



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

June 3, 2004

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-32

Albert J. Huizenga, Owner  
Fir Crest Hauling  
6571 Hannegan Road  
Lynden, Washington 98264

**WARNING LETTER**

Dear Mr. Huizenga:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in a calf that originated from your calf raising/buying/hauling operation located at 6571 Hannegan Road, Lynden, Washington. As a follow-up to USDA's finding, an investigation of your calf buying/hauling operation was conducted by a Food and Drug Administration (FDA) investigator on April 2 and 6, 2004, and confirmed that you offered an animal for sale for slaughter as food which was adulterated, in violation of Sections 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 meaning of Section 512 of the Act. On or about December 1, 2003, you sold a calf with back tag number [REDACTED] identified on USDA-FSIS Lab Form #417267. This calf was sold for slaughter as human food to [REDACTED] United States Department of Agriculture (USDA) analysis of a tissue sample collected from that calf identified the presence of Neomycin at 7.37 parts per million (PPM) in the kidney. There is no established tolerance for residues of Neomycin in the kidney tissue of calves. Therefore, the presence of Neomycin in the edible tissues of this animal caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) 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 injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately

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offered for sale for slaughter as food under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. Our investigator noted several deficiencies that cause food held by you to be considered adulterated:

1. You lack an adequate system for assuring that animals you purchase are properly identified in that you fail to place proper identification on calves before calves from multiple sources are commingled. In this regard, we determined that on one day you commingled calves from different dairies in one trailer without first placing any identification on these animals. Later, you relied on your memory to identify which calf came from which dairy.
2. You lack an adequate system for assuring that animals you purchase have not been treated with drugs in a manner contrary to the directions contained in their approved labeling.
3. You failed to obtain treatment records or assurances from the dairies where you purchase animals that they had not been treated with drugs.

You should be aware that 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 offered an adulterated animal for sale that was shipped in interstate commerce to a slaughterhouse is sufficient to make you responsible for violations of the Act.

This is not the first time calves or cows from your operation have been identified as having illegal drug residues, particularly Neomycin residues. It is also not the first time that you were unable to positively identify the source of the calf in question. Failure to properly identify animals you purchase is a serious matter that needs your immediate attention. Animals purchased by you should be tagged prior to loading to avoid misidentification or lack of identification.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for sale for use as food, you are responsible for ensuring that your operations 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 occur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond within fifteen (15) days of receipt of this letter and 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.

Albert Huizenga  
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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,

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

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