



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

510
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San Francisco District
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Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-51255

August 6, 1997

Joe A. Sozinho Sr.
Joe Sozinho Dairy
11447 8½ Avenue
Hanford, California 93230-9327

WARNING LETTER

Dear Mr. Sozinho:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 9 and 10, 1997, 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)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On May 1, 1997, you sold a dairy cow (identified by USDA laboratory report number 382788) for slaughter as human food. This dairy 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 dairy cow revealed oxytetracycline in the kidney at 3.10 parts per million (ppm) and in the liver at 0.44 ppm. Tolerances for

oxytetracycline in beef have been established at 12.00 ppm in kidney, 6.00 ppm in liver and 2.00 ppm in muscle tissue. A tolerance level for oxytetracycline in the edible tissues of lactating dairy cows has not been established.

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 not contrary to the directions contained in their labeling.
5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The drug Oxyject 100 brand of Oxytetracycline Hydrochloride that you use to medicate your 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

Joe Sozinho Dairy
Hanford, California

-3-

specifically states it is for use in non-lactating dairy cattle. Your practice of using oxytetracycline to treat lactating cows is likely the cause of the illegal residues found in the animal you consigned for slaughter.

Your use of penicillin G procaine is not in conformance with its approved labeling. Product labeling states it is to be administered intramuscularly in cows. Your practice of administering an intramammary injection of 5 mLs of penicillin G procaine is likely to result in harmful residue levels in the cows you sell for slaughter and auction.

Failure to comply with the label instructions on the drugs you use to treat your cows presents the likely possibility that illegal residues will occur and makes the drugs 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 an auction yard 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 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, during the period of March 11, 1994, through October 30, 1996, your firm offered three dairy cows which contained violative levels of penicillin and oxytetracycline. During the same period, you offered a calf which was found by USDA to be CAST positive

Joe Sozinho Dairy
Hanford, California

-4-

because of the possible presence of antibiotics. An inspection of your dairy was conducted on May 11, 1994, and you were warned that it is illegal to market animals containing violative levels of antibiotics in their edible tissues. As a result, a Warning Letter dated June 20, 1994, was sent to you for the violations found during that inspection. Also, the United States Department of Agriculture (USDA) sent you a letter for each instance in which USDA 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 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 address each discrepancy brought to your attention during the current 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, 2202 Monterey Avenue, Suite 104 E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

Joe Sozinho Dairy
Hanford, California

-5-

cc: Joe A. Sozinho Jr.
Joe Sozinho Dairy #2
15336 10th Avenue
Hanford, CA 93230

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