



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: 29-51303

October 23, 1997

William Tolsma, Managing Partner  
Cal Chris Holsteins  
4190 Tuolumne Drive  
Turlock, California 95382

WARNING LETTER

Dear Mr. Tolsma:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 6, 1997, by Food and Drug Administration (FDA) Investigator Robert J. Anderson 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 July 22, 1997, you consigned a dairy cow (identified by USDA laboratory report number 395411) for sale 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 16.00 parts per million (ppm), in the liver at 9.60 ppm and in the muscle at 3.70 ppm. There is no tolerance for tetracycline for the edible tissues of lactating dairy 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 that animals have been treated only with drugs which have been approved for use in their species or class.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The [REDACTED] brand of tetracycline hydrochloride that you use to treat your 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) of the Act since it is not being used in conformance with approved labeling. Labeling for [REDACTED] warns against its use in lactating dairy cattle. Your practice of treating your cows with injections of 90 to 100 mLs is likely the cause of the presence of the violative levels of tetracycline in the tissue of the animal you sold for food use.

You are adulterating the drug [REDACTED] brand of tetracycline 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. The labeling states that it is to be used in the drinking water of calves, swine, turkeys and chickens only. Your practice of using [REDACTED] and gelatin capsules to create intrauterine boluses is an unapproved use for which safety and

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efficacy has not been established, and it constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for FDA approval.

You are not using the drug Crysticillin 300 A.S. brand of procaine G penicillin in accordance with its approved label directions. The labeling states that 1 mL is to be used for every one hundred pounds of body weight and no more than ten mLs in any one injection site. Your practice of administering 40 mLs in a split dose on your lactating dairy cows results in a dosage in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur.

You are not using the drug Sulfa-Max III brand of sulfamethazine boluses in accordance with approved labeling directions. The labeling directs that Sulfa-Max is not to be used in dairy cattle over twenty months of age. Your practice of administering it to heifers up to twenty-seven months of age exceeds the age limitation of twenty months. This presents a possibility that illegal residues will occur.

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.

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 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 Robert J. Anderson, Investigator, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Cal Chris Holsteins  
Turlock, California

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Sincerely yours,

A handwritten signature in cursive script that reads "Charles D. Moss". The signature is written in dark ink and is positioned above the typed name.

Charles D. Moss  
Acting District Director  
San Francisco District