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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug AdministrationSan Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Our Reference: 29-52738

January 6, 1997

Durval F. Gomes, Owner
Gomes Dairy
11495 S. Van Allen Rd.
Escalon, California 95320**WARNING LETTER**

Dear Mr. Gomes:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on November 27, 1996, by Food and Drug Administration (FDA) Investigator Alice A. Blair, 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 of the Act. On October 28, 1996, you consigned a cow (identified by USDA laboratory report number 382826) for sale 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 tissue residues. USDA analysis of tissues from this animal revealed the presence of sulfamethazine in the liver tissue at 51.00 parts per million (ppm) and in the muscle tissue at 45.00 ppm. The tolerance level for sulfamethazine in the edible tissue of cattle has been established at 0.1 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, such as sulfamethazine are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. 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.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

The Sanofi Sustain III brand of sulfamethazine boluses that you use to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(w), and they are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling for Sustain III requires a twelve day withdrawal period prior to slaughter for food use. Not adhering to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfamethazine in the tissues of the animal you sold for food use. Failure to comply with the label instructions on a drug makes the drug unsafe to 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.

This is not intended to be an all-inclusive list of violations. 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 this 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 include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

CC:

