

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Minneapolis District 250 Marquette Ave. Suite 600 Minneapolis, MN 55401 612-334-4100 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/30/11; 03/31/11
	FEI NUMBER 3002662136

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Gregory P. Lanoue - Owner

FIRM NAME Greg Lanoue Farm	STREET ADDRESS 1892 330 Ave.
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CITY, STATE AND ZIP CODE Tracy, MN 56175	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Producer
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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) (WE) OBSERVED:

Observation #1:

You did not maintain records documenting compliance with biosecurity measures.

Specifically, Your biosecurity measures for Protective Clothing, Good Sanitation, Keeping Buildings free from stray poultry, pets and wild animals and Employees Possession of birds at home: does not include record keeping to monitor employee compliance with these Biosecurity Measures.

Additionally, you do not document compliance of the Biosecurity Measures in your SE plan for visitors to your facility.

Observation #2:

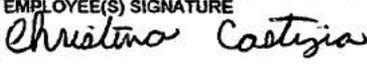
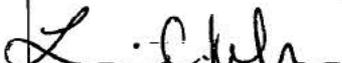
The presence of rodents is not monitored by appropriate monitoring methods.

Specifically, Your rodent monitoring practices consists of weekly visual inspection of the facility, collection of (b) (4) stations monitoring. You do not record and document counts or utilize other means for monitoring to determine if activity is acceptable or unacceptable. Counts, Records and Documentation will indicate levels of rodent activity actually present in your laying house.

Observation #3:

The presence of flies is not monitored by appropriate monitoring methods.

Specifically, Your fly monitoring practices consists of daily visual inspection of the facility. You do not record and document, counts/ levels or utilize other means for monitoring to determine if activity is acceptable or unacceptable. Counts, Records and Documentation will indicate levels of fly activity actually present in your laying house.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Christina A. Castineyra-CSO	DATE ISSUED 03/31/11
		Traci C. Kelm - CSO	