



DEPARTMENT OF HEALTH AND HUMAN SERVICES

938088

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

Telephone: 425-486-8788  
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January 22, 2003

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-13

Jose L. Lourenco, Owner  
Lourenco Dairy #2  
19524 U.S. Highway 30  
Buhl, Idaho 83316

**WARNING LETTER**

Dear Mr. Lourenco:

An investigation at your dairy located at 19524 U.S. Highway 30, Buhl, Idaho, by our investigators on December 12, 2002, 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. From July 22, 2002 to August 29, 2002, you sold cull dairy cows for slaughter as human food to [REDACTED]

[REDACTED]. Some of the cows had illegal tissue residues as follows:

1. On or about July 22, 2002, you sold a culled dairy cow to [REDACTED] with no tag. The cow was subsequently tagged as carcass tag 659, and identified on USDA form #433453. USDA analysis of tissue samples collected from the cow identified the presence of Sulfadimethoxine at 2.12 parts per million (ppm) in the liver, and 1.52 ppm in muscle tissue. The maximum allowable tolerance for Sulfadimethoxine in edible tissue of cattle is .1 ppm. In addition, this animal was found to contain Tilimicosin at 16.90 ppm in the liver and 16.70 ppm in the kidney. The maximum allowable tolerance for Tilimicosin in edible tissue of cattle is 1.2 ppm.

2. On or about August 12, 2002, you sold a culled dairy cow with tag number 1222 ET to [REDACTED]. This cow was subsequently identified on USDA form # 433458. USDA analysis of tissue samples collected from this animal identified the presence of Penicillin at .98 ppm in the kidney and at .47 ppm in the liver. The maximum allowable tolerance for Penicillin in edible tissue of cattle is 0.05 ppm.

3. On or about August 22, 2002, you sold a downer cow to [REDACTED] with tag number 842 ET. This cow was subsequently identified on USDA form # 433460. USDA analysis of tissue samples collected from this animal identified the presence of Oxytetracycline at 8.47 ppm in the liver and 3.20 ppm in muscle tissue. The maximum allowable tolerance for Oxytetracycline in cattle is 6 ppm in the liver and 2 ppm in muscle tissue. In addition, Sulfadimethoxine was found at 12.03 ppm in the liver and at 5.83 ppm in muscle tissue. The maximum tolerance for Sulfadimethoxine in edible tissue of cattle is 0.1 ppm.

4. On or about August 22, 2002, you sold a culled dairy cow to [REDACTED] with ear tag number 718. This cow was subsequently identified on USDA form 433459. USDA analysis of tissue samples collected from this animal identified the presence of Penicillin at .84 ppm in the kidney. The maximum tolerance for penicillin in edible tissue of cattle is 0.05 ppm. In addition, USDA found Sulfadimethoxine 6.41 ppm in the liver and at 3.32 ppm in muscle tissue. The maximum allowable tolerance for Sulfadimethoxine in edible tissue of cattle is 0.1 ppm.

5. On or about August 29, 2002, you sold a culled dairy cow to [REDACTED] with no ear tag. The cow was subsequently identified with carcass tag number 282, and identified on USDA form #433461. USDA analysis of tissue samples collected from this animal identified the presence of Penicillin at .77 ppm in the kidney and .38 in the liver. The maximum tolerance for penicillin in edible tissue of cattle is 0.05 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...w hereby 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.

Jose L. Lourenco, Owner  
Lorenco Dairy #2 Buhl, ID.  
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For example, our investigator noted the following conditions on your farm:

1. You failed to maintain medication records which identify the animal, the date of medication, the drug, the dosage administered and the pre-slaughter withdrawal time.
2. You failed to follow label directions for medications you administered to your animals in that you failed to follow the labeled pre-slaughter withdrawal times.
3. You failed to have a system of reviewing treatment records prior to offering an animal for slaughter for human food, to assure that drugs had been used only as directed and that the appropriate withdrawal times had been observed.
4. You failed to have a valid veterinarian prescription for the use of Penicillin in an Extra-label manor.

Our investigation revealed that the Penicillin residue came from your use of Over the Counter Penicillin at dosages above the labeled amount on your dairy herd. The use of Penicillin at amounts greater than that stated on the label requires a valid prescription from a licensed veterinarian. Your extra label use of Penicillin is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530, Extra label Drug Use in Animals, which causes certain animal drugs used to medicate food producing animals, to be adulterated within the meaning of Section 501(a)(5) of the Act, in that they are new animal drugs which are unsafe within the meaning of Section 512(a)(4).

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. 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 Part 530.

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.

Jose L. Lourenco, Owner  
Lorenco Dairy #2 Buhl, ID.  
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The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall 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 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.

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. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, at (425) 483-4976.

Sincerely,



Charles M. Breen  
District Director

Enclosure:  
Form FDA 483

cc: Julie A. Cornett, D.V.M./USDA/FSIS/Tissue Residue Case No. 02-1028-ID