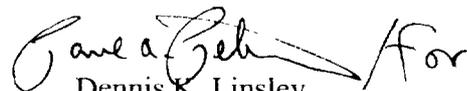
The violations listed above are not meant to be all-inclusive. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violations. If you cannot complete all corrections before responding, we expect you will explain the reason for any delay and the time period within which the corrections will be completed.

Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions regarding any issue in this letter, you may contact Mr. Peterson at (510) 337-6856.

Sincerely,

  
Dennis K. Linsley  
District Director