

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry		08/14/2009 - 09/18/2009*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
TO: Mark A. Lucas, Farm Manager		3003380618
FIRM NAME	STREET ADDRESS	
Scenic View Dairy LLC	1510 62nd St	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Fennville, MI 49408-8541	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 01/05/2009 you sold ^{(b) (4)} head of cattle to a USDA/FSIS inspected slaughter facility to be slaughtered for human consumption. One of the ^{(b) (4)} head resulted in a violative drug residue identified below:

1. Dairy cow identified with Ear Tag # ^{(b) (4)} (House Tag # ^{(b) (4)}) was found to have a tissue drug level (Flunixin) of 0.1525 ppm in the liver. The tolerance level for Flunixin in the uncooked edible tissue (liver) is 0.125 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 on your farm, you routinely medicate the animals with 40 cc of Penicillin (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, you medicated a dairy cow identified with Ear Tag # ^{(b) (4)} with 40 cc of Penicillin (PEN) on 08/07/2009.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Donald W Myrick, Investigator <i>Donald W. Myrick</i>	09/18/2009

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TO: Mark A. Lucas, Farm Manager

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<small>CITY, STATE, ZIP CODE, COUNTRY</small> Fennville, MI 49408-8541	<small>TYPE ESTABLISHMENT INSPECTED</small> Dairy Farm

- b. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with 40 cc of Penicillin (PEN) on 08/08/2009.
- c. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with 40 cc of Penicillin (PEN) on 08/12/2009.

OBSERVATION 3

Failure to follow your veterinarian's prescription for route of administration.

Specifically,

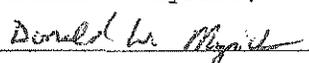
On 12/30/2008, you medicated a dairy cow identified with Ear Tag # (b) (4) with Flunixin (Banamine, BANA, BAN) via Intramuscular (IM) route of administration. The veterinarian prescription label indicates Flunixin should be administered via slow Intravenous (IV) route of administration.

OBSERVATION 4

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 Flunixin (Banamine, BAN, BANA) on 12/30/2008. Your computer generated and written records do not indicate the route of administration.
 - b. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Penicillin (PEN) on 08/08/2009. Your computer generated and written records do not indicate the route of administration.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Donald W Myrick, Investigator 	<small>DATE ISSUED</small> 09/18/2009
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TO: Mark A. Lucas, Farm Manager

FIRM NAME

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STREET ADDRESS

1510 62nd St

CITY, STATE, ZIP CODE, COUNTRY

Fennville, MI 49408-8541

TYPE ESTABLISHMENT INSPECTED

Dairy Farm

c. 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 records do 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 (Banamine, BAN, BANA) on 12/30/2008. Your computer generated and written records do not indicate the dosage of Flunixin that was administered to this dairy cow.

b. For example, you medicated a dairy cow identified with Ear Tag # (b) (4) with Flunixin (Banamine, BAN) on 08/04/2009. Your computer generated and written records do not indicate the dosage of Flunixin that was administered to this dairy cow.

c. 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 records do not indicate the dosage of Flunixin that was administered to this dairy cow.

*** DATES OF INSPECTION:**

08/14/2009(Fri), 08/20/2009(Thu), 08/31/2009(Mon), 09/18/2009(Fri)

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Donald W Myrick, Investigator

Donald W Myrick

DATE ISSUED

09/18/2009