



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1293B

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53373

March 26, 1997

Blake J. Alexandre
8371 Lower Lake Road
Crescent City, California 95531-9749

WARNING LETTER

Dear Mr. Alexandre:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 26, 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 January 22, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 391966) for sale 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 animal revealed the presence of penicillin at a level of 0.06 parts per million (ppm) in the kidney. The tolerance level for penicillin for the edible tissues of cattle has been established at 0.05 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 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 Pen-Aqueous brand of penicillin G procaine that you use to treat 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) since it is not being used in conformance with its approved labeling. Penicillin G procaine labeling specifies it is to be administered at a dosage of 1 milliliter (mL) per 100 pounds of body weight and warns against using more than 10 mLs per injection site. Labeling for this drug requires a ten day withdrawal time prior to slaughter.

The Tetracycline Soluble Powder 324 brand of tetracycline hydrochloride that your establishment uses on lactating dairy cows is also 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) since it is not being used in conformance with its approved labeling. This product is approved orally for use in calves only and requires a five day withdrawal period when used as directed by the drug's labeling directions. Your practice of using tetracycline hydrochloride and water to create a uterine infusion to medicate your dairy cows is an unapproved use for which safety and efficacy has not been proven. Creating this product constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for FDA approval.

Your use of drugs for treating your dairy cows does not conform to approved labeling instructions. Failure to adhere to labeling directions, including recommended withdrawal times, presents the possibility that illegal residues will occur and makes the drugs unsafe to use.

We expect 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.

Introduction of adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Alexandre Dairy
Crescent City, California

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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.

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,

Charles D. Moss Acting DD

Per Patricia C. Ziobro
District Director
San Francisco District

cc:

