



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1129B

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53093

January 27, 1997

Orlando F. Toste
9551 New Hope Road
Galt, CA 95632

WARNING LETTER

Dear Mr. Toste:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 10, 1996, by Food and Drug Administration (FDA) Investigator Robert J. Anderson 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 or about September 29, 1996, you consigned a cow (identified by USDA laboratory report number 259015) 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 drug residues. USDA analysis of tissues from this cow revealed oxytetracycline in the kidney at 3.90 parts per million (ppm), and in the liver at 0.63 ppm. The tolerance level for residues of oxytetracycline in the edible tissues of cattle has been established at 0.1 ppm.

Your firm has established a history of offering animals 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, on or about January 3, 1996, your firm offered one other cow which contained violative levels of antibiotics.

Orlando F. Toste
Galt, CA

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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 drugs are used in a manner not contrary to the directions contained in their labeling.

You are adulterating the drug Aspen Terra-Vet 100 brand of oxytetracycline hydrochloride within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with its approved labeling. Terra-Vet 100 labeling specifies that it is not to be used to medicate lactating dairy cattle. Your practice of injecting 30 cc's of this product into the muscle is not in accordance with approved label directions and is likely the cause of the residues in the cow you sold for food 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 corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Orlando F. Toste
Galt, CA

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Within fifteen (15) days of the receipt of this letter, please 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,

Charles D. Moss, Acting Director

for Patricia C. Ziobro
District Director
San Francisco District

cc: 