

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  
60 Eighth Street, NE  
Atlanta, GA 30309  
(404) 253-1200

DATE(S) OF INSPECTION  
09/28/10-10/15/10  
FEI NUMBER  
3002954898

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Douglas C. Wicker - Vice President

FIRM NAME  
ISE America, Inc./ISE Newberry, Inc

STREET ADDRESS  
2063 Alexander Street

CITY, STATE AND ZIP CODE  
Newberry, SC 29108

TYPE OF ESTABLISHMENT INSPECTED  
Egg Producer/Processor

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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.

1. Records documenting compliance with rodents and other pest control measures show documentation inconsistencies among layer houses, which are adverse to the requirements specified in the firm's established SE Prevention Plans. For example:

Pest control records (Sighting Log or House Sheet) are not in use to record the day-to-day activity, sighting or evidence of rodents, wild animals or pests in the (b) (4) poultry houses (b) (4)(b) (4)

Documentation of daily rodent activity is not maintained consistently at all contractor poultry houses. Several contractors document daily rodent sightings as an observed activity. Other contractors noted a daily check and others do not document daily. Additionally, the manner in which the required documentation should be gathered is unclear in the SE Prevention Plans.

Pesticide Usage Forms are not utilized at all of the contractor poultry houses (b) (4)(b) (4) Additionally, the information maintained in the forms is not consistent among the contractors. Pesticide usage quantities are not documented in some instances (b) (4)(b) (4)(b) (4)(b) (4)

2. Complex and contractor logbooks are in need of update with currently approved forms and required information. For example, Pesticide Usage Forms/Pest Control Logs, Fly Monitoring documents differ among contractors.

3. The time of activity that the record reflects is not documented. For example, Layer Service Report, Rodent Sightings Log, Fly Control do not include time of activity.

4. Refrigeration temperatures of the egg storage cooler in use at the (b) (4) poultry house was in excess of 45°F, which is the specified temperature in the established SE Prevention Plan. The cooler temperature was consistently above 45°F for the period of 9/17/10-10/7/10. Reportedly, eggs are picked up from this house on a weekly basis.

Continued on Page 2:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>[Handwritten signatures]</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) T. Linda Stewart / CSO Claudette D. Brooks / CSO Amanda E. Hancock / CSO Richard L. Garcia / CSO E. Harold Blackwood / CSO ATLISS M. JONES, CSO	DATE ISSUED 10/15/10
	<p align="right">KOBERT? NE/9/10</p>		

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Egg Producer/Processor

Continued from Page 1:

**Feed Mill Area:**

1. The firm does not have adequate screening to exclude pests from the feed loading room and protect against the contamination of feed during the feed loading process. For example, on 10/08/2010 an excess of 10 unidentified birds were observed flying/hovering and/or perching above six open feed storage compartments of a feed tanker during the loading process.

2. The building grounds are not routinely maintained so that they are reasonably free from litter, waste, and refuse, uncut weeds and grass, and improperly stored equipment.

Specifically, located with-in the feed mill premises, miscellaneous debris to include tires, pipes, moldy corn and pallets were observed directly behind the maintenance facility, directly behind the shelled corn storage silo (b) (4) and directly behind the firm's abandoned hatchery building.

3. Buildings and equipment are not maintained in a reasonably clean manner, for example the feed loading room interior wall structure, interior beam framework, and loading hopper is saturated with an unidentified residue. This residue appeared to be attracting the live birds mentioned in Item 1, cited in the Feed Mill Area of Inspectional Observations.

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REVERSE  
OF THIS  
PAGE

**EMPLOYEE(S) SIGNATURE**

*Linda Stewart*  
*Gladette D. Brooks*  
*Amenda Evans*  
*Richard C. Jerven*  
*E. Harold Blackwood*  
*ATLUS M. Woods*

**EMPLOYEE(S) NAME AND TITLE (Print or Type) (SEE REVERSE OF THIS PAGE)**

Linda Stewart / CSO  
Gladette D. Brooks / CSO  
Amenda Evans / CSO  
Richard C. Jerven / CSO  
E. Harold Blackwood / CSO  
ATLUS M. Woods, CSO

10/15/10