

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

11630 W. 80th Street
Lenexa, KS 62214
(913)752-2100

DATE(S) OF INSPECTION

04/04/2011, 04/05/2011

FEI NUMBER

3002891352

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mike A. Clayton, Complex Manager

FIRM NAME

Rose Acre Farms, Inc. (Guthrie Center location)

STREET ADDRESS

2143 215th Road

CITY, STATE AND ZIP CODE

Guthrie Center, IA 50115

TYPE OF ESTABLISHMENT INSPECTED

Shell Egg Producer

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:

Your written SE prevention plan is not fully implemented and followed.

Specifically, your Biosecurity Plan July 2010, version 2, revised 11/29/2010 states in part: when a flock on a farm site has a diagnosed infectious disease of poultry, additional steps will be written by executive management and delivered to the farm or complex manager to put into effect immediately. Executive management will notify the State Veterinarian for any infectious poultry disease that is reportable in that state. During the inspection, your management indicated hens in house one of your farm has been diagnosed with Marek's Virus by your firm's veterinarian. The Iowa State Veterinarian, has not received notification of this reportable virus.

For testing to detect SE in environmental samples, you did not have the sample testing conducted by the method entitled "Environmental Sampling and Detection of Salmonella in Poultry Houses." most current edition, or an equivalent method in accuracy, precision and sensitivity in detecting SE.

Specifically, your firm's method, Title: Poultry Environmental Salmonella Test, Document No: 10.1.8 Poultry. Env.Sal.Testing, Version Date: 2-14-11 (version 1) does not follow the method indicated in 21 CFR 118.8 (a).

All required records do not have the signature or initials of the person performing the operation or creating the record.

Specifically, during a review of required records for the months of September 2010 through November 2010 of your firms IPM Form C, there were no initials of the person performing the operation in the available space on these forms identified as follows:

Facility GCEF - 6, Start Date 9-25-10, End Date, 10-30-10.

Facility GCEF - 6, Start Date 10-31-10, End Date, 11-27-10.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Candace S. Tucker, Investigator	04/05/2011
		Meisha R. Waters, Investigator	
		Donald S. Duden, Investigator	