



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District *94418d*

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

December 17, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 13-04

John A. White
Owner
Joharra Dairy Farms
1643 S. Peart Rd.
Casa Grande, AZ 85222

Dear Mr. White:

Our records reflect you are one of the partners of Joharra Dairy Farms located at 1643 South Peart Road, Casa Grande, AZ. An investigation of your dairy operation conducted by a Food and Drug Administration (FDA) investigator on October 21-22, 2003, confirmed that you offered an animal for sale for slaughter as food which is in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You also caused the adulteration of animal drugs within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that does not conform with their approved use or the extra-label use regulations at 21 C.F.R. Part 530.

On or about August 18, 2003, you sold a culled dairy cow identified by USDA Laboratory report 283623 for slaughter as human food to [REDACTED] of [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the liver at 0.42 parts per million (ppm) and in the muscle at 0.40 ppm. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle. 21 C.F.R. § 556.640. The presence of 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.

Our investigation also found that you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues could enter the food supply. For

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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 adulterated within the meaning of Section 402(a)(4) 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 ensuring 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 offered an animal 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 injunction, without further notice.

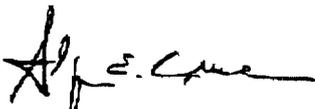
Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. 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 completed. Please include copies of any available documentation demonstrating that corrections have been 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) 608-4439.

Your written response should be directed to:

Acting Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director