

**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

12/18/2007 - 01/07/2008*

FBI NUMBER

3003380618

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael J. Van Dam, Farm Manager

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

Use of an animal drug in a manner contrary to label directions without benefit of a valid veterinary client-patient relationship. Specifically, your farm is not following the label directions for the drug Penicillin. For example:

1) Written medical records dated 10/11/2007 - 10/14/2007 show the two dairy cows identified respectively with Ear Tag # (b) (4) as being treated with 100cc of Penicillin.

2) Also, current written medical records dated 12/17/2007 - 12/19/2007 show the dairy cow identified with Ear Tag # (b) (4) as being treated with 40cc, 60cc, and 40cc of Penicillin respectively.

Penicillin is labeled per DOC sample # 434543 to be administered as 3,000 units per pound of body weight (1cc per 100lbs body weight) daily by intramuscular injection.

OBSERVATION 2

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 06/19/2007, your farm offered (b) (4) dairy cows for sale for human consumption. One of the (b) (4) cows was subsequently slaughtered and resulted in violative drug residues identified as follows:

Dairy Cow Identified with Back Tag # (b) (4) had a tissue drug level (Sulfadimethoxine) of 0.24 ppm in the Liver and 0.20 ppm in the Muscle. The established Tolerance Level for Sulfadimethoxine is 0.1 ppm in the Liver and Muscle.

Also, on 10/17/2007, your farm offered a dairy cow identified with Ear Tag # (b) (4) for sale for human consumption. This dairy cow identified with Ear Tag # (b) (4) was subsequently slaughtered and resulted in a violative drug residue identified as follows:

Dairy Cow identified with Ear Tag # (b) (4) had a tissue drug level (Penicillin) of 0.24 ppm in the Kidney. The established Tolerance Level for Penicillin is 0.05 ppm in the Kidney.

SEE REVERSE OF THIS PAGE

Donald W. Myrick, Investigator

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Fennville, MI 49408-8528	Dairy Farm	

OBSERVATION 3

Treatment records were not complete.

Specifically, your written and computer generated medical records do not consistently have the route of administration, dosage, and withdrawal time recorded for the drugs used to treat the dairy cows on your farm. For example:

- 1) Current written medical records dated 12/17/2007 - 12/20/2007 do not consistently have the route of administration, dosage, and withdrawal times recorded for the drugs used to treat the dairy cows on your farm.
- 2) The written and computer generated records dated 10/10/2007 - 10/16/2007 for the dairy cow identified with Ear Tag # (b) (4) do not consistently have the route of administration, dosage, and withdrawal times recorded for the drugs used to treat this animal. This dairy cow at slaughter resulted in a violative drug residue (Penicillin).

OBSERVATION 4

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 (b) (4) dairy cows for sale for human consumption on 06/19/2007. One of the (b) (4) cows was subsequently slaughtered and resulted in violative drug residues identified as follows:

Dairy cow identified with Back Tag # (b) (4) had a tissue drug level (Sulfadimethoxine) of 0.24 ppm in the Liver and 0.20 ppm in the Muscle. The established Tolerance Level for Sulfadimethoxine is 0.1 ppm in the Liver and Muscle.

Also, on 10/17/2007, your farm offered a dairy cow for sale for human consumption. This dairy cow identified with Ear Tag (b) (4) was subsequently slaughtered and resulted in a violative drug residue identified as follows:

Dairy cow identified with Ear Tag # (b) (4) had a tissue drug level (Penicillin) of 0.24 ppm in the Kidney. The established Tolerance Level for Penicillin is 0.05 ppm in the Kidney.

Withdrawal times were not observed before the animals were culled and sold at auction.

OBSERVATION 5

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

Specifically, records and documentation could not be found that documented where the (b) (4) dairy cows which were sold to slaughter for human consumption on 06/19/2007 originated. Also, records and documentation could not be found that documented where the dairy cow attached with Ear Tag # (b) (4) which was sold to slaughter for human consumption on 10/17/2007 originated. Your farm is receiving approximately (b) (4) of your dairy cows from out of state sources mainly

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Pennsylvania, New Hampshire, and Vermont. One of the (b)(4) dairy cows and the dairy cow identified with Ear Tag # (b)(4) were found to contain violative drug residues (as noted in Item # 2).

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Dairy Farm

*** DATES OF INSPECTION:**

12/18/2007(Tue), 12/19/2007(Wed), 12/21/2007(Fri), 01/07/2008(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Donald W. Myrick

Donald W Myrick, Investigator

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