



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g3773d

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December 23, 2002

WARNING LETTER

NWE-05-03W

VIA FEDERAL EXPRESS

Mr. Peter M. Zacharais, Owner
DBA Zacharias Holsteins
31 Eureka Street
Falmouth, ME 04105

Dear Mr. Zacharias:

An inspection of your dairy farm located in Falmouth, ME was conducted by our investigators on September 11, 18, and 19, 2002. That inspection 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 (the Act). You caused the new animal drug gentamicin sulfate to become adulterated within the meaning of Section 501 (a)(5) of the Act, because the drug was used in a manner that does not conform with extralabel use regulations in Title 21 Code of Federal Regulations (21 CFR) Part 530. You can find the Act and associated regulations on the Internet through links on FDA's web page www.fda.gov.

On June 11, 2002, you sold a dairy cow, identified by back tag [REDACTED] for slaughter as human food to [REDACTED] a licensed livestock dealer in [REDACTED]. This animal was shipped to the [REDACTED] where it was slaughtered for human food. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the animal's kidney at a level of 2.19 ppm. There is no established tolerance for residues of gentamicin in the edible tissues of cattle in 21 CFR 556.300. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

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." 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 that may allow medicated animals bearing possibly harmful drug residues to enter the food supply.

For example, our investigator noted the following conditions on your farm:

1. You lack an adequate record system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate record system for assuring that animals to which you administer medication, have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their label.

You used a drug containing [REDACTED] which contains gentamicin sulfate. Gentamicin has not been approved for use in dairy cows. The extralabel use of approved animal drugs is allowed under section 512(a)(4)(A) of the Act provided that extralabel use regulations at 21 CFR Part 530 are followed. You cause this drug to be adulterated within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with 21 CFR Part 530. Because your use of gentamicin resulted in the presence of drug residue in edible tissue that might present a risk to public health, use of the drug was not in compliance with extralabel use regulations 21 CFR 530.11(c). Your use of this drug in a manner not in compliance with extralabel use regulations causes the drug to be unsafe within the meaning of section 512 of the Act and therefore adulterated within the meaning of section 501(a)(5) of the Act.

For your information, in October 1994 Congress passed the Animal Medicinal Drug Use Clarification Act which permits extralabel use of drugs under certain controlled conditions as specified in 21 CFR Part 530. "Extralabel use" means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. Extralabel 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 21 CFR Part 530. This includes any withhold or discard time for meat, milk, eggs or any other food which might be derived from the treated animal or animals.

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 be aware that it is not necessary for you to have personally shipped 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 to a slaughterhouse engaged in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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 or/ and injunction. **This letter constitutes official notification under the law.**

You should notify this office in writing within fifteen (15) working days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrections cannot be completed within fifteen (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 Patricia Murphy, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mrs. Murphy at (781) 596-7758.

Sincerely,



Gail T. Costello
District Director
New England District Office

cc:
Dr. Rebecca Myers
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