



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M. Z. Zermeno

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

Via Federal Express

Our Reference 29-54137

December 21, 1998

Manuel Zermeno
Pinecrest Jersey Farm
5302 Langworth Road
Oakdale, California 95361

WARNING LETTER

Dear Mr. Zermeno:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on December 10, 1998, by Food and Drug Administration (FDA) Investigator Karen L. Robles has 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 September 29, 1998, you sold a calf (identified by USDA laboratory report number 256492) for slaughter as human food. This calf 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 calf revealed streptomycin in the kidney at 8.0 parts per million (ppm). Presently, the tolerance level for streptomycin is 2.0 ppm in the uncooked edible kidney 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 assuring treated animals are kept separate from untreated animals.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cattle.

Your use of Pirsue brand of pirlimycin hydrochloride is not in conformance with the approved labeling for this drug product. Labeling specifies that milk taken from cows during treatment with Pirsue, and for thirty-six hours (three milkings) following the last treatment, must not be used for food. Further, your practice of allowing bull calves to suckle from cows treated with Pirsue presents a possibility that illegal residues will be present in the calves when they are sold for human food use. 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.

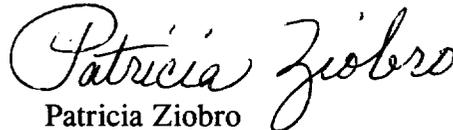
Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

Zermeno, Manuel
Oakdale, CA.

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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. Within fifteen (15) days of the receipt of this letter, notify our Sacramento 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 Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,



Patricia Ziobro
District Director
San Francisco District

cc:

