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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: 29-39718

October 14, 1997

Manuel Goncalves  
15724 Arroya Road  
Dos Palos, California 93620

WARNING LETTER

Dear Mr. Goncalves:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 18, 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 December 5, 1994 you consigned a cull dairy cow (identified by USDA laboratory report number 913810) 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 animal revealed the presence of penicillin in tissues of the liver at 1.09 parts per million (ppm), muscle at 0.73 ppm, and kidney at 6.93 ppm. The tolerance level for penicillin in the edible tissues of cattle is 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, such as penicillin, 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 drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Pen-Aqueous brand of 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 requires a dosage of 1 milliliter (mL) per 100 pounds of body weight and warns against using more than 10 mLs per injection site. Your practice of administering 20 mLs in one site is likely the cause of the violative levels of penicillin in the tissues of the cow you sold for food use.

You are adulterating the drug Agri-Labs Agrimycin-100 brand of oxytetracycline 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. Agrimycin-100 labeling specifies that it is not to be used to medicate lactating dairy cattle. Your practice of mixing Agrimycin with dextrose for the treatment of mastitis in your dairy cows is an unapproved use for which safety and efficacy have not been established and constitutes the manufacturing of a new animal drug which require the submission of a New Animal Drug Application for FDA approval.

You are also adulterating the Albon brand sulfadimethoxine boluses that you use to treat your dairy cows within the meaning of 501(a)(5) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. Your practice of administering three boluses for three consecutive days is likely to cause violative levels of sulfadimethoxine in the tissues of the animals you sell for food use.

Failure to adhere to the instructions for use and withdrawal times specified in the labeling for the drugs you use prior to consigning your cull dairy cows to sale for slaughter, is likely the cause of the illegal residues found in the animals you sold for slaughter. Failure to comply with the label instructions on the drugs you use to treat your animals makes the drugs unsafe.

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.

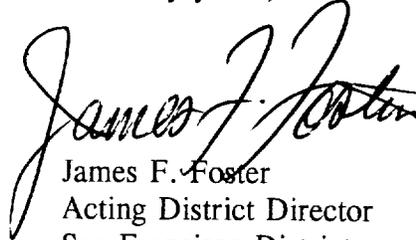
Your firm has a history of offering calves and cows for sale for human food use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, during the period of March 25, 1987, through July 29, 1997, you delivered one calf and eight cows for food use which were found to contain illegal antibiotic residues. An inspection was conducted of your dairy on October 27, 1989, and you were warned that it is illegal to market cull dairy cows and calves with illegal levels of antibiotics. A regulatory letter was sent to you on January 26, 1990, as a result of the violations found during the inspection. Also, USDA sent you a letter for each instance in which its analysis found violative levels of antibiotics in the animals you sold for food use. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Manuel Goncalves  
Dos Palos, California

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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 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 104 E, Fresno California 93721.

Sincerely yours,

A handwritten signature in black ink that reads "James F. Foster". The signature is written in a cursive style with a large initial "J".

James F. Foster  
Acting District Director  
San Francisco District

CC:

A large black rectangular redaction box covering several lines of text, likely a list of names or email addresses.