



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93807d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

January 22, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L # 18-03

Arthur H. Marquez
Owner
Marquez Dairy LLC
7360 Pine Ave.
Chino, CA 91710

Dear Mr. Marquez:

An investigation at your dairy operation located at 7360 Pine Avenue Chino California, conducted by our investigators on November 13, 2002, 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 (henceforth the "Act").

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 of the Act. A food is further adulterated under Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health.

On or about August 5, 2002, you sold a culled dairy cow identified by USDA Laboratory report 427797 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the muscle at 11.24 parts per million (ppm) and in the liver at 14.80 ppm. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle. (Title 21, Code of Federal Regulations, Section 556.640).

Our investigation also found that you hold animals under improper conditions whereby diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for the appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible

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tissues. Foods from animals held under such conditions are considered adulterated under the Act.

Please note that 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 to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. Government records available to us indicate there have been other occasions when you have offered drug-adulterated animals for sale as human food. As a producer of animals, which are 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.

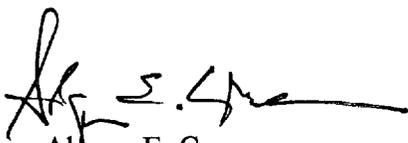
You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice. This letter constitutes official notification under the law and provides you an opportunity to correct.

Please advise this office in writing within fifteen (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 that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 798-7739.

Your written response should be directed to:

Robert B. McNab
Acting Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse
District Director