



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94702d

San Francisco District
50 United Nations Plaza, Room 526
San Francisco, California 94102
Telephone: 415-556-2062

VIA FEDERAL EXPRESS
Our Reference: 3004445070

March 17, 2004

Edward L. Hoekstra, Managing Partner
Hillcrest Dairy, LLC
1901 North Hayden Road
Le Grand, California 95333

WARNING LETTER

Dear Mr. Hoekstra:

An investigation of your dairy operation in Planada, California conducted by a Food and Drug Administration (FDA) investigator on February 9 and 12, 2004, confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4). You also caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351, because the drugs were used in a manner that does not conform with their approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 C.F.R. Part 530).

On or about September 16, 2003, September 19, 2003 and November 18, 2003, you consigned three cows identified by United States Department of Agriculture (USDA) laboratory report numbers 366568, 366523, and 366549, respectively, to be slaughtered for human food to [REDACTED]. USDA analyses of tissue samples collected from these animals identified the presence of penicillin in the tissues of the cows, as follows:

Date of Consignment	USDA Laboratory Report Number	Amount of Penicillin found	Tissue
9-16-03	366568	0.17 ppm	Kidney
9-19-03	366523	0.14 ppm	Kidney
11-18-03	366549	0.13 ppm	Kidney
		0.09 ppm	Liver

A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (21 C.F.R. Part 556.510). The presence of penicillin above

established tolerance levels in the edible tissues from these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

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 whereby medicated animals bearing possibly harmful drug residues could enter the food supply. For example, our investigator observed the following:

1. Your firm fails to maintain an adequate system for assuring that drugs, specifically, PEN-AQUEOUS® brand PENICILLIN G PROCAINE, ToDAY® brand cephapirin sodium, and PIRSUE® brand pirlimycin hydrochloride sterile solution, are used in a manner consistent with their approved labeling or a written prescription from your veterinarian;
2. Your firm fails to maintain a complete, written medication treatment record system for your animals that includes all treatments, the amount of each drug administered, the route of administration, the drug pre-slaughter time, and the person who administered each drug; and
3. Your firm fails to maintain a drug inventory/accountability system.

Our investigator also observed that you have adulterated the drugs

PEN-AQUEOUS® brand PENICILLIN G PROCAINE,
ToDAY® brand cephapirin sodium, and
PIRSUE® brand pirlimycin hydrochloride sterile solution

that your firm uses on cattle within the meaning of Section 501(a)(5) of the Act when you failed to use the drugs in conformance with their approved labeling or in accordance with a written prescription from your veterinarian pursuant to 21 C.F.R. Part 530.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action, such as a seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken, that has been taken, or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Roderick V. Asmundson
Acting District Director
San Francisco District