



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

WARNING LETTER

JUN 21 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Bernard L. Zinke
Zinke Dairy
16005 East Germann Road
Gilbert, AZ 85234

W/L 55-00

Dear Mr. Zinke:

A tissue residue report from the United States Department of Agriculture (USDA) and an inspection of your dairy operation conducted March 27 and 28 of this year by our investigator has confirmed that you offered an animal 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 that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about December 30, 1999, a culled dairy cow identified with State – Fed back tag number 86-PF7-607 and USDA laboratory report number 307953 was slaughtered at [REDACTED]. The USDA analysis of tissue from this animal revealed sulfamethazine levels at 20 parts per million (ppm) in liver and 22 ppm in muscle. A tolerance of 0.1 ppm has been established for the uncooked edible tissues of cattle in Title 21, Code of Federal Regulations (CFR), Section 556.670. The presence of this drug in the edible tissue of this animal causes the food to be adulterated under section 402 (a)(2)(C)(ii) of the Act. You sold a cow identified with the auction back tag number 607 at [REDACTED], on December 29, 1999, which was traced by our investigator through this tag number to the animal received and tested by [REDACTED]. Because your record keeping system is inadequate, you were unable to provide any other information to our investigator regarding the sale of this cow or its drug treatment record. You do use the drug [REDACTED] bolus (containing sulfamethazine) for the treatment of foot rot at your dairy.

Our inspection also determined that you hold animals under such inadequate conditions that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate record keeping system that records all pertinent information to assure that drugs are used as labeled or as prescribed by a veterinarian. Because of these

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inadequacies, you cannot ensure that animals at your dairy have been withheld for slaughter for the appropriate period of time to permit depletion/elimination 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.

In addition, you are adulterating the drug [REDACTED] penicillin that your firm uses on cattle within the meaning of section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug at higher than labeled dosages, for conditions/indications not stated on the label and/or without following the labeled withdrawal period causes the drug to be unsafe for use.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your dairy. As a producer of animals that are offered for use as human food, you are responsible for assuring that your establishment is in compliance with all requirements of the federal regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action could include, but is not limited to, seizure and/or injunction.

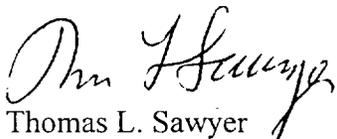
In addition to the specific violations noted above, we have the following comments:

Our records indicate you received a Warning Letter from our agency in 1993 regarding violations similar in nature to those observed during the current inspection. In addition, our records indicate you have had three illegal tissue residue levels since the issuance of the warning letter, one in 1995 and two in 1999. We consider the continued offering of animals containing illegal tissue residues for sale in interstate commerce a serious violation and are very concerned that you have not voluntarily corrected this problem by implementing a record keeping system designed to prevent the recurrence of the violation.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please direct your written response to the attention of:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Thomas L. Sawyer
Acting District Director