



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

October 16, 2003

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-04

Henry C. Haffiger, Owner  
Desert Rose Farms  
2175 E. 3500 N.  
Filer, Idaho 83328

**WARNING LETTER**

Dear Mr. Haffiger:

An investigation at your dairy located at 2175 E. 3500 N., Filer, Idaho, by our investigator on August 27-28, 2003, confirmed that you offered an animal 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). The investigation also revealed that you administer drugs to cattle in violation of Section 501(a)(5) of 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 May 9, 2003, you sold a dairy cow identified with Ear Tag #12020 and listed as USDA Case # 02-1295-ID, Form # 433563, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of Flunixin in the liver tissue at 4.97 parts per million (ppm). A tolerance of 0.125 ppm has been established for residues of Flunixin in the cattle liver. See Title 21, Code of Federal Regulations (C.F.R.), Section 556.286.

Henry C. Hafliger, Owner  
Desert Rose Farms, 2175 E. 3500 N., Filer, Idaho 83328  
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- On or about May 9, 2003, you sold a dairy cow identified with Back Tag # 82NE88868 and listed as USDA Case # 03-0585-ID, Form #440249, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney tissue at 0.19 ppm. A tolerance of 0.05 ppm has been established for residues of Penicillin in the uncooked edible tissues of cattle. See 21 C.F.R. § 556.510.
- On or about May 30, 2003, you sold a dairy cow identified with Ear Tag #12926 and listed as USDA Case # 02-1295-ID, Form # 433567, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of Flunixin in the liver tissue at 7.77 ppm and Penicillin in the kidney tissue at 0.27 ppm. See 21 C.F.R. § 556.286 and 21 C.F.R. § 556.510.

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." Insanitary conditions exist at your dairy because you hold and process animals under conditions that are inadequate to assure that medicated animals containing excessive and possibly harmful drug residues do not enter the food supply.

For example, our investigator noted, during the inspection of your farm, that you failed to maintain a system of treatment/medication records which include an inventory system for determining the quantities of drugs used to medicate your cows and complete treatment records that identify the type of drugs used to medicate your cows. Specifically, you did not record the use of the drug, Flunixin.

Additionally, failure to use a drug in conformance with its approved labeling renders it unsafe within the meaning of Section 512(a)(1) of the Act and, therefore, adulterated within the meaning of Section 501(a)(5) of the Act. During the inspection, you stated that you did not know that the drug, Flunixin, required a withdrawal time, even though the labeling on the drug stated that a four day withdrawal period was required prior to sending an animal to slaughter. This acknowledgement, along with your statement that you treated cattle with Flunixin just prior to sale, and the presence of excessive levels of Flunixin residues in cattle that you offered for sale, establish that this drug was not used in conformance with its approved labeling.

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.

Henry C. Hafliger, Owner  
Desert Rose Farms, 2175 E. 3500 N., Filer, Idaho 83328  
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You should take prompt action to correct the above violations and to establish procedures to prevent future violations. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Michael J. Donovan, Compliance Officer at (425) 483-4906.

Sincerely,



Charles M. Breen  
District Director

Enclosure:  
Form FDA 483

cc: Dr. Ahmed/USDA/FSIS/Tissue Residue  
Landmark Center, Suite 300  
1299 Farnam St.  
Omaha, Nebraska 68102