



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4134

December 18, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 04 - 09

Robert J. Schell, DVM  
Co-owner  
Schell's Pine Grove Dairy  
203 First Avenue SE  
Altura, Minnesota 55910

Dear Dr. Schell:

On October 30, 2003, investigators from the Food and Drug Administration (FDA) conducted an inspection at your dairy farm located at R.R. 1, Box 128, Altura, MN. 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). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to its approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about June 30, 2003, you sold a cow identified with ear tag number 41BJN9842 (cow #540) for slaughter as human food to  U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow (backtag 41NT6772) identified the presence of flunixin at 0.463 parts per million (ppm) in the liver. Because flunixin is not approved for use in lactating or dry dairy cows (per 21 CFR 522.970, copy enclosed), the tolerance in those animals is zero. The presence of flunixin in the edible tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from

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entering the food supply. For example, you fail to maintain complete and accurate treatment records. Specifically, not all medication treatments are permanently recorded in the treatment records, i.e., cow #540 was treated with flunixin on June 18, 2003, for ketosis and there is no permanent record of the treatment. Your system is inadequate for assuring that animals medicated by you have been withheld from slaughter for appropriate periods 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.

Flunixin is not approved for use in lactating or dry dairy cows. However, the extralabel use of an approved veterinary or human drug is permitted if it complies with Sections 512(a)(4) and (a)(5) of the Act, and 21 CFR Part 530. Our investigation found that your extralabel use of flunixin failed to comply with these requirements because its use resulted in an illegal drug residue. An FDA regulation, 21 CFR 530.11(d), prohibits any extralabel use that results in a residue exceeding an established tolerance level. Because your extralabel use of flunixin was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act, causing it to be adulterated within the meaning of Section 501(a)(5) of the Act.

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of a drug that had been shipped in interstate commerce is sufficient to hold you responsible for violations of the Act.

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. 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.

We have enclosed a copy of 21 CFR Part 530 for your reference. We strongly suggest that you review 21 CFR Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

You should notify this office in writing within 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 prevent the recurrence of similar violations. 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 your corrections have been made.

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Your reply should be directed to Catherine Leonard, Legal Instruments Examiner,  
at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat  
Director  
Minneapolis District

/cc

JS

Enclosures: 21 CFR 530  
21 CFR 522.970

xc: Steven C. Schell  
Co-owner  
Schell's Pine Grove Dairy  
R.R. 1, Box 128  
Altura, MN 55910

John King, DVM  
Director  
Minnesota Board of Veterinary Medicine  
2829 University Avenue SE  
Minneapolis, MN 55414