



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February 20, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-33

Larry J. Vanderstelt, Co-Owner
Dry Lake Dairy
12492 Big Foot Road
Nampa, Idaho 83686

WARNING LETTER

Dear Mr. Vanderstelt:

An investigation at your dairy located at 12492 Big Foot Road, Nampa, Idaho, by our investigator on January 10, 2002, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

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. On or about November 9, 2001, you sold a cow to _____, who in turn identified the cow with back tag # 9588 and sold the cow to _____. This cow, identified with back tag # 9588, was identified on USDA lab report # 428327. USDA analysis of tissue samples collected from that animal identified the presence of 5.89 parts per million (PPM) of sulfadimethoxine in the muscle tissue, and 5.40 parts per million (PPM) of sulfadimethoxine in the liver tissue. The allowable tolerance for sulfadimethoxine in the uncooked edible tissue of cattle is 0.1 PPM.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions... whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

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For example, our investigator noted the following conditions on your farm:

1. You failed to have a system in place to assure that all treated animals had treatment records which should include:
 - a. the animal's identity
 - b. the date of treatment
 - c. the drug administered
 - d. the dosage administered and
 - e. the drug pre-slaughter withdrawal time
2. A failure to follow label directions for the medication (sulfadimethoxine) you administered to your animals in that either you or your staff administered the product in excess of the recommended dosage, or you failed to follow the labeled pre-slaughter withdrawal time.
3. You failed to have a system in place to assure that the treated calf was withheld from slaughter in accordance with instructions for use of the drug.

We request that you take prompt action to ensure that dairy cows and calves, which you offer for sale as human food, will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Our investigation revealed that the residue came from your use of Albon, which contains sulfadimethoxine. The dosage instructions and withdrawal times provided by the manufacturer of the Albon is intended to provide you with withdrawal time information, which you are required to follow. Not following the manufacturer instructions can be considered off label use. Off label use of veterinary drugs is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

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Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, (425) 483-4976.

Sincerely,



Charles M. Breen
District Director

Enclosure:
Form FDA 483

Cc:

