

**Establishment Inspection Report**

Abbott Laboratories, Inc.  
Sturgis, MI 49091

FEI: 1815692  
EI Start: 02/09/2009  
EI End: 02/13/2009

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**SUMMARY**

This was an inspection of a manufacturer of infant formulas, medical foods, and nutritional foods conducted in accordance with CP 7321.006, Infant Formula program; CP 7321.002, Medical Foods Program; CP 7303.803, Domestic Food Safety Program; and CP 7303.803A, Domestic Acidified and Low Acid Canned Food Program; per FACTS assignment # 983954, op id # 3878364. The firm manufactures powdered infant formulas (regular and exempt), one liquid infant formula, powdered and liquid medical foods and nutritional products. This inspection covered the processing of infant formula from raw materials to drying in dryer [REDACTED] the LACF processing of Alimentum into 8-oz cans and processing records.

The previous IF/MF inspection was conducted 3/17-20/08 and was classified NAI. A limited inspection was conducted 6/08 to cover a recall of Calcilo XD powder and exempt infant formula; the inspection was classified NAI. Limited inspections were also conducted 9/08 and 10/08 to collect samples and information for melamine and melamine analog testing; these inspections were also classified NAI.

Current inspection found no significant deficiencies and no FDA 483, Inspectional Observations list was issued. Two issues were discussed concerning not testing recirculated water for chlorine at the water discharge point of the [REDACTED] on the LACF retort system and condensate was observed on the liquid product feed line above the [REDACTED] on the 8 oz LACF processing line. The firm promised correction to both issues discussed.

Samples 440862/440863 were collected of Similac Sensitive infant formula powder for nutrient and microbiological analysis. Samples 440864/440865 were collected of Vital HN medical food powder for nutrient and microbiological analysis.

**ADMINISTRATIVE DATA**

Inspected firm: Abbott Laboratories, Inc.  
Location: 901 N Centerville Rd  
Sturgis, MI 49091  
Phone: 269-651-0600  
FAX: 269-651-0959  
Mailing address: 901 N Centerville Rd  
Sturgis, MI 49091  
  
Dates of inspection: 2/9/2009, 2/10/2009, 2/11/2009, 2/12/2009, 2/13/2009  
Days in the facility: 5  
Participants: Kelley L Clark, Investigator

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### HISTORY

The firm is incorporated as Abbott Laboratories, Inc. The infant formula divisional management is located in Columbus, OH. Abbott Laboratories corporate headquarters are located in North Chicago, IL. The most responsible person for this facility is Ms. Marlene R. Hernandez, Plant Manager; correspondence with the firm should be sent to Ms. Hernandez at the above address

Approximately (b) (4) people work at this facility. Office hours are 8:00 am to 4:00 pm, (b) (4) (b) (4) The firm is registered as a food establishment and canning establishment as required. An overflow storage and distribution facility is located at (b) (4) The warehouse was not visited during this inspection.

### INTERSTATE COMMERCE

Approximately (b) (4) of products are sent to customers or distribution centers in the U.S. and world. Several ingredients are received from interstate suppliers; for example the vitamin A, D, E, & K premix is received from (b) (4)

### JURISDICTION

The firm manufactures infant formulas under the Similac and Isomil brand names. Several OTC or prescription exempt infant formulas are manufactured. This includes Alimentum liquid and powder, Calcilo XD, ProViMin, Pro-Phree, Elecare, Human Milk Fortifier, Similac PM 60/40, and Ross Metabolic Formula System (RMFS) products (Cyclinex-1, etc.).

Medical foods include powders Vital HN, Elecare, Alitraq and Ross Metabolic Formula System (RMFS) products (Cyclinex-2, etc.) and liquids Jevity, Nepro, Oxepa, Advera, Glucerna, Pulmocare, and Perative. Nutritional products include Ensure, Prosure, Pediasure, (b) (4) and Pedialyte.

The firm has discontinued having (b) (4) package 8 oz. sample cans of Similac and Isomil for them.

Vitamin, mineral, and premix vendors suppliers for this firm include: (b) (4) (b) (4) and (b) (4)

### INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

My credentials were shown to and a Notice of Inspection issued to Ms. Marlene R. Hernandez, Plant Manager. Ms. Hernandez identified herself as the most responsible person for this facility with oversight of all of the facilities manufacturing operations. Managers of Manufacturing, Quality

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Assurance, and other areas report to Ms. Hernandez; an organization chart for the firm was collected, exhibit A. Mr. Matthew Painter, Plant Quality Assurance Manager reports to the Director of QA in Columbus, OH and by dotted line to Ms. Hernandez. Information during the inspection was primarily provided by Mr. Painter, Ms. Susan Elgan, Manager, Plant Quality Systems and Mr. Thomas Darrington, Manager, Plant Analytical and Incoming Materials Lab. Several other persons in various departments provided information and accompaniment during the inspection of their areas.

**FIRM'S TRAINING PROGRAM**

This facility had an (b) (4) training course conducted on site by (b) (4) (b) (4) Persons who received (b) (4) training at this course are as follows:

(b) (6)

(b) (6)

**MANUFACTURING/DESIGN OPERATIONS**

General: Operations, equipment, and storage were reviewed in the warehouse, milk/oil receiving, ingredient addition/blending, vitamin/mineral premix addition, liquid blending, spray drying, and packaging areas. LACF processing of an Alimentum RTF lot was observed processed according to the scheduled process. A general plant diagram was collected, exhibit B. Most equipment is CIP, though some manual cleaning is also performed on smaller pieces.

One of the firm's reported infant formula changes was the packaging of infant formula into a Luxor plastic container. The operation of the processing line with the Luxor package was observed in operation. Immediately after filling the Luxor container is sealed with an airtight, tamper evident seal to secure the product. (b) (4)

(b) (4)

Two other reported changes involved changes to manufacturing equipment. 1) The addition of Golacto Oligo Saccharide (GOS) to infant formula. (b) (4)

(b) (4)

(b) (4)

## Establishment Inspection Report

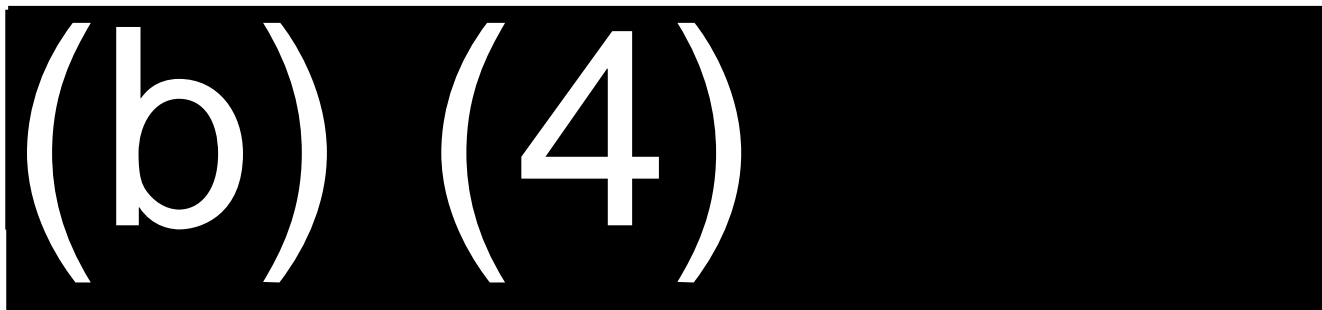
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Infant formula changes <sup>(b) (4)</sup> are also included on Attachment A forms, attached to this report.

Several labels were reported as changed since the previous inspection, a listing of labels changed was provided, exhibit C. Copies of the changed labels were collected for the US products. The Safeway Mom to Mom label was not available at this location and the product is no longer produced at this location. The Similac Advanced Early Shield and Similac Early Shield products listed are the same product and do not represent different labels.

### Label Exhibits:

- Label Exhibit A – Cyclinex 1 Amino Acid Modified Medical Food w/Iron, powder, 14.1 oz
- Label Exhibit B – Elecare Hypoallergenic, powder, 14.1 oz
- Label Exhibit C – Glucerna snack shake vanilla for people with diabetes, liquid, 8 oz
- Label Exhibit D – Ensure medical food for weight gain, liquid, 8 oz
- Label Exhibit E – Glucerna snack shake chocolate for people with diabetes, liquid, 8 oz
- Label Exhibit F – Similac Go & Grow Soy-based infant formula, powder, 22 oz
- Label Exhibit G – Similac Go & Grow Milk-based infant formula, powder, 22 oz
- Label Exhibit H – Similac Isomil Advance Soy infant formula, powder, 34 oz
- Label Exhibit I – PediaSure chocolate medical food for weight gain, liquid, 8 oz
- Label Exhibit J – PediaSure banana cream medical food for weight gain, liquid, 8 oz
- Label Exhibit K – PediaSure vanilla medical food for weight gain, liquid, 8 oz
- Label Exhibit L – PediaSure vanilla with fiber medical food for weight gain, liquid, 8 oz
- Label Exhibit M – Similac Early Shield Advance w/iron infant formula, powder, 12.9 oz
- Label Exhibit N – Similac Early Shield Advance w/iron infant formula, powder, 23.2 oz
- Label Exhibit O – Similac Early Shield Advance w/iron infant formula, powder, 34 oz
- Label Exhibit P – Similac Advance w/iron infant formula, powder, 23.2 oz
- Label Exhibit Q – Similac Organic w/iron infant formula, powder, 34 oz
- Label Exhibit R – Similac Organic w/iron infant formula, powder, 23.2 oz
- Label Exhibit S – Similac Organic w/iron infant formula, powder, 12.9 oz

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---

Label Exhibit T – Similac Sensitive w/iron infant formula, powder, 8 oz  
Label Exhibit U – Similac Sensitive w/iron infant formula, powder, 23.2 oz  
Label Exhibit V – Similac Sensitive w/iron infant formula, powder, 34 oz  
Label Exhibit W – Similac Sensitive w/iron infant formula, powder, 12.9 oz

Stability testing was collected for products reporting major changes; all tests are at the zero time test stage, exhibit D:

Similac Organic 23.2 oz powder in Luxor package, batch 71175T200  
Similac Organic 34 oz powder in Luxor package, batch 71164T200  
Similac Sensitive 12.9 oz powder, batch 684714RB  
Similac Sensitive 23.2 oz powder, batch 69784T210  
Similac Sensitive 34 oz powder, batch 69784T200  
Similac Advance Early Shield 23.2 oz powder with GOS in Luxor package, batch 67388T230  
Similac Advance Early Shield 34 oz powder with GOS in Luxor package, batch 67388T200  
Similac Advance Early Shield 12.9 oz powder with GOS, batch 66185RB60  
Isomil Advance 23.2 oz powder, in Luxor package batch 69736T201  
Isomil Advance 34 oz powder, in Luxor package batch 68676T200  
Similac Advance 23.2 oz powder, in Luxor package batch 67266T200  
Similac Advance 34 oz powder, in Luxor package batch 67289T210  
Go & Grow Soy 22 oz powder, batch 70929T200  
Go & Grow Milk 22 oz powder, batch 70996T200  
Similac Advance with Iron 23.2 oz powder in Luxor package, batch 71175T200  
Similac Advance with Iron 34 oz powder in Luxor package, batch 71164T200  
Elecare with DHA and ARA 14 oz powder, batch 69715T300

Records for infant formula Alimentum and Similac Sensitive were reviewed during this inspection. Information on nutrient testing and comparison of firm test methods to compendial methodology for the Similac Sensitive was collected, exhibit E. An Infant Formula Nutrient Information Reporting Form, Attachment B was completed for Similac Sensitive.

LACF operations – The firm operates (b) (4) exhibit F. The retort has (b) (4) The firm processes medical foods, nutritional foods, and one infant formula product (Alimentum) in 8 oz cans in the retort. The firm was processing Alimentum lot #74635RB during my review of the system. LACF and infant formula records for Alimentum and Jevity were reviewed during the inspection and a LACF Inspection report was completed for these products. A retort survey was conducted during the 3/08 inspection; there were no reported changes to the retort since the previous inspection.

**Establishment Inspection Report**

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Powder processing – The firm operates a liquid process area that feeds (b) (4) dryers (dryers (b) (4)). The basic operation for infant formula processing is:

Liquid processing - (b) (4)

(b) (4)

Dryer powder operation - (b) (4)

(b) (4)

All ingredients in the infant formula and medical food products receive a (b) (4) step during processing. The only products (b) (4) at the firm are the Ross Metabolic Formula System (RMFS) that have proteins added to the base product. The firm is planning to add Similac RS in the next year which will have (b) (4) into Similac powder.

**MANUFACTURING CODES**

Similac Sensitive lot 73468RB00 0512 018 USE BY 1AUG2010 SSENPWD. The “73” represents a manufacturing month and year, in this case January 2009; “74” would be February, etc. The “468” is a sequential number. “RB” represents the Sturgis plant packaging line 1 and 8 oz. LACF filling line (“T2” represents powder line 2; T3 for powder line 3). The “00” is used to represent any divisions of the main batch into different sub batches for variances in packaging. The “0512” is a time of packaging code and the “018” is the Julian date. The expiration date and product identification is also applied to the bottom of the can of powder products. The LACF line does not include the expiration date and product identification.

**COMPLAINTS**

Infant formula complaints are generally covered, as noted in the assignment and CP 7321.006, at the Columbus, OH facility. There were no current complaints for follow-up at the Sturgis facility.

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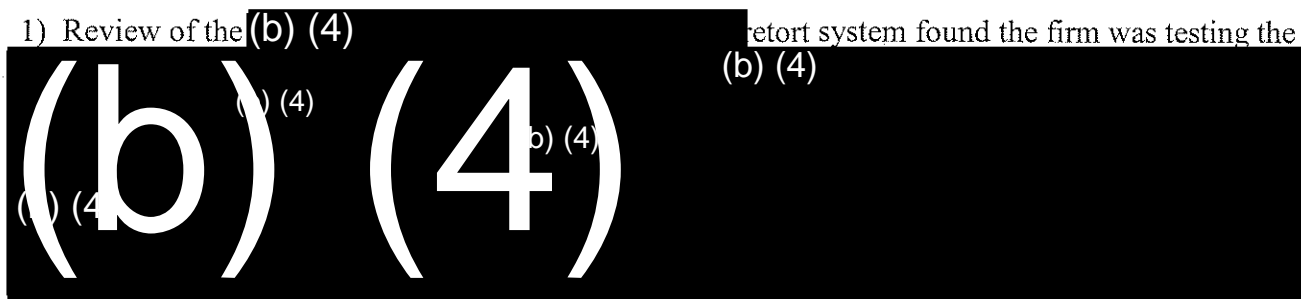
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**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

A closing meeting was held with Ms. Marlene R. Hernandez, Plant Manager; Mr. Matthew Painter, Plant Quality Assurance Manager; Ms. Susan Elgan, Manager Plant Quality System; Mr. Thomas Darrington, Laboratory Manager; Mr. Darryl Threadgill, Manager Technical Systems; Mr. TJ Hathaway, Manufacturing Manager; Ms. Mary Scott, Materials Manager; Mr. Michael Collins, Manager Engineering; Ms. Andrea Katz, Plant Controller; Mr. Keenan Gale, Dryer Supervisor; and Mr. Ned Perke, Manager Liquid Operations. No FDA 483, Inspectional Observations list was issued. Two observations were discussed with the firm and the firm promised correction to both issues.

1) Review of the (b) (4) retort system found the firm was testing the (b) (4)



I discussed the need to test for residual chlorine at the water discharge end of the (b) (4) during the inspection. Ms. Hernandez agreed the (b) (4) should be monitored at the opposite end. Ms Henderson had the water tested at (b) (4) minute intervals during the inspection at both ends of the (b) (4) to provide a comparison of the chlorine levels between the inlet and discharge end of the (b) (4) exhibit H. The comparison showed the chlorine levels were within 1 ppm at the discharge end as compared to the water inlet end. A change request was initiated to move the chlorine test port from the (b) (4) exhibit I.

2) During the walk through of the filling room for the 8 oz filling line I observed condensate on the in-feed line for the filler surge bowl; there was no protection to prevent condensate from dripping into the product. The 8 oz line feeds the retort system; all product (b) (4) would receive a (b) (4). Mr. Painter stated a work order has been initiated to angle the slope of the feed line to allow for any condensate to flow away from the (b) (4) exhibit J. I discussed my concern that the angling of the line may be inadequate to prevent condensate from dripping into the product. Mr. Painter stated the change would be monitored to assure it is effective.

**REFUSALS**

No refusals were encountered during the inspection.

**SAMPLES COLLECTED**

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The following samples were collected, to fulfill the CFSAN assignment request:

- 440862 - Similac Sensitive infant formula powder for microbiological analysis.
- 440863 - Similac Sensitive infant formula powder for nutrient analysis.
- 440864 - Vital HN medical food powder for microbiological analysis.
- 440865 - Vital HN medical food powder for nutrient analysis.

**EXHIBITS**

- Exhibit A – Abbott Laboratories Sturgis Plant Organizational Chart, 1 pg  
Exhibit B – Abbott Laboratories Sturgis Plant diagram, 2 pgs  
Exhibit C – Abbott Laboratories list of label changes 3/08 to present, 1 pg  
Exhibit D – Abbott Laboratories zero time stability test records for infant formula products, 17 pgs  
Exhibit E – Abbott Laboratories memo Abbot Nutrition Method Summary, dtd 2/18/09, 3 pgs  
Exhibit F – Abbott Laboratories diagram of (b) (4) can retort system, 1 pg  
Exhibit G – Abbott Laboratories diagrams of cooling water for (b) (4) can retort system, 2 pgs  
Exhibit H – Abbott Laboratories chlorine test results, dtd 2/11-12/09, 2 pgs  
Exhibit I – Abbott Laboratories change request for chlorine test sample port, 3 pgs  
Exhibit J – Abbott Laboratories work request to modify product infeed line, 1 pg

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**ATTACHMENTS**

FDA 482 - Notice of Inspection

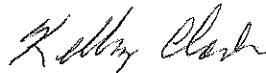
FDA 482a - Demand for Records

FDA 482b - Request for Information

FDA LACF Inspection Report, 11 pgs

Attachment A forms for infant formula changes, 7 pgs

Attachment B form for infant formula nutrient testing – Similac Sensitive powder



Kelley L Clark, Investigator