



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

4027d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2003-DT-15

May 15, 2003

Mr. Michael D. Geerlings, Owner
Scenic View Dairy, LLC
1162 62nd Street
Fennville, MI 49408

Dear Mr. Geerlings:

An investigation of your dairy operation located at 1162 62nd Street, Fennville, MI, conducted by our Food and Drug Administration investigators on November 2, thru December 5, 2002, confirmed that you offered two animals for sale for slaughter for human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). In addition, extra label animal drug usage at your facility caused the drugs to be adulterated within the meaning of Section 501(a)(5) of the Act.

On June 17, 2002, you sold an adult [REDACTED] dairy cow identified at [REDACTED] with back tag #34 WL 9/669 for slaughter as human food to [REDACTED]. This cow was slaughtered on June 18, 2002 and USDA analysis of tissue samples collected from that animal identified the presence of 254.50 parts per million (ppm) of neomycin in the kidney tissue and 15.27 ppm neomycin in the liver. In addition, on August 7, 2002 you sold an adult [REDACTED] dairy cow identified with ear tag #5627 for slaughter as human food to [REDACTED]. This cow was slaughtered on August 7, 2002 and USDA analysis of tissue samples collected from that animal identified the presence of 7.90 ppm neomycin in the kidney tissue. A tolerance of 7.2 ppm has been established for residues of neomycin in kidney tissue and 3.6 ppm for liver tissue of cattle. The presence of this drug, at levels above the established tolerances, in edible tissue from these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

We also note that USDA reported the finding of illegal residues in three other dairy cows sold by you and offered for slaughter for human food in 2001 (dairy cow on April 5, 2001 with sulfadimethoxine residue; dairy cow on February 15,

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2001 with sulfadimethoxine residue; and dairy cow on February 7, 2001 with penicillin residue).

Our investigation also found that you hold animals under conditions which are inadequate in that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example:

1. Failure to maintain medication/treatment records to identify the drug dosage administered, route of medication, or pre-slaughter withdrawal time. For example, the medical treatment records for [REDACTED] dairy cows #105 and #5627 offered for sale for slaughter for human food on June 17, 2002 and August 7, 2002, respectively, lacked this information. These same two animals were found to contain violative tissue levels of neomycin.
2. Failure to systematically review treatment records prior to offering an animal for slaughter for human food to assure that drugs have been used only as directed and that appropriate withdrawal times have been followed.

Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, your failure to use the drug neomycin in conformance with the approved labeling causes it to be adulterated within the meaning of Section 501(a)(5) of the Act. The use of neomycin in lactating dairy cows, for which it is not approved, may only be done in compliance with 21 CFR Part 530, Extra label Drug Use in Animals. These regulations require, among other conditions, that the extra label use not result in residues above the established tolerance and that the use is by or on the order of a veterinarian within the context of a valid veterinarian/client/patient relationship.

The above is not intended to be an all-inclusive list of violations. As a producer of dairy cows that are offered for use as food, you are responsible for assuring that your overall operations 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 sanctions without further notice. These sanctions include, but are not limited to, seizure or injunction. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

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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 in interstate commerce to a slaughter facility is sufficient to hold you responsible for 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 taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Mr. David M. Kaszubski, Director Compliance Branch, at the above address.

Sincerely yours,



Joann M. Givens
District Director
Detroit District Office