



DEPARTMENT OF HEALTH AND HUMAN SERVICES

93391d

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

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

July 1, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-53

Chan R. Teel, President
Teel Dairy Farm, Inc.
8304 West Greenwood Road
Spokane, Washington 99204

WARNING LETTER

Dear Mr. Teel:

Inspections were conducted at your dairy farms located at 8304 West Greenwood Road, Spokane, Washington, and at 15810 West Lance Hill Road, Cheney, Washington, by our investigators on March 11, March 12 and April 17, 2002. These inspections confirmed that you offered animals 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).

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 5, 2001, you sold a culled dairy cow, back tag # 91 SL1 485, identified on USDA Case # 01-1704-WA, and further identified on USDA-FSIS lab report # 411334, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 0.64 parts per million (ppm). There is no tolerance for gentamicin in dairy cattle.

Then, on or about January 14, 2002, you sold a second culled dairy cow, back tag # 91 SL7 719, identified on USDA Case # 01-1704-WA, and further identified on USDA-FSIS lab report # 411342, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 1.07 parts per million (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

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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 farms:

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.
4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

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 product "NFZ Puffer" for treatment of pink eye in dairy cattle, a use contradictory to the labeled restriction for use on cats and dogs only.

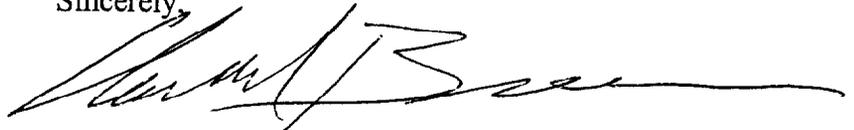
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

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

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Please send your reply to the Food and Drug Administration, Attention: Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Mr. Piekarski, Compliance Officer, (425) 483-4975.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written over a horizontal line.

Charles M. Breen
District Director

Enclosure:
FD&C Sections 402(a)(2)(C)(ii) and 402(a)(4)

cc:
North C. Teel, Vice-President, Teel Dairy Farm, Inc., Spokane, Washington

(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