

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	DATE(S) OF INSPECTION 01/23/2007 - 01/25/2007
	FET NUMBER 3003380618

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Michael D. Geerlings, Owner

FIRM NAME Scenic View Dairy LLC	STREET ADDRESS 1510 62nd St
CITY, STATE, ZIP CODE, COUNTRY Fennville, MI 49408-8528	TYPE ESTABLISHMENT INSPECTED Dairy Farm

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Causing a residue of an approved human or animal drug above an established safe level, safe concentration, or tolerance, through use of the drug contrary to its labeling.

Specifically, on 11/06/2006, your farm offered **(b) (4)** dairy cows for sale for human consumption. Three of the cows were subsequently slaughtered and resulted in violative tissue drug residues identified as follows:

- A) Back Tag # **(b) (4)** had a tissue drug level (Sulfadimethoxine) of 0.23 in the Liver and 0.185 in the Muscle.
- B) Back Tag # **(b) (4)** had a tissue drug level (Sulfadimethoxine) of 0.78 in the Liver and 0.57 in the Muscle.
- C) Back Tag # **(b) (4)** had a tissue drug level (Sulfadimethoxine) of 0.57 in the Liver and 0.38 in the Muscle. This same cow also had a tissue drug level (Penicillin) of 0.51 in the Kidney and 0.08 in the Liver.

OBSERVATION 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 observed.

Specifically, your farm offered three dairy cows (Back Tag **(b) (4)**) for sale for human consumption on 11/06/2006. These animals were found to have violative tissue levels (as noted in Item # 1). Withdrawal times were not observed before the animals were culled and sold at auction.

OBSERVATION 3

Failure to maintain treatment records.

Specifically, adequate records are not kept on your farm. The medical treatment records for th **(b) (4)** treated animals which were

SEE REVERSE OF THIS PAGE	DATE ISSUED 01/25/2007
<i>Donald W. Myrick, Investigator</i>	

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sold on 11/06/2006 to slaughter for human consumption lacked the drug amount administered, the route of administration, (b) (4) withdrawal time. These records include the animals identified with Back Tag (b) (4) and (b) (4) that were found to contain violative tissue levels of Sulfadimethoxine and the latter to contain violative tissue level of Penicillin as well (as noted in Item # 1).

OBSERVATION 4

Failure to segregate treated animals.

Specifically, your farm does not segregate the treated animals from the rest of the herd. The farm does not have a designated separate hospital pen for the treated animals.

OBSERVATION 5

Failure to maintain records regarding the identity of the animal(s) that you purchased and delivered for sale at an auction yard.

Specifically, records and documentation could not be found that showed from where the (b) (4) animals that were sold to slaughter for human consumption on 11/06/2006 originated. Your farm is receiving approximately (b) (4) of your animals from out of state sources mainly Pennsylvania, New Hampshire, and Vermont. Three of the (b) (4) animals sold were found to contain violative tissue residues (as noted in Item # 1).

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Donald W Myrick, Investigator

Donald W. Myrick, Investigator

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OF THIS PAGE

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