



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94283d  
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 22, 2003

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-39

Arie Roeloffs, Co-Owner  
Southfield Dairy  
3308 South 1600 East  
Wendell, Idaho 83355

**WARNING LETTER**

Dear Mr. Roeloffs:

On July 21 and July 28, 2003, our investigator inspected your dairy farm located at 3308 South 1600 East, Wendell, Idaho. 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 caused a new animal drug to become adulterated within the meaning of section 501(a)(5).

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. You sold a dairy cow on or about April 14, 2003, identified with back tag #82NE410 and USDA Case # 8-0652-01, and further identified as USDA-FSIS lab report # 440237, for slaughter as human food to [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney at 0.24 parts per million (ppm). The tolerance for Penicillin in edible tissues of dairy cattle is 0.05 ppm (Title 21, Code of Federal Regulations, section 556.510).

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 may enter the food supply.

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

Arie Roeloffs, Co-Owner  
Southfield Dairy, Wendell, Idaho  
Re: Warning Letter SEA 03-39  
Page 2

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. 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 ensuring that medicated animals have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous drug residues.
3. You lack an adequate system for ensuring 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. Such extra-label use would include, for example, the use of Penicillin at 30-35cc's when the label indicates a dose of 15cc's in dairy cattle.

The above is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for ensuring 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.

Within fifteen (15) days of the receipt of this letter, please advise this office 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.

Arie Roeloffs, Co-Owner  
Southfield Dairy, Wendell, Idaho  
Re: Warning Letter SEA 03-39  
Page 3

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Ms. Althar at (425) 483-4940.

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

cc: (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