



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50193

October 6, 1997

Tony C. Mello
Buena Vista Dairy
21207 Road 60
Tulare, California 93274-9468

WARNING LETTER

Dear Mr. Mello:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 11 through 16, 1997, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has 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 July 15, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 395409) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of oxytetracycline in the kidney at 4.10 parts per million (ppm), and in the liver at 1.50 ppm. A tolerance level for oxytetracycline has not been established for the edible tissue of lactating dairy cattle.

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 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 not contrary to 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 OXYJECT 100 brand of oxytetracycline HCL injectable that your establishment uses to treat lactating 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 OXYJECT 100 specifically states it is for use only in non-lactating dairy cattle and prescribes a twenty-day withdrawal time. Your practice of using oxytetracycline to treat lactating cows, coupled with an inadequate withdrawal time, is likely the cause of the illegal residues found in the animal you consigned for slaughter.

Your use of the drug [REDACTED] brand of tetracycline hydrochloride soluble powder is not in conformance with approved labeling. Product labeling states that it is to be administered in the drinking water of calves for the treatment of scours and pneumonia. Your practice of using [REDACTED] to create a foot bath for your lactating dairy cows is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Buena Vista Dairy
Tulare, California

3

Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

We request that you take prompt action to ensure that dairy cows and calves 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 into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption 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 dairy cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports during the period of May 16, 1983, through July 15, 1997, your firm sold ten animals which contained violative levels of oxytetracycline, penicillin, or neomycin. As a result of the violative residues, inspections were conducted of your dairy on June 22 and 23, 1983; March 13, 1991; and on June 17 and 21, 1994. During each of the inspections you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Notice of Adverse Findings Letter or Warning Letter was issued to you as a result of these inspections. Also, the U.S. Department of Agriculture has sent you letters for cull cows and calves in which analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act 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 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 Thomas W. Gordon, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Buena Vista Dairy
Tulare, California

4

Sincerely yours,

Charles D. Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District