



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M. J. Gordon

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

Via Federal Express

Our Reference: 29-54439

August 6, 1999

Bernard Arthur te Velde Sr.
Bernard A. te Velde Sr. Dairy #2
5821 West Prospect Drive
Visalia, California 93291

WARNING LETTER

Dear Mr. te Velde:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 14 and 16, 1999, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

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. On June 4, 1999, you consigned a dairy cow (identified by USDA laboratory report number 277164) to be slaughtered for 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 sulfadimethoxine in the liver at 2.20 parts per million (ppm), and in the muscle at 3.10 ppm. Presently, the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.10 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 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 consistent with the directions contained on their labeling.
4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
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 Osborn brand of sulfadimethoxine soluble powder 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(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling directions for sulfadimethoxine soluble powder indicate the product is for use in dairy calves, dairy heifers, and beef cattle, and treated cattle require a seven day withdrawal period prior to slaughter. Your practice of using a shared water tank, medicated with sulfadimethoxine soluble powder, for use between two cattle holding pens and allowing dairy cows access to this treated water, coupled with an inadequate withdrawal time, presents a possibility that illegal residues will occur and is likely the cause of the illegal residue found in the cow you sold for food use.

You are adulterating the drug Pirsue brand of pirlimycin hydrochloride 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(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling directions for Pirsue prescribe a twenty-eight day withdrawal prior to slaughter. Your practice of administering Pirsue coupled with a twenty-three day withdrawal period prior to slaughter is contrary to directions contained in the labeling.

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.

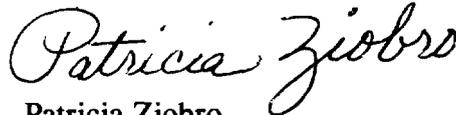
Your firm has established a history of offering cull cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of September 29, 1986, through July 7, 1992, you sold twenty animals for food use from your dairy facility located in Corona, California, which were found to contain illegal drug residues. Analytical reports also show that during the period of August 4 through 31, 1993, you sold three animals for food use from your dairy facility located in Hanford, California, which were found to contain illegal drug residues. An inspection was conducted, by FDA, of your dairy facility located in Hanford on October 19, 20 and 25, 1993. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated December 9, 1993, was sent to you as a result of the violations found during the inspection. Additional analytical reports show that during the period of January 18 through June 4, 1999, you sold three animals for food use from your dairy facility located in Tipton, California, which contained illegal drug residues. An inspection was conducted on March 18, 1999, by the State of California, of your dairy facility located in Tipton. During the inspection you were warned again that it is illegal to market animals with illegal levels of antibiotics. Also, USDA sent you a letter for each instance in which their 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 met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Bernard A. te Velde Sr. Dairy #2
Tipton, CA 93291

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Within fifteen (15) days of the receipt of this letter, please notify our Fresno resident post 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 Thomas W. Gordon, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia Ziobro
Director
San Francisco District

cc:

