

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax: (215) 597-0875 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/10/2011 FBI NUMBER
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Lloyd S. Brubacker, Owner/SE Plan Administrator

FIRM NAME Lloyd Brubacker	STREET ADDRESS 595 Brown Road
CITY, STATE, ZIP CODE, COUNTRY Myerstown, PA 17067	TYPE 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

- Your SE prevention plan states under section 9. (b) (4) (b) (4) (b) (4) Mr. Lloyd Brubacker, Owner/SE Plan Administrator said he does not place any (b) (4) in the manure pit. In addition, when conducting the walk through of the poultry house manure pit, we did not observe (b) (4) as your SE prevention plan states.
- We observed that your rodent monitoring records do not reflect (b) (4) monitoring as stated in your SE prevention plan. For example, we observed that you monitored for rodents on 10/26/10 and not again until 11/19/10.

OBSERVATION 2

Your firm does not have a written SE prevention plan that is specific to the farm where you produce eggs.

Specifically, from 07/9/10 to 03/29/11 your firm did not implement a SE prevention plan while producing shell eggs that may go to the table market. The current SE prevention plan on file is dated 03/30/11.

OBSERVATION 3

You did not maintain records documenting compliance with rodent and other pest control measures.

Specifically, you failed to implement fly monitoring using the (b) (4) method from 07/09/10 08/17/10 to 09/05/10.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE LCDR Michael J. Mero, Investigator <i>Michael J. Mero</i> Brandon J. Brookens, Investigator <i>Brandon J. Brookens</i>	DATE ISSUED 06/10/2011
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OBSERVATION 4

All your required records do not include the time of the activity that the records reflect.

Specifically,

- Fly monitoring records do not include the time.
- Rodent monitoring records do not include a time from ~~07/09/10~~ **08/17/10** through 05/31/11.
- Refrigeration temperature logs do not include a time from ~~07/09/10~~ **08/17/10** through 05/08/11.

OBSERVATION 5

All required records do not include your name and the location of your farm.

Specifically,

- Fly monitoring records do not include the name and location of your farm.
- Rodent monitoring records do not include the name and location of the farm from ~~07/09/10~~ **08/17/10** through 05/31/11.
- Refrigeration temperature logs do not include the location of the farm from ~~07/09/10~~ **08/17/10** through 05/08/11.

OBSERVATION 6

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

Specifically,

- Fly monitoring records do not include a signature or initials of the person performing the activity.
- Refrigeration temperature logs do not include a signature or initials of the person performing the activity from ~~07/09/10~~ **08/17/10** through 05/08/11.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	LCDR Michael J. Mero, Investigator <i>Michael J. Mero</i> Brandon J. Brookens, Investigator <i>BJB BB</i>	06/10/2011