



DEPARTMENT OF HEALTH AND HUMAN SERVICES

24217d

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

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

August 13, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-27

Jack Verbree, Owner
Jack Verbree Dairies
1570 East 2900 South
Wendell, Idaho 83355

WARNING LETTER

Dear Mr. Verbree:

An Inspection was conducted at your dairy farm #4 located at 2750 South 1500 East., Wendell, Idaho, by our investigator on June 25-26, 2003. This inspection 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 you caused a new animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about March 18, 2003, you sold a downer cow, back tag # 4417, identified on USDA Case # 02-0422-ID, and further identified on USDA-FSIS lab report # 433553, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of Flunixin in the liver tissue at 14.12 parts per million (ppm). The tolerance for Flunixin in cattle liver is 0.125ppm. (Title 21, Code of Federal Regulations, Section 556.286).

A new animal drug is adulterated under Section 501(a)(5) of the Act if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B). 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. 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

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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 may enter the food supply.

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

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

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.

For your information, in October 1994 Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use of drugs under certain controlled conditions as specified in 21 Code of Federal Regulations (CFR) Part 530. "Extra-label use" means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. Extra-label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in the regulation.

The above is not intended to be an all-inclusive list of violations. Government records available to us indicate there have been other occasions when you have offered drug adulterated animals for sale as human food. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food 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. This letter constitutes official notification under the law and provides you an opportunity to correct.

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

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Please send your written reply to the Food and Drug Administration, Attention: Lisa Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Ms. Elrand, Compliance Officer, at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

(w/copy of FDA-483):
Lael Alberg, DVM
U.S. Department of Agriculture
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501