

**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  
Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

DATE(S) OF INSPECTION

08/11/2009 - 10/01/2009\*

FEI NUMBER

3006577714

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Michael J. Van Dam, Farm Manager

FIRM NAME

Scenic View Dairy, LLC

STREET ADDRESS

10560 Freeport Ave

CITY, STATE, ZIP CODE, COUNTRY

Freeport, MI 49325-9505

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 11/25/2008 you sold <sup>(b) (4)</sup> head of cattle through an auction house to be slaughtered for human consumption. One of the <sup>(b) (4)</sup> head resulted in a violative drug residue identified below:

1. Dairy cow identified with Ear Tag # <sup>(b) (4)</sup> (Plastic Ear Button # <sup>(b) (4)</sup> and Back Tag # <sup>(b) (4)</sup> was found to have a tissue drug level (Penicillin) of 0.10 ppm in the kidney. The tolerance level for Penicillin in the uncooked edible tissues including the kidney in cattle is 0.05 ppm.

**OBSERVATION 2**

Use of an animal drug in a manner contrary to label directions without benefit of a valid veterinary client-patient relationship.

Specifically,

1. When Penicillin is used, you routinely medicate the animals with 20 cc and/or 40 cc of Penicillin (Pen G, Pen) in a 24 hour period. The labeled dosage for Penicillin as indicated on the label states 1 cc per 100 pounds (10 cc per 1,000 pounds) body weight. There is not a veterinary prescription label on the bottles of Penicillin at your farm authorizing the administering of the drug in excess of the indicated dosage.
  - a. For example, the dairy cow identified with Ear Tag # <sup>(b) (4)</sup> was administered 40 cc of Penicillin (Pen G, Pen) on 11/10/2008 and 20 cc of Penicillin on 11/11/2008, 11/12/2008, and 11/13/2008.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Donald W Myrick, Investigator

*Donald W. Myrick, Investigator*

DATE ISSUED

10/01/2009

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- b. For example, the dairy cow identified with Ear Tag # (b) (4) was administered 40 cc of Penicillin (Pen G, Pen) on 08/08/2009 and 08/10/2009.
- c. For example, the dairy cow identified with Ear Tag # (b) (4) was administered 40 cc of Penicillin (Pen G, Pen) on 08/02/2009 and 08/03/2009.

**OBSERVATION 3**

Treatment records were not complete.

Specifically,

1. You do not routinely record the route of administration of each drug administered to the dairy cows on your farm.
  - a. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Penicillin (Pen G, PEN) on 11/13/2008. Your computer generated and written record does not indicate the route of administration.
  - b. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Sulfadimethoxine (SDM) on 08/05/2009. Your computer generated and written record does not indicate the route of administration.
  - c. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Polyflex (Poly) on 08/04/2009 and 08/05/2009. Your computer generated and written record does not indicate the route of administration.
2. You do not always record the dosage of each drug administered to the dairy cows on your farm.
  - a. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Flunixin

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Donald W Myrick, Investigator <i>DW</i>	DATE ISSUED 10/01/2009
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Dairy Farm

(Banamine; Benamine, BN) on 11/13/2008. Your written and computer generated record does not indicate the dosage of Flunixin (Banamine) that was administered to this dairy cow.

- b. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Polyflex (Poly) on 08/05/2009. Your computer generated and written record does not indicate the dosage of Polyflex that was administered to this dairy cow.
- c. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Penicillin (Pen G, Pen) on 08/08/2009. Your computer generated and written record does not indicate the dosage of Penicillin that was administered to this dairy cow.

**\* DATES OF INSPECTION:**

08/11/2009(Tue), 08/12/2009(Wed), 09/01/2009(Tue), 09/15/2009(Tue), 10/01/2009(Thu)

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