



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

V. L. W. S.

HFI-35

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-20-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 21, 1999

Mark St. Pierre
Box 566
Provence Street
Richford, VT 05476

Dear Mr. St. Pierre:

An investigation at your dairy operation located at 1954 Richford Road, Richford, VT, conducted by representatives of the Vermont Department of Agriculture and the Food and Drug Administration, on March 2 and 12, 1999, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

On or about January 11, 1999, you sold a cow, identified with back tag #9060, and ear tag #VTA003947, for slaughter as human food to the McCracken Livestock Auction, St. Albans, VT. USDA analysis of tissue samples collected from this animal identified the presence of 0.06 parts per million (ppm) penicillin in the kidney, and 0.35 ppm of sulfadimethoxine in the liver of this animal. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cows, (Title 21 Code of Federal Regulations Part 556.510). A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cows, (Title 21 Code of Federal Regulations Part 556.640). The presence of these drugs in edible tissues from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful residues are likely to enter the food supply. For example, you lack an adequate system to identify and segregate treated animals. Also, you do not maintain medication/treatment records which identify the animal, the date of medication, the drug, the dosage administered and the drug pre-slaughter withdrawal time. Additionally, you do not have a system to review treatment records prior to offering an animal for slaughter for human food to assure that drugs have been used only as directed and to assure that appropriate withdrawal times have been observed. Foods from animals held under such conditions are adulterated.

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 operation and the foods you distribute are in compliance with the law.

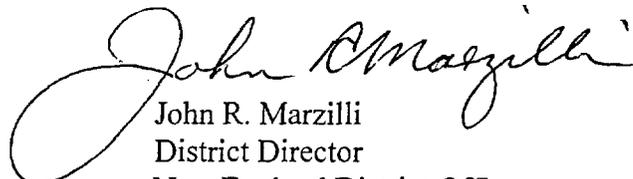
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the 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 receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,


John R. Marzilli
District Director
New England District Office