



DEPARTMENT OF HEALTH AND HUMAN SERVICES

95010d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

September 28, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 38

Gene A. Martin
35004 County Road 18
Sauk Centre, Minnesota 56378

Dear Mr. Martin:

A tissue residue report received by the U.S. Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in a dairy cow that originated from your dairy farm in Sauk Centre, MN. On July 8, 2004, an investigator from the Minnesota Department of Agriculture, acting on behalf of the FDA, conducted an inspection at your dairy farm. That inspection confirmed that you offered a dairy cow 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), 21 U.S.C. §§ 342(a)(2)(C)(ii) and (a)(4). You also caused the adulteration of animal drugs because the drugs were used in a manner that does not conform to their approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations (21 CFR), Part 530 (copy enclosed). This caused the animal drugs to be unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

On or about May 24, 2004, you sold a dairy cow (identified with back tag [REDACTED] to be slaughtered for human food at [REDACTED]. USDA analysis of tissue samples collected from this cow identified the presence of oxytetracycline at 2.86 parts per million (ppm) in the muscle and 14.83 ppm in the kidney (USDA laboratory report number 450154). A tolerance of 2 ppm has been established for residues of oxytetracycline in muscle and 12 ppm in kidney. 21 CFR § 556.500 (copy enclosed). The presence of this drug at levels above the tolerances in edible tissue from this animal causes the food to be

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adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you failed to maintain drug treatment records and you failed to assure that a medicated animal was withheld from slaughter for an appropriate period of time to permit depletion of potentially hazardous residues of drugs in edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4).

Moreover, our investigation found that you fail to use animal drugs in conformance with the drugs' approved labeling and/or the extralabel use regulations. The extralabel use of an approved veterinary or human drug is permitted only if it complies with Sections 512(a)(4) and (a)(5) of the Act, 21 U.S.C. § 360b(a)(4) and (a)(5), and 21 CFR Part 530. Pursuant to 21 CFR § 530.11(a), extralabel use of an animal drug by a lay person is prohibited except when under the supervision of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. In addition, 21 CFR § 530.11(d) prohibits any extralabel use that results in a residue exceeding an established safe level, safe concentration, or tolerance. Our investigation revealed that you administered more than 10 milliliters per injection site of oxytetracycline (), when that drug's approved labeling limits its administration to no more than 10 milliliters per injection site in adult cattle. 21 CFR § 522.1660 (copy enclosed). You also administered penicillin () at 20 milliliters per animal, a higher dose than specified in the labeling for the drug. 21 CFR § 522.1696b (copy enclosed). Accordingly, because your use of these drugs did not conform to the drugs' approved labeling or the extralabel use regulations, the drugs are unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b, and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

It is not necessary for you personally to ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act. Similarly, it is not necessary for you personally to ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of animal drugs that had been shipped in interstate commerce is sufficient to hold you responsible.

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.

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You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. 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 dairy into compliance with the law. Your response should include each step being taken, that has been taken, or that will be 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 time 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 Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TGP/ccl *rd*

Enclosures: 21 CFR Part 530, 21 CFR §§ 522.1660, 522.1696b, 556.500