



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94757d

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

VIA FEDERAL EXPRESS

Our Reference: 3004027103

May 19, 2004

Manuel F. and Mary F. Barcelos, Co-Owners
M & M Barcelos Dairy
5220 Coronado Street
Chowchilla, California 93610

WARNING LETTER

Dear Mr. & Mrs. Barcelos:

An investigation of your dairy operation at 13611 Avenue 23 ½ Chowchilla, California conducted by a Food and Drug Administration (FDA) investigator on November 24 and 25 and December 9 and 12, 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 Title 21, Code of Federal Regulations, Part 530 (21 C.F.R. § 530).

On or about December 11, 2003, you consigned a cow identified by United States Department of Agriculture (USDA) laboratory report number 447819 to be slaughtered for human food to [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of the following residues:

Residue Type	Residue Level	Site	Tolerance	21 CFR Reference
Neomycin	15.09 ppm	Kidney	7.2 ppm in kidney	21 CFR § 556.430
Sulfadimethoxine	4.52 ppm	Liver	0.1 ppm	21 CFR § 556.640
Sulfadimethoxine	1.37 ppm	Muscle	0.1 ppm	21 CFR § 556.640

The presence of neomycin and sulfadimethoxine 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.

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 a complete, written medication treatment record system for your animals that includes all treatments, the dosage of each drug administered, the route of administration, the meat or milk withdrawal time, and the person who administered each drug;
2. Your firm fails to follow the labeled directions of the following drugs:
 - [REDACTED] --The labeled directions for use state that this product is not for use in calves to be processed for veal. Your firm medicated a calf with [REDACTED] that was sold to be processed into veal.
 - [REDACTED] --The labeled directions for use state that this product is not for use in calves to be processed for veal. Your firm medicated a calf with [REDACTED] Injection that was sold to be processed into veal.
3. Your firm fails to quarantine treated animals to assure that proper withdrawal times for drugs have been observed prior to offering an animal for slaughter for human food.
4. 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. § 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. § 530. Because your use of the drugs [REDACTED] and [REDACTED] 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,



Barbara J. Cassens
District Director
San Francisco District