



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50618

July 17, 1997

Mario M. Simoes, Sr.
13440 Road 136
Tipton, California 93272

WARNING LETTER

Dear Mr. Simoes:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on June 25 and 26, 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 May 13, 1997, you sold a cow (identified by USDA laboratory report number 382796) to be slaughtered for human food. This cow 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 cow revealed penicillin in the kidney at .38 parts per million (ppm), and in the liver at .13 ppm. The tolerance level for penicillin in the edible tissues of cows has been established at .05 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 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.

You are adulterating the drug AGRI-CILLIN brand Penicillin G Procaine within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with its approved labeling. Penicillin G Procaine labeling prescribes a dosage of 1 mL per 100 pounds of body weight and warns against using more than 10 mLs per injection site. Your practice of administering up to 25 mLs in one site in an animal results in a dosage in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur and is likely the cause of the illegal residues found in the cow you sold for slaughter.

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 dairy cow in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated dairy cow 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.

Mario M. Simoes
Tipton, California

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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 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

cc:

