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**PURGED** FAX

October 28, 1999

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 05

Robert M. Palmer  
Palmer Farms, Inc.  
E5711 Irish Valley Road  
Plain, Wisconsin 53577

Dear Mr. Palmer:

An investigation at your dairy operation located at Plain, WI, conducted by our investigator on June 29, 1999, confirmed that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about May 5, 1999, you sold a dairy cow, identified with back tag number 35XV9-035, to [redacted] to be delivered to [redacted] for slaughter as human food. United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of the following drugs:

Liver	Oxytetracycline	8.60 parts per million
	Sulfadimethoxine	50.00 parts per million
Muscle	Oxytetracycline	8.20 parts per million
	Sulfadimethoxine	39.00 parts per million

Tolerances of 6 parts per million in the liver and 2 parts per million in the muscle have been established for oxytetracycline in dairy cows (Title 21, Code of Federal Regulations, Part 556.500). A tolerance of 0.1 ppm in uncooked edible tissues of cattle has been established for sulfadimethoxine in cattle (Title 21, Code of Federal Regulations, Part 556.640).

You are adulterating the drug [redacted] brand of oxytetracycline hydrochloride that your firm uses on dairy cows within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling or as directed by your veterinarian. The directions on the bottle supplied by your veterinarian direct you to use the drug one time and infuse 20-40 cc of the drug intrauterine. You mixed the drug with Sulforal and administered the mixture

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intravenously two times on consecutive days. Since your records do not indicate what animal was treated with what drug and when it was treated, you do not know how long the animal had to be held since the last treatment. This causes the drug to be unsafe to use.

In addition, our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

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 ensuring that your overall operation 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.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Compliance Officer Robert P. Snell at the address on the letterhead.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

RPS/ccl

xc: 