



December 12, 1996

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

VIA FEDERAL EXPRESS

Telephone: 206-486-8788
Fax: 206-403-4996

In reply refer to Warning Letter SEA 97-07

Michael Landolt, Owner
Landolt Dairy
695 Tone Road
Tillamook, Washington 97141WARNING LETTER

Dear Mr. Landolt:

An investigation at your dairy operation located at Tillamook, Washington, conducted on November 20, 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 caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On August 6, 1996, you sold a calf, identified with back tag number 92RF1920, for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from this calf identified the presence of 31.0 ppm of sulfadimethoxine. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of calves, Title 21, Code of Federal Regulations, Part 556.640. The presence of this drug in edible tissues from this calf causes the food to be adulterated.

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.

You are adulterating the drug Albon that your dairy uses on calves within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with its labeling. Your use of the drug without following the 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

copy: Lael Alberg, DVM
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501