



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI-35 1/24
D1097B

January 15, 1997

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
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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-10

WARNING LETTER

Dwight Spaulding
2485 South 4000 North
Rexburg, Idaho 83440

Dear Mr. Spaulding:

An investigation at your dairy operation located at Rexburg, Idaho, conducted on December 12, 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).

On August 14, 1996, you sold a cow, identified with back tag number 82OX9609, for slaughter as human food to [REDACTED] [REDACTED] USDA analysis of tissue samples collected from this cow identified the presence of 1.80 ppm of gentamicin in the kidney. There has been no tolerance established for residues of gentamicin in edible tissues of cows. The presence of this drug in edible tissues from this cow 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.

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.

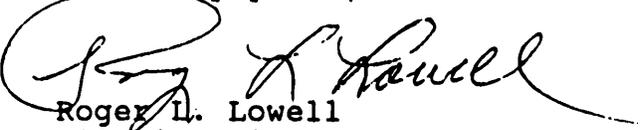
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The inspection also found that you may be adulterating Gentamicin Sulfate Injection USP brand of gentamicin that your firm uses when you fail to use the drug in conformance with the prescription furnished by the veterinarian who prescribed the drug. Your use of the drug without following the prescription causes the drug to be unsafe to use.

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

copy: 