

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 US-FDA New England Office One Montvale Avenue- 4th Floor Stoneham, MA 02180-3500 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/04-07/2010
	FEI NUMBER 3007919151

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: John C. Lough, Owner

FIRM NAME Mountain Hollow Farm, LLC	STREET ADDRESS Plant Six Road
CITY, STATE AND ZIP CODE Leeds, ME 04263	TYPE OF ESTABLISHMENT INSPECTED Egg Shell 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:

1. Eggs intended to be processed as table eggs were not held as required at or below 45 degrees F.
Specifically, eggs stored at your Plant (b) (4) Cooler had temperature recordings on 9/30/10 at the Bay (b) (4) location of 45.5 F at 8:30 A.M. , 46.8 F at 10:30 A.M. , and 47.9 F at 2:30 P.M.

2. When your monitoring indicated unacceptable rodent activity within a poultry house, appropriate methods were not used to achieve satisfactory rodent control.
Specifically, in poultry house (b) (4) while conducting environmental sampling on 10/5/10, twenty-three (23) rodents were observed running across walkways in between poultry rows.

3. You did not maintain records documenting compliance with biosecurity measures.
Specifically, you do not document personnel biosecurity measures as per your Bio-security Plan dated 9/17/10.

4. All required records do not include "Your Name" and "the location of your farm" on the records.
Specifically your "Moving Tape Fly Count" records dated 9/12/10, 9/28/10 and 10/3/10 do not have your firm name and address on the record.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alas Provest, CSO	DATE ISSUED 10/7/10
		Bruce Cooper CSO	