



DEPARTMENT OF HEALTH AND HUMAN SERVICES

945113
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

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

January 26, 2004

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 04-17

Jason E. Nunes, Co-Owner
Nunes Family Dairy, LLC
937 E. 4000 N.
Buhl, ID 83316

WARNING LETTER

Dear Mr. Nunes:

An investigation conducted at your dairy located at 937 E. 4000 N., Buhl, Idaho, by our investigator on December 3 & 10, 2003, 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 August 23, 2003, you sold a culled dairy cow, back tag #82TF006, identified on USDA-FSIS Lab Form #435810. This cow was sold for slaughter as human food to [REDACTED] a commercial cattle hauler, who in turn delivered the cow, back tag # 82TF006 to [REDACTED]

[REDACTED] sold the cow to [REDACTED] USDA analysis of a tissue sample from the cow with back tag # 82TF006 identified the presence of Sulfamethazine at 7.01 parts per million (PPM) in the Liver and 4.93 ppm in the Kidney. The established tolerance for Sulfamethazine in edible tissue is 0.1 PPM. Title 21, Code of Federal Regulations Section 556.670.

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:

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1. 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.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

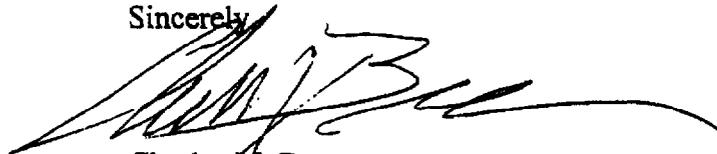
You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in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

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.

Please respond to this letter within fifteen (15) working days of the receipt of this letter 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 23rd 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:
Dr. Murli M. Prasad
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501