



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District **D1134B**  
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Alameda, California 94102-7070  
Telephone: 510-337-6700

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our Reference: 29-39469

January 28, 1997

Peter C. Vander Werff  
24654 Lone Tree Road  
Escalon, California 95320

**WARNING LETTER**

Dear Mr. Vander Werff:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 7, 1997, by Food and Drug Administration (FDA) Investigator Karen L. Robles have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the 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 October 30, 1996 you sold a calf (identified by USDA laboratory report number 243840) for slaughter as human food. This calf 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 calf revealed tetracycline in the kidney at 12.00 parts per million (ppm), in the liver at 9.10 parts per million (ppm), and in the muscle at 2.80 parts per million (ppm). Presently, the tolerance levels for tetracycline in the uncooked edible tissues of calves has been established at 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney tissues.

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 assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
3. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals at your dairy.

You are adulterating the drug Stockade brand Calf Formula Plus, containing neomycin and oxytetracycline within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(w) and 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 Stockade specifies a thirty day withdrawal period prior to slaughter for food use. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug 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.

Your firm has a history of offering calves 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 May 21, 1993, through March 27, 1995, your firm delivered one other calf which was found to contain illegal drug residues. During this same period, you sold two more calves which were found CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. An inspection was conducted of your dairy on May 16, 1995. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics in the tissues of dairy animals. A Warning Letter, dated June 8, 1995, was sent to you as a result of the violations found during the inspection. Also, the U.S. Department of Agriculture sent you a letter for each instance in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being

Peter C. Vander Werff  
Escalon, California

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met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

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 John M. Reves, Compliance Officer.

Sincerely yours,

*Charles P. Moss*  
*Acting Director*

*for*

Patricia Ziobro  
District Director  
San Francisco District