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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53423

June 13, 1997

Antonio L. Martins
20751 River Road
Stevinson, California 95374-9706

WARNING LETTER

Dear Mr. Martins:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 9 and 14, 1997, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon 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 February 27, 1997, you sold a calf (identified by USDA laboratory report number 307823) to be slaughtered for human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this calf revealed neomycin in the kidney at 18 parts per million (ppm). The tolerance level for neomycin in the edible tissues of calves has been established at .25 ppm.

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

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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 system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

Your use of the product Triple P Feeds brand Super Calf Formula containing the drugs neomycin and oxytetracycline causes the drugs to be adulterated within the meaning of Section 501(a)(5) of the Act when you do not use this product in conformance with its approved labeling. Labeling prescribes a thirty day withdrawal period prior to slaughter. Your practice of feeding calves Super Calf Formula mixed with water or milk, and failure to heed full slaughter withdrawal times, is likely the cause of the illegal residue found in the calf you sold for slaughter.

Your use of the drug Crysticillin brand penicillin G procaine is not in conformance with its approved labeling directions. Labeling for penicillin G procaine requires a dosage of 1 mL per 100 pounds of body weight with no more than 10 mLs injected into one site. Your practice of administering up to 15 mLs per injection all on one site in your dairy cows, results in a dosage in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur.

Your use of the drug Tetra-Bac 324 brand oxytetracycline 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 placing Tetra-Bac 324 in a gelatin capsule to create a uterine bolus 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.

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Failure to comply with the label instructions on the drugs you use to treat your cows and calves 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.

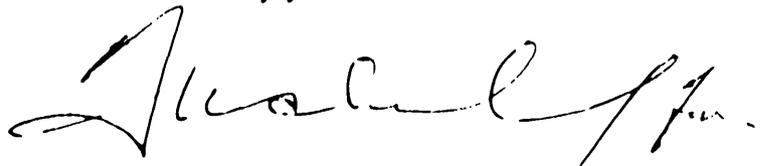
Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated dairy cow or calf in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated dairy calf 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 are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen 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, CSO, Post Office Box 169, Fresno, California, 93707.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

Antonio L. Martins
Stevinson, California

cc:

