



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 26, 2002

W/L 15-03

Eric J. Boersma
Owner
Boersma #2 Dairy
12541 Schleisman Road
Mira Loma, CA 91752

Dear Mr. Boersma:

An investigation at your dairy operation located at 12541 Schleisman Road, Mira Loma California, conducted by our investigators on November 5-6, 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 (the Act), and you caused a new animal drug to become adulterated within the meaning of Section 501(a)(5).

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 adulterated under Section 402(a)(4) of the Act if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions," refers to your lack of records for animals which you medicate. Consequently, you held an animal, which was ultimately offered for sale for human food, under conditions which are so inadequate that a medicated animal bearing potentially harmful drug residues was likely to enter the food supply.

On or about August 27, 2002, you sold a culled dairy cow identified by USDA Laboratory report 265742 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 1.16 parts per million (ppm) and in the liver at 0.10 ppm. The analysis also identified the presence of sulfadimethoxine in the liver at 0.45 ppm and in the muscle at 0.52 ppm. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle. (Title 21, Code of Federal Regulations, Section 556.510). A tolerance of 0.10 ppm has

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been established for 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 tissues. Foods from animals held under such conditions are adulterated.

A drug is adulterated under Section 501(a)(5) of the Act if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B). You are adulterating the drugs injectable penicillin and oral tetracycline powder that your dairy uses on cattle, when they are used, as was indicated to our investigators, in a manner contrary to the approved labeling. For example, the administration of 30 cc of injectable penicillin is greater than the labeled directions of 1 cc per hundred pounds of body weight. Additionally, your use of tetracycline soluble powder for an intra-uterine flush is not in accordance with the approved labeling.

While a licensed veterinarian, under certain well-defined circumstances, may administer or prescribe drugs in a manner not approved in the labeling, such authority has not been extended to non-veterinarians under any circumstances.

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 seizure and/or 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

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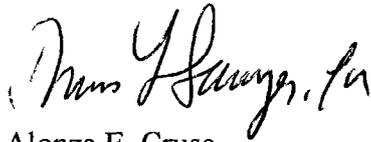
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prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this 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:

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

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is written in a cursive style with a large initial "A".

Alonza E. Cruse
District Director