



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

91050d

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

Via Federal Express

Our Reference: 29-51387

March 23, 2001

David B. Hankal, Manager  
Kephart Farms  
9115 Fulkerth Road  
Turlock, California 95380

**WARNING LETTER**

Dear Mr. Hankal:

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 heifer calf that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation in Ceres, California, on March 8, 2001. The inspection revealed serious violations of Sections 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On January 17, 2001, you sold a heifer calf to a calf buyer who identified the calf with back tag number 129. On January 17, 2001, this heifer calf was then identified with back tag number 93 DH 274 and sold for human food through [REDACTED] [REDACTED] USDA analysis (USDA laboratory report number 391898) of tissue samples collected from that heifer calf identified the presence of the drug neomycin in the kidney at 10.52 parts per million (ppm). Presently, the tolerance level for neomycin in the uncooked edible kidney tissue of cattle is 7.2 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.430). Your use of neomycin in a heifer calf resulted in the illegal drug residue found in the kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

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 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.
2. You lack an adequate system for determining the medication status of animals you offer for slaughter.
3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Calva Products brand of Medicated Calf Formula containing Neo-Terramycin (neomycin and oxytetracycline) 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 since it is not being used in conformance with its approved labeling. Labeling for Calva Products Medicated Calf Formula specifies a thirty-day withdrawal period prior to slaughter. Failure to comply with the withdrawal time is likely the cause of the neomycin residue in the heifer calf you sold for slaughter.

Failure to comply with the label instructions on drugs you use to treat your animals 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 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 are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, 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 Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, CA 94502.

Sincerely yours,



Dennis K. Linsley  
District Director  
San Francisco District