



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94733d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-23-04W

April 7, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Frederick R. Schultze, Owner
335 Goodwin Road
Eliot, Maine 03903

Dear Mr. Schultze:

An inspection of your dairy farm located in Eliot, Maine was conducted by our investigators on January 22, 2004. 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 also 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 the extralabel use regulations in Title 21, Code of Federal Regulations Part 530 (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 or about November 2, 2003, you sold a dairy cow, identified by the back tag number #11EG7519 for slaughter as human food to [REDACTED] a livestock hauler. The animal was then sold to [REDACTED] and transported by that firm to [REDACTED] where it was slaughtered for human food. USDA analysis of tissue samples collected from the animal identified the presence of gentamicin in the animal's kidney at a level of 10.14 parts per million (ppm), and liver at a level of 0.33 ppm. There is no established tolerance for residues of gentamicin in the edible tissues of cattle, see 21 CFR 556.300. The presence of this drug in the edible tissues of this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii).

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 keeping 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.

Gentamicin has not been approved for use in cattle and therefore, no tolerance has been established for residues of gentamicin in the edible tissues of cattle. The extralabel use of approved animal drugs is allowed under section 512(a)(4)(A) of the Act provided that the extralabel use regulations at 21 CFR Part 530 are followed. You caused this drug to be adulterated within the meaning of section 501(a)(5) of the Act when you failed to use the drug in conformance with 21 CFR Part 530. These regulations require, among other conditions, that the extralabel use not result in residues above the established tolerance, 21 CFR 530.11(d). Your extralabel use of this drug resulted in a residue, which 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(s) for meat, milk, eggs, or any other food which might be derived from the animal or animals.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals that 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.

Frederick R. Schultze, Owner
Eliot, Maine 03903
Page 3

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 and/or injunction.

You should notify this office in writing with fifteen (15) working days of receiving this letter 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 Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have any questions you can contact Mr. Ota at the above phone number.

Sincerely,



Gail T. Costello
District Director
New England District

cc:



New Hampshire Board of Veterinary Medicine
25 Capitol Street
Box 2042
Concord, New Hampshire 03302-2042
Attn: Patricia Duncklee, Administrative Secretary