

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

FDA Kansas City District Office
11630 W 80th St
Lenexa, KS 66214-3340 (913) 752 2100

DATE(S) OF INSPECTION

8/19/10-8/26/10

FEI NUMBER

3004354976, 3004404403, 3006481690

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Gary W Bartness, General Manager*

FIRM NAME

Hillandale Farms of Iowa, Inc

STREET ADDRESS

19 1/2 West Main

CITY, STATE AND ZIP CODE

New Hampton, IA 50659

TYPE OF ESTABLISHMENT INSPECTED

Egg Manufacturer

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (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.

Observations listed below cover inspections of your egg laying farms/plants inspected from 08/19/2010 through 08/26/2010.

FEI: 3004354976 - Hillandale Farms of Iowa, Inc, 19 1/2 West Main, New Hampton, IA 50659

FEI: 3004404403 - Hillandale Iowa II, LLP, 13706 230th St, West Union, IA 52175 (referred to as West Union)

FEI: 3006481690 - Hillandale Farms, LLC, 13998 140th St, Alden, IA 50006 (referred to as Alden)

1. You did not maintain documentation that the 19 week old pullets in house 4 at the Alden facility were "SE monitored" or were raised under "SE monitored" conditions, including environmental testing records for pullets.

2. The written SE prevention plan was not fully implemented and followed.

Specifically,

a) Your document "Hillandale II LLP Bio-security Plan" (referenced in your Hillandale II LLP Salmonella Enteritidis Prevention Plan) created 5/1/10 states on p. 7 under the section entitled, "**** (b) (4) ****" states, you will "**** (b) (4) ****" You failed to follow your plan as evidenced by the following observations on 8/23/10:

- West Union House 1 - There were 3 unsealed rodent holes observed along east wall.
- West Union House 4 - There were 16 unsealed rodent holes along row 1. Two live rodents were observed entering into 2 of the rodent holes.
- West Union House 5 - There were approximately 20 unsealed rodent holes on south wall along row 7. A rodent was observed running into one of the rodent holes.
- West Union House 8 - There were 26 unsealed rodent holes on the south wall of the house. In addition, there were 5 unsealed rodent holes on the east side of the house.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>[Signature]</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jeffrey B. Moody, Investigator Joseph R. Lambert, Investigator Carmen Y. Fisher, Investigator Monica M. McClure, Investigator Gerardo A. Ramirez, Investigator Robert T. Hall, Investigator	DATE ISSUED 8/26/10
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
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DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 th St Lenexa, KS 66214-3340 (913) 752 2100		DATE(S) OF INSPECTION 8/19/10-8/26/10
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Gary W Bartness, General Manager		FEI NUMBER 3004354976, 3004404403, 3006481690
FIRM NAME Hillandale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main	
CITY, STATE AND ZIP CODE New Hampton, IA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer	

• Alden House 7 – Light was observed coming in around the perimeter of the west door due to inadequate seal. No seal was on the north rear manure door.

• Alden House 8 – Holes were observed in the walls on the north side of the building, approximately 1 foot by 2 feet, protruding into the manure pit.

• Alden House 9 – An approximate 1 inch gap was observed on the manure pit door at the west end of the house. Two holes were observed in the building: 1 hole, approximately 2 inches in diameter, on the south side of the building underneath the walkway and a hole on the right side of the entrance door approximately 2 inches in diameter.

c) Your document "Hillandale Iowa LLC Bio-security Plan" (referenced in your Hillandale Iowa LLC, Salmonella Enteritidis Prevention Plan) created 5/1/10 states under "(b) (4)" on page 12, "(b) (4)". You failed to follow your plan as evidenced by the following observations on 8/20/10:

• Alden House 2 – Standing water approximately ¼ inch deep was observed on the floor adjacent to the manure pit where the foot bath was located inside the building.

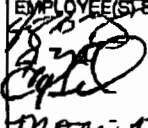
• Alden House 8 – Liquid manure was observed leaking into the east section of the first floor. Plant manager reported that a water line leak occurred several weeks ago causing the manure pit to flood.

d) Your document "Hillandale II, LLP Bio-security Plan" (referenced in your Hillandale II, LLP, Salmonella Enteritidis Prevention Plan) created 5/1/10 states under "(b) (4)" on page 12, "(b) (4)". You failed to follow your plan as evidenced by the following observation on 8/23/10:

• West Union House 7 - Liquid manure was observed streaming out of an approximate 6 inch gap of the east door of the manure pit. Plant manager reported a water leak had occurred.

e) Your document "Hillandale Iowa LLC Bio-security Plan" (referenced in your Hillandale Iowa LLC Salmonella Enteritidis Prevention Plan) created 5/1/10 states on page 8, "(b) (4)". You failed to follow your plan as evidenced by the following observation on 8/20/10:

• Alden House 7 – Weeds, approximately 12 inches tall, were observed growing along the exterior wall around the entire house.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Brett T. Hall	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brett T. Hall, Investigator Joseph E. Lambert, Investigator Carmen Y. Fisher, Investigator Marlene M. Miller, Investigator Gerardo R. Ramirez, Investigator Brett T. Hall, Investigator	DATE ISSUED 8/26/10
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3004354976, 3004404403, 3006481690

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gary W Bartness, General Manager

FIRM NAME

Hillandale Farms of Iowa, Inc

STREET ADDRESS

19 1/2 West Main

CITY, STATE AND ZIP CODE

New Hampton, IA 50659

TYPE OF ESTABLISHMENT INSPECTED

Egg Manufacturer

3. You failed to take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. This is evidenced by the following observations on 8/23/10:

- West Union House 7 - Approximately 35 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.
- West Union House 4 - Approximately 14 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.

4. All required records did not include the location of the farm and the signature or initials of the person who performed the operation.

Specifically,

- The "Fly Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 8/6/10, 8/13/10, and 8/20/10 did not include the specific farm location of the fly monitoring and the name or initials of the person who performed the inspection.
- The "Rodent Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, and 9) performed on the dates 7/12/10, 7/19/10, 8/2/10, and 8/23/10 did not include the specific farm location of the rodent monitoring and the name or initials of the person who performed the inspection.
- The "Moving Tape Fly Count" for the Alden site (Houses 1, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/29/10, 8/12/10, and 8/19/10 did not include the specific farm of the houses inspected.
- The "Pest B Gone" rodent activity logs for the Alden site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/22/10, 7/29/10, 8/5/10 and 8/19/10 did not include the specific location of the farm inspected and did not always include the name or initials of the person who performed the inspection.

5. Your written SE plan titled "Hillandale Iowa LLC Salmonella Enteritidis Prevention Plan" and "Hillandale II LLP Salmonella Enteritidis Prevention Plan" did not include the signature of your plan administrator.

6. Samples collected during the course of this inspection and tested by a FDA laboratory, revealed the following positive analytical test results: Spent water from egg wash station from Plant 5, sampled on 8/19/2010, tested positive for Salmonella enteritidis.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

[Handwritten signatures]
Mona M. McClure

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Jeffrey B. Moody, Investigator
Joseph E. Lambert, Investigator
Carmen Y. Fisher, Investigator
Mona M. McClure, Investigator
Gerardo A. Ramirez, Investigator
Robert J. Hall, Investigator

DATE ISSUED

8/26/10