



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

34142d

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

Via Federal Express

Our Reference: 1000123906

July 14, 2003

Samuel J. Knevelbaard, Owner
Bayou Vista Dairy
P.O. Box 1015
Tipton, CA 93272

WARNING LETTER

Dear Mr. Knevelbaard:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from Bayou Vista Dairy. As a follow-up to USDA's finding, our investigators performed an inspection of your operation on March 13, 20, and 21, 2003. This inspection revealed serious violations of Sections 512 and 402 of the Federal Food, Drug, and Cosmetic Act (the Act).

On January 28, 2003, the dairy sold a cull dairy cow, identified with [REDACTED] back tag number 0131, last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA's Lab Report 440191) collected from that animal identified the presence of the drug penicillin in the kidney at 1.00 parts per million (ppm), and in the liver at 0.08 ppm. The tolerance level for penicillin in uncooked edible tissue of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), section 556.510). The presence of penicillin above this level causes the animal to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

In addition, it is adulterated under Section 402(a)(4) of the Act since "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 lack an adequate system for determining the medication status of animals, and assuring that animals to which you administer medication, such as a dairy cow, have been withheld from slaughter for the appropriate period of time to deplete potentially hazardous residues of drug. For example, our investigators noted the following:

You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosages administered, the dates administered, or the pre-slaughter withdrawal times.

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.

You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in the product's or your veterinarian's labeling.

You are also adulterating the drug Agripharm Product brand PEN-AQUEOUS (Penicillin G Procaine), within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act. The manufacturer's labeling directs that no more than 10 ml be administered to any given injection site. Your practice of administering 50-60 ml injection per day at one site for cows weighing 1500 - 2000 pounds results in a dosage in excess of that allowed in the labeling. Your failure to use the drug, penicillin, in conformance with the approved labeling causes it to be adulterated. The extra-label use of penicillin in dairy cows may only be done in compliance with 21 CFR Part 530, Extralabel Drug Use in Animals. These regulations require, among other conditions, that the extra-label use not result in residues above the established tolerance.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated.

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 a violation 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, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, 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 Lawton W. Lum, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Bayou Vista Dairy
Tipton, California

3

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert J. McDonald". The signature is written in a cursive style with a large, prominent "R" and "M".

for
Dennis K. Linsley
District Director
San Francisco District