



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District *94341d*

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

WARNING LETTER

October 8, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 01-04

Tom Osterkamp
Owner
Osterkamp Dairy
8301 Archibald Ave.
Corona, CA 92880

Dear Mr. Osterkamp:

Our records reflect that you are the owner of Osterkamp Dairy, located at 8301 Archibald, St. Corona, CA. An investigation of your dairy operation conducted by our investigator on August 1-8, 2003, confirmed that you offered animals for sale for slaughter as food in a manner that violated Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (henceforth the "Act"). The inspection also revealed that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of 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 March 12, 2003, you sold a culled dairy cow identified by USDA Laboratory report 265749 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the liver at 02.57 parts per million (ppm) and in the muscle at 04.86 ppm. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, Code of Federal Regulations (CFR), Section 556.640). The presence of this drug at the level

reported in the edible tissue 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 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 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. You are adulterating injectable penicillin that you use on dairy cattle in a manner contrary to the approved labeling. Injectable penicillin is labeled for intramuscular use at 1 cc per hundred pounds of body weight, with a maximum of 10 ccs per injection site for pneumonia. Your use of this drug at 30 ccs per injection site to treat foot rot is not in agreement with the 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.

The above is not intended to be an all-inclusive list of violations. As a producer of animals, which are offered for use as food, you are responsible for assuring that your overall operations and the food that you distribute comply 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 which 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 that 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 working days of receipt of this letter of the steps that you have taken, or will take, to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and to prevent their recurrence. If corrective action cannot be taken within fifteen working days, state the reason for the delay and the time within which such corrections

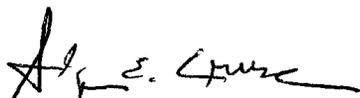
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will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Your written response should be directed to:

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

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is stylized with a large initial "A" and a long horizontal stroke at the end.

Alonza E. Cruse
District Director