

m3581n

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Via Federal Express

Our Reference: 29-54617

March 23, 2000

Joe Andrade, Owner
Joe Andrade Family Dairy
22929 Road 140
Tulare, California 93274

WARNING LETTER

Dear Mr. Andrade:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 14 and 18, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On December 29, 1999, you consigned a dairy cow (identified by USDA laboratory report number 281427) to be slaughtered for 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 the presence of sulfamethazine in the muscle at 107.0 parts per million (ppm) and in the liver at 20.00 ppm. Presently, the tolerance level for sulfamethazine in the uncooked edible tissues of cattle is 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 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 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 system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug Sustain III brand of Sulfamethazine that you use to treat your dairy cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Labeling for Sustain III specifically states it is not for use in female dairy cattle twenty months of age or older. The labeling also requires a twelve day withdrawal period prior to releasing animals for slaughter for food use. Your practice of using Sustain III to medicate lactating dairy cows over twenty months of age is likely the cause of the illegal residue found in the animal you sold for food use. Failure to adhere to the label instructions 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.

Joe Andrade Family Dairy
Tulare, California 93274

Page 3

You have failed to take adequate 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 Fresno 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 John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Charles D. Moss

District Director
San Francisco District

cc:

