

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/20/2010 - 10/22/2010*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Marlene R. Hernandez, Plant Manager	FEI NUMBER 1815692

FIRM NAME Abbott Nutrition	STREET ADDRESS 901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY Sturgis, MI 49091	TYPE ESTABLISHMENT INSPECTED Manufacturer

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

Failure to manufacture foods under conditions and controls necessary to minimize contamination.

Specifically, based your investigation, the root cause for the small beetles (*Trogoderma variabile Ballion* a.k.a. warehouse beetle) entering the product stream was defective design elements (hopper vent lines and diverter valve) specific to Building (b) (4) Line (b) (4) resulting in a breach to otherwise closed direct product contact system.

Specifically, the design elements were:

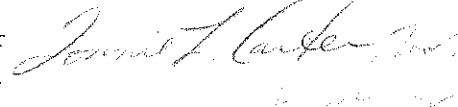
- Building (b) (4) and Building Hopper Vent Systems (including the vent manifold, dust collectors, and waste bag-off station) which are opened periodically for cleaning and to dump the collected dust may have allowed for the ingress of beetles into the otherwise closed system during periods of maintenance. The (b) (4) removal of the collection bin allowed for periods of time when the system was open and exposed to the environment where warehouse beetles were present.
- Building (b) (4) Basement diverter valve safety guard design in the product transfer station system was found to have beetles inside a sealed shroud along with escaped powder from the valve, indicating the valves had failed and potentially allowed ingress into the otherwise closed system. The opaque shroud prevented the periodic visual inspection of the divert valve for evidence of valve failure and beetles were able to infiltrate the shroud and enter the system.

OBSERVATION 2

Effective measures are not being taken to exclude pests from the processing areas.

Specifically, a review of your pest control audit records provided by (b) (4) for the period of January 2007 through September 2010 revealed the presence of Warehouse Beetles and Flour Beetles in the plant and warehouse, for example:

- Review of the 2007 Quarterly Pest Reports revealed the warehouse beetle was identified in Insect Light Traps in buildings (b) (4) and (b) (4)
- Review of the 2008 Quarterly Pest Reports revealed the warehouse beetle was identified in Insect Light Traps in Buildings (b) (4) and (b) (4)
- Review of the 2009 Quarterly Pest Reports revealed the warehouse beetle was identified in Insect Light Traps in Buildings (b) (4) and (b) (4) and, in addition, the following (b) (4) Pest Records 'Service Related Comments' indicated high levels:
 - o 3/30/09 Pest Record indicated warehouse beetle larva found under trap (b) (4) in building (b) (4)

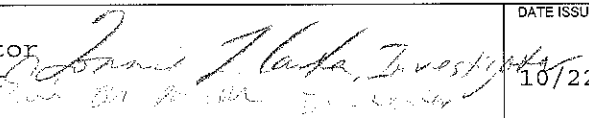
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tonnie L. Carter, Investigator Erin M. Miller, Investigator	DATE ISSUED 10/22/2010
		

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- o 6/27/09 Pest Record indicated high levels of warehouse beetles in buildings (b) (4) and (b) (4)
- o 10/09/09 Pest Record indicated high levels of warehouse beetles in building (b) (4) hopper room and flour beetles in main warehouse (building (b) (4))
- o 10/16/09 Pest Record indicated high levels of warehouse beetles in building (b) (4) hopper room and flour beetles in main warehouse (building (b) (4))
- o 10/23/00 Pest Record indicated high levels of warehouse and flour beetles in main warehouse.
- o 11/13/09 Pest Record indicated high levels of warehouse beetles in building (b) (4) and flour beetles in main warehouse (building (b) (4)).
- o 11/20/09 Pest Record indicated high levels of warehouse beetles in building (b) (4) and flour beetles in main warehouse.
- o 11/25/09 Pest Record indicated high levels of warehouse beetles in building (b) (4) hopper room.
- o 12/13/09 Pest Record indicated high levels of warehouse beetles in warehouse.
- o 12/11/09 Pest Record indicated high levels of warehouse beetles in the basement of building (b) (4)
- o 12/18/09 Pest record indicated high levels of warehouse beetles in basement of building (b) (4)
- o 12/24/09 Pest record indicated high levels of warehouse beetles in basement of building (b) (4)
- o 12/31/09 Pest Record indicated high levels of warehouse beetles in warehouse.
- Review of the 2010 Quarterly Pest Reports revealed the warehouse beetle was identified in Insect Light Traps in Buildings (b) (4) and (b) (4) and, in addition, the following (b) (4) Pest Records 'Service Related Comments' indicated high levels:
 - o 1/9/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 1/15/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 1/22/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 1/29/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 2/5/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 2/13/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 2/19/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 2/26/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement and hopper room of building (b) (4)
 - o 3/5/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 3/12/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement and hopper room of building (b) (4)
 - o 3/19/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 3/26/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 4/16/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement and hopper room of building (b) (4)
 - o 4/23/10 (b) (4) Pest Record indicated warehouse beetle numbers were high in basement of building (b) (4)
 - o 9/17/10 (b) (4) Pest Record indicated warehouse beetle and flour beetle numbers were high in building (b) (4)

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OBSERVATION 3

There is no assurance that raw materials which are susceptible to contamination with extraneous materials comply with current FDA standards and defect action levels.

Specifically, in that, metal fragments from one raw material--Micronized Tricalcium Phosphate--were found in the CIP system on the following dates:

- On 08/20/10, extraneous material metal pieces were found on the rare earth magnet for CIP unit (b) (4). One piece was 7/8" x 1/16" x 1/32" and the other 7/16" x 1/16" x 1/32".
- On 08/29/10 in Building (b) (4) extraneous material was found in the tank door gasket of carbohydrate tank (b) (4). The metal was 1/2" x 1/16" x 1/32" thick.
- On 09/20/10 four additional pieces of metal similar to those found on 08/20/10 were found on the rare earth magnet on CIP (b) (4).
- On 09/28/10 three additional pieces of metal similar to those found on 08/20/10 were found in a filter sock after flushing PIF tank (b) (4) sources matching the metal found on the magnets in this facility.

The initial internal investigation initiated on 8/20/2010 was inconclusive with no root cause determined. The raw material Micronized Tricalcium Phosphate; Lot # (b) (4) received on 07/19/2010 was used in the manufacture of Infant Formula from 08/11/2010 through 09/16/2010 was found to contain metal fragments as reported by the supplier on 10/6/2010. Your investigation failed to identify the source of metal fragments and proactively investigate the source in a timely manner.

*** DATES OF INSPECTION:**

09/20/2010(Mon), 09/21/2010(Tue), 09/28/2010(Tue), 09/29/2010(Wed), 09/30/2010(Thu), 10/01/2010(Fri), 10/07/2010(Thu), 10/12/2010(Tue), 10/22/2010(Fri)

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