



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m4854n  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

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

November 8, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-02

John Reitsma, Co-Owner  
Jesus M. Hurtado, Co-Owner  
Rotary Dairy  
2300 East 2300 North  
Hollister, Idaho 83301

WARNING LETTER

Dear Mr. Reitsma and Mr. Hurtado:

An investigation at your dairy located at 2300 East 2300 North, Hollister, Idaho, by our investigator on May 10, and 17, 2000, confirmed that you offered animals 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 16, 1999, you sold a culled dairy cow, back tag #990, identified on USDA-FSIS Lab Form # 403839 and sold to [REDACTED] for slaughter as human food. USDA analysis of tissue sample from the cow with back tag # 990 identified the presence of sulfadimethoxine at 17.0 PPM in the liver and 7.5 PPM in the muscle. The permitted tolerance for sulfadimethoxine in uncooked edible tissue in 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. 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.

John Reitsma, Co-Owner  
Jesus M. Hurtado, Co-Owner  
Rotary Dairy  
Hollister, Idaho 83301  
Re: Warning Letter SEA 01-02  
Page 2

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.

Please respond 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.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021-4421. 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 w/copy of FDA-483:  
Lael Alberg, DVM  
Food Safety & Inspection Service  
Western Regional Office  
620 Central Avenue, Building 2C  
Alameda, California 94501