



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94585d

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

VIA FEDERAL EXPRESS

Our Reference: 3000215053

December 18, 2003

Joseph M. Simoes, Owner
Joe M. Simoes Family Dairy
13585 Road 136
Tipton, California 93272

WARNING LETTER

Dear Mr. Simoes:

An investigation of your dairy operation in Tipton, California conducted by Food and Drug Administration (FDA) investigators on September 30 and October 2, 6, and 8, 2003, confirmed that you offered an animal 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 use or the extralabel use regulations at 21 C.F.R. Part 530.

On or about June 23, 2003, you consigned a cow identified by United States Department of Agriculture (USDA) laboratory report number 431584 to be slaughtered for human food to Central Valley Meat Co., Inc. USDA analysis of tissue samples collected from that animal identified the presence of tetracycline at 39.22 parts per million (ppm) in the kidney and 2.77 ppm in the muscle. A tolerance of 12 ppm has been established for residues of tetracycline in cattle kidney and 2 ppm for residues of tetracycline in cattle muscle. 21 C.F.R. § 556.720. The presence of tetracycline above established tolerance levels in the edible tissues from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. We acknowledge that USDA's letter of July 28, 2003 was mis-addressed to Mario Simoes, Jr. & Son Dairy and sent to 13440 Road 136, Tipton, CA, the office shared by the Simoes family, and we have enclosed a copy of that letter.

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, [REDACTED] (Tetracycline Hydrochloride) and [REDACTED] (Cephapirin Sodium), are used in a manner consistent with their approved labeling or a written prescription from your veterinarian;
2. Your firm fails to follow your veterinarian's prescription for [REDACTED] Flunixin Meglumine, and [REDACTED] (Prednisolone Sodium Succinate). The veterinarian's prescription states a dosage of 1 cc of Flunixin Meglumine per 100 lb bodyweight to reduce pain and inflammation in dairy cows. The veterinarian's prescription states a dosage of one 10-mL vial for the treatment of swelling and coliform mastitis. Your firm is mixing 15 cc Flunixin Meglumine with 10 cc [REDACTED] for the treatment of E. coli in your dairy cows;
3. 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, and the person who administered each drug;
4. Your firm fails to review treatment records prior to offering an animal for slaughter for human food to assure that appropriate withdrawal times for drugs have been observed;
5. Your firm fails to maintain a drug inventory/accountability system.

You adulterated animal drugs within the meaning of Section 501(a)(5) of the Act when you failed to use the drugs in conformance with their approved conditions of use or the extralabel use regulations at 21 C.F.R. Part 530. Extralabel use of animal drugs is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with the criteria set forth at 21 C.F.R. Part 530. Because your use of the drugs [REDACTED] (Tetracycline Hydrochloride), [REDACTED] (Cephapirin Sodium), RXV brand Flunixin Meglumine, and [REDACTED] (Prednisolone Sodium Succinate) on your cattle did not conform with the drugs' approved labeling or the extralabel use regulations, the drugs are unsafe under Section 512(a) of the Act. As a result, your use of these drugs caused them to be adulterated within the meaning of Section 501(a)(5) of the Act.

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.

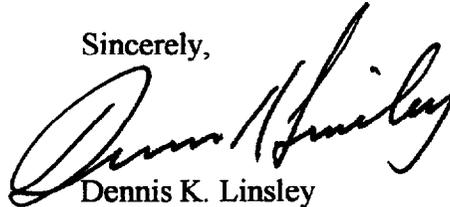
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient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



Dennis K. Linsley
District Director
San Francisco District

Enclosure: USDA Letter of July 28, 2003