



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

September 26, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-59

John Reitsma, Co-owner
J & J Dairy
75 North 400 West
Jerome, Idaho 83333

WARNING LETTER

Dear Mr. Reitsma:

An inspection was conducted at your dairy farm located at 1800 East 3200 South, Wendell, Idaho, by Investigator Marcus A. Goshen, on August 15 and 21, 2002. This inspection confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) [21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 [21 U.S.C. § 360b(a)(1)(B)] of the Act. Recently, you offered for slaughter three dairy cows which had penicillin residues.

On June 27, 2002, you sold a culled dairy cow, hauler's back tag # 82 NE 6008, identified on USDA Case # 02-0911-ID, and further identified on USDA-FSIS lab report # 440091, for slaughter as human food. The cow was hauled by [REDACTED] to [REDACTED], where it was slaughtered. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.21 parts per million (ppm). The tolerance for penicillin is 0.05 ppm in the uncooked edible tissues of cattle.

Later, on July 9, 2002, you sold a second culled dairy cow, ear tag #3227, identified on USDA Case # 02-0911-ID, and further identified on USDA-FSIS lab report # 439550, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney and liver at 0.26 ppm and 0.08 ppm, respectively.

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Finally, on July 22, 2002, you sold a third culled dairy cow, hauler's back tag #82 NE 100, identified on USDA Case # 02-0911-ID, and further identified on USDA-FSIS lab report # 440101, for slaughter as human food to [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.06 ppm.

A food is adulterated under Section 402(a)(4) [21 U.S.C. § 342(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.

For example, our investigator noted the following conditions on your dairy:

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.

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.

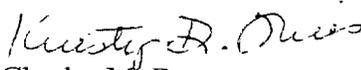
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

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 at (425) 483-4975.

Sincerely,

for 
Charles M. Breen
District Director

Enclosure:
FD&C Sections 402(a)(2)(C)(ii) and 402(a)(4)
FDA 483

cc (via certified mail):
Jesus Hurtado, Co-owner
J & J Dairy
1950 East 3249 South
Wendell, Idaho 83355

(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