



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1087B

January 10, 1997

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell WA 98041-3012

Telephone: 206-486-8788  
Fax: 206-483-4996

In reply refer to Warning Letter SEA 97-09

WARNING LETTER

David H. Brewer  
P.O. Box 67  
Ringling, Montana 59044-8716

Dear Mr. Brewer:

An investigation at your dairy operation located at Ringling, Montana, conducted on December 10, 1996, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On September 24, 1996, you sent a bull, identified with back tag number PA1037, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from this bull identified the presence of 18.0 ppm and 9.10 ppm of sulfamethazine in the liver and muscle, respectively. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle, Title 21, Code of Federal Regulations, Part 556.670. The presence of this drug in edible tissues from this bull causes the food to be adulterated within the meaning of Section 402(a)(2)(D) of the Act.

Our investigation also found that you hold animals under conditions which are so inadequate that 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 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.

You are adulterating the drug [REDACTED] brand of sulfamethazine that your firm uses on bulls 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 without following the

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labeled withdrawal period causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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 and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,



Roger L. Lowell  
District Director