



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

2004d

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

**WARNING LETTER**

November 23, 2001

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

W/L # 17-02

Jean Gastelluberry  
Owner  
Basque American Dairy  
8484 Schaefer Ave.  
Ontario, CA 91761

Dear Mr. Gastelluberry:

Our records reflect you are the owner of Basque American Dairy consisting of multiple locations including Basque #1 located at 8484 Schaefer Ave., Ontario, CA, Basque #2 located at 13101 Cloverdale Rd., Corona, CA and Basque #3 located at 13575 Walker Ave., Ontario, CA. An investigation of your dairy operation located at 8484 Schaefer Ave., Ontario, California conducted by our investigator on October 22-26, 2001, 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 July 2, 2001, you sold a culled dairy cow identified by USDA Laboratory report 407607 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the muscle at 7.90 parts per million (ppm) and in the liver at 8.96 ppm. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle.

Our investigation also found that you hold animals under improper conditions whereby diseased animals and/or medicated animals bearing potentially harmful drug residues are

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

It was further determined that you are using drugs in a manner contrary to their approved labeling. Such extra-label use is not permitted, except by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and otherwise in compliance with the limitations set forth for specific extra-label uses. [21 CFR 530.10 and 530.11] Your use of drugs in any manner other than as labeled causes those drugs to be adulterated under Section 501 (a)(5) of the Act because there is no approval for such use as required by Section 512 (a)(1)(B) of the Act.

- You are adulterating injectable penicillin, such as [REDACTED] that you use on dairy cattle in a manner contrary to the approved labeling. Injectable penicillin is labeled for use in cattle at a dose of 1 ml per 100 pounds of body weight to be administered at no greater than 10 mls per injection site. Your use of this drug at 20 mls in one injection site is not in accordance with the approved labeling.

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.

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.

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.

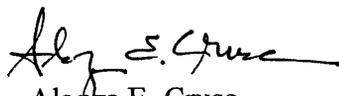
Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective 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.

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Your written response should be directed to:

Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food and Drug Administration  
19900 MacArthur Blvd., Ste. 300  
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse  
District Director