



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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-51523

December 9, 1996

Joseph M. Silva
Silva Brothers Dairy
12997 E. Peltier Road
Acampo, California 95220

WARNING LETTER

Dear Mr. Silva:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on November 15 and 18, 1996, by Food and Drug Administration (FDA) Investigator Karen L. Robles 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 September 4, 1996, you sold a cow (identified by USDA laboratory report number 383374) 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 tetracycline in the kidney at 2.30 parts per million (ppm) and in the liver at 1.80 ppm. No tolerance level for tetracycline has been established for the edible tissues of 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 that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals at your dairy.

You are adulterating the drug Oxy-mycin 100 brand 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. Labeling for Oxy-mycin 100 specifies a dosage of 3 to 5 milligrams per pound of body weight with a withholding time for slaughter of twenty-two days for calves and non-lactating cows only. Labeling for this product specifically states that it is not approved for use in lactating dairy cows. Failure to comply with the label instructions on a drug 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.

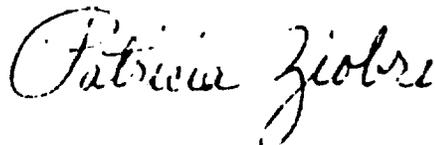
Silva Bros. Dairy
Acampo, CA

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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.

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 John M. Reves, Compliance Officer.

Sincerely yours,

A handwritten signature in cursive script that reads "Patricia Ziobro". The signature is written in black ink and is positioned above the typed name and title.

Patricia Ziobro
District Director
San Francisco District