



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

VIA FEDERAL EXPRESS

Our Reference: 3003381803

March 29, 2004

Pete Dykstra, Co-Owner
John P. Dykstra, Co-Owner
John Dykstra Dairy
6801 Avenue 176
Tulare, California 93274

WARNING LETTER

Dear Mssrs. Dykstra and Dykstra:

An investigation of your dairy operation in Tulare, California conducted by a Food and Drug Administration (FDA) investigator on February 9, 10, 13, and 17, 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 an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351, because the drug was used in a manner that does not conform with its approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 C.F.R. § 530).

On or about August 7, 2003, September 10, 2003, and January 15, 2004 you consigned three cows identified by United States Department of Agriculture (USDA) laboratory report numbers 431697, 431744, and 442325, respectively, to be slaughtered for human food. You consigned the first cow to [REDACTED] and the second and third cows to [REDACTED]. USDA analyses of tissue samples collected from these animals identified the presence of sulfadimethoxine and penicillin in the tissues of the cows, as follows:

Date of Consignment	USDA Laboratory Report Number	Residue Level	Residue Type	Site
8/7/03	431697	0.10 ppm	Sulfadimethoxine	Liver
		0.14 ppm	Sulfadimethoxine	Muscle
9/10/03	431744	0.11 ppm	Penicillin	Kidney
1/15/04	442325	1.14 ppm	Penicillin	Kidney
		0.48 ppm	Penicillin	Liver

A tolerance of 0.1 ppm is established for negligible residues of sulfadimethoxine in uncooked edible tissues of cattle (21 C.F.R. § 556.640). A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (21 C.F.R. § 556.510). The presence of sulfadimethoxine and penicillin above established tolerance levels in the edible tissues from these animals causes the foods 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 the drug, [REDACTED] Penicillin G Procaine, is used in a manner consistent with its approved labeling or a written prescription from your veterinarian;
2. Your firm fails to have veterinarian prescription labeling that provides adequate directions for use of bottles of [REDACTED] ceftiofur hydrochloride sterile suspension (50 mg per mL), which FDA found in your drug storage area.
3. Your firm fails to establish and maintain a drug inventory/accountability system.

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.

Our investigator also observed that you have adulterated the drug, [REDACTED] Penicillin G Procaine, that your firm uses on cattle within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling or in accordance with a written prescription from your veterinarian. Specifically, you offered a cow for slaughter only one day after treating it with [REDACTED] Sterile Penicillin G

Procaine, despite the warning on the drug's labeling to discontinue use of the drug 10 days before treated animals are slaughtered for food.

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,



Barbara J. Cassens
District Director
San Francisco District