



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

D1374 B

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: 29-51644

February 3, 1998

Joe Da Silva  
27398 East Dodds Road  
Escalon, California 95320

**WARNING LETTER**

Dear Mr. Da Silva:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 26 and 27, 1998, by Food and Drug Administration (FDA) Investigator Karen L. Robles have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On December 5, 1997, you sold a cow (identified by USDA laboratory report number 256449) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed [REDACTED] in the liver at 1.06 parts per million (ppm) and in the muscle at 1.90 ppm. Presently, the tolerance levels for [REDACTED] in the uncooked edible tissues of cattle have been established at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug [REDACTED] within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Labeling for [REDACTED] specifies a withdrawal time of five days for the [REDACTED] injectable form and seven days for the [REDACTED] form of this drug. Failure to adhere to an adequate withdrawal time is likely the cause of the harmful levels of residues in the cow you sold for food use. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cull cows and calves for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of November 22, 1988, through January 21, 1997, your firm offered six cows and five calves for food use which were found to contain

Joe Da Silva Dairy  
Escalon, CA.

3

illegal drug residues. During this same period you delivered six calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. As a result, an inspection of your dairy was conducted on May 29 and 30, 1991. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated August 1, 1991, was sent to you due to the violations found during the inspection. Another inspection of your dairy was conducted on June 22 and 23, 1995. During that inspection you received additional warning that it is illegal to market animals with illegal levels of antibiotics. Another Warning Letter, dated August 4, 1995, was sent to you as a result of the violations found during the June 1995 inspection. Also, the United States Department of Agriculture (USDA) sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Sacramento resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,



Patricia Ziobro  
District Director  
San Francisco District

cc:



Joe Da Silva Dairy  
Escalon, CA.

4

bcc: HFR-PA1 (WAM)  
HFA-224  
HFC-230  
HFC-210  
HFI-35 (through FOI Officer)  
HFV-230  
HFR-PA140 (Legal correspondence file)  
HFR-PA140 (Warning Letter jacket)  
HFR-PA140 (JMR reading file)  
HFR-PA150 (Program Monitor/Fresno-RP)  
Sacramento Resident Post (KLR)  
Stockton RP

Central File 29-51644

Steve Wong, Branch Chief  
State of Calif. Dept. of Food and Agriculture  
1220 N Street, Room A 372  
Sacramento, CA 95814

Lael M. Alberg, Staff Officer/Residue  
USDA/FSIS/Meat and Poultry Inspection  
620 Central Ave., Bldg. 2B  
Alameda, CA 94501

Trak 3: 98-331

*file*  
*2-3-98*