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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35

Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, Florida 32809

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

**WARNING LETTER**

ORL-98-12

December 16, 1997

Daniel T. Aprile, Co-Owner/Vice-President  
Aprile Farms, Inc.  
6704 Drifting Sands Road  
Temple Terrace, FL 33617

Dear Mr. Aprile:

An investigation of your dairy farm located at 11513 Balm Riverview Road in Riverview, FL conducted by our investigator Christine M. Humphrey on October 31 and November 3, 1997, confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

On or about July 21, 1997 you sold a dairy cow, identified by back tag #4443 and USDA laboratory case report # 5-0207-97, for slaughter as human food at the Cattleman's Livestock Auction Market in Tampa, FL. USDA analysis of tissue samples collected from that animal identified the presence of Sulfadimethoxine in the liver of the animal at a level of 8.50 ppm and in the muscle tissue at a level of 4.40 ppm. A tolerance of 0.10 ppm has been established for residues of Sulfadimethoxine in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are inadequate to ensure that diseased animals and/or medicated animals bearing potentially harmful drug residues are prevented from entering the food supply. Specifically, you fail to keep medication records which identify the amount of drug administered, date administered and adherence to the proper withdrawal time to permit depletion of potentially hazardous residues from the edible tissues. Your medication records are not maintained for a sufficient length of time after the sale of the animal to permit investigation of any drugs administered to the animal. You also fail to maintain drug inventory records and expired drugs were found in your drug storage area. Food from animals held under these conditions is adulterated.

Mr. Daniel T. Aprile  
Aprile Farms, Inc.  
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This letter is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

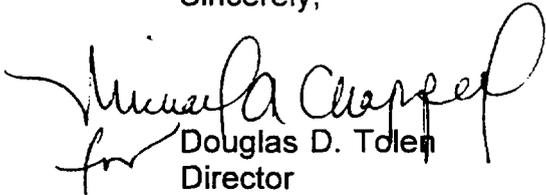
You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Kendall W. Hester, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, ext. 261.

Sincerely,

  
for Douglas D. Tolen  
Director  
Florida District