

**Establishment Inspection Report**

Abbott Laboratories, Inc.  
Sturgis, MI 49091

FEI: **1815692**  
EI Start: 03/15/2010  
EI End: 03/24/2010

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**SUMMARY**

This was an inspection of a manufacturer of infant formula, medical foods, and nutritional foods conducted in accordance with CP 7321.002-Medical Foods Program, CP 7321.006-Infant Formula Program, CP 7303.803-Domestic Food Safety Program, CP 7303.803A-Domestic Acidified and Low Acid Canned Food Program, and FACTS Assignment ID# 1107400, OP ID# 4561942. The inspection also included the CFSAN assignment "Environmental Sampling for Salmonella during Routine Inspections at Powdered Infant Formula Plants-Routine Priority, DFPG No: 10-13; ORA Concurrence #2010010601". The firm manufactures powdered infant formula (regular and exempt), one liquid infant formula, powdered and liquid medical foods, and nutritional products. This inspection covered all of the firm's operations.

The previous IF/MF inspection was conducted 2/9-13/09 and was classified NAI. No significant deficiencies were found and no FDA 483 was issued. Two issues were discussed concerning not testing recirculated water for chlorine at the water discharge point of the (b) (4) on the LACF

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retort system and condensate was observed on the liquid product feed line above the (b) (4) on the 8 oz. LACF processing line. The firm promised correction on both issues. An infant formula and a medical foods product were sampled for nutrient and microbiological analysis.

Current inspection found no significant deficiencies and no FDA 483, Inspectional Observations list was issued. Four discussion items were covered with management during the inspection and at the closeout meeting with them. These included a) the firm was not verifying hand sanitization at the (b) (4) hand "cleansing" systems at the employee entrance to the processing area of the plant; b) the container lids left on the Line lid machine in the "common area" outside the fill room were not protected and appeared to have some accumulation of "dust" or product particle buildup on them; c) exposed insulation on a section of overhead piping in the tanker bay area; and d) the hand sink in the tanker bay area drains onto the tiled floor. Management stated all items would be corrected as soon as possible.

Samples 612563/612564 were collected of Similac Advance Early Shield infant formula powder for nutrient and microbiological analysis. Samples 614375/614376 were collected of Vital HN medical food powder for nutrient and microbiological analysis.

Food security, reconciliation exams, and the FDA Reportable Food Registry (RFR) were discussed with management. The firm is registered with FDA as required by the BT Act of 2002.

**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: 3/15/2010, 3/16/2010, 3/17/2010, 3/18/2010, 3/19/2010, 3/22/2010,  
3/23/2010, 3/24/2010

Days in the facility: 8

Participants: Tonnie L. Carter, Investigator  
Robert G. Taylor, Investigator  
Margaret N. Persich, Investigator

This inspection and sampling assignment was completed by FDA Investigators Tonnie L. Carter, Robert G. Taylor, and Margaret N. Persich. Our credentials were shown to Ms. Marlene R. Hernandez, Plant Manager, and the FDA 482, Notice of Inspection was issued to her as the most

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responsible person at the facility. We also were joined by Mr. Matthew S. Painter, Plant Quality Assurance Manager, and Mr. Steven E. Cooper, Compliance Manager, Sturgis Plant. This report was written by Investigators Carter, Taylor and Persich.

All future FDA correspondence with the firm should be sent to Mr. Matthew S. Painter, Plant Quality Assurance Manager, at the firm's business address.

### 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. Approximately (b) (4) work at this facility. Office hours are 8:00 am to 4:00 pm, (b) (4) (b) (4) A diagram of the floor plan of the facility is included as **Exhibit # 1**.

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

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An updated in-process and finished products listing was collected and will be included with this report as **Exhibit # 2**.

Specimen samples of the labels of any new products since the last inspection, the products viewed in production during the inspection, and/or products sampled during this inspection, were collected and will be included as exhibits with this report.

New products since the last inspection:

**Exhibit A** – Similac Isomil Advance Soy infant formula, powder, 8.0 oz

**Exhibit B** – Similac Sensitive w/iron infant formula, powder, 8.0 oz

**Exhibit C** – Similac Sensitive R.S. w/iron infant formula, powder, 8.0 oz

**Exhibit D** – Similac Sensitive R.S. w/iron infant formula, powder, 12.9 oz

**Exhibit E** – Similac Sensitive R.S. w/iron infant formula, powder, 23.2 oz

**Exhibit F** – Similac Advance EarlyShield w/iron infant formula, powder, 8.0 oz

**Exhibit G** – Similac Advance EarlyShield w/iron infant formula, powder, 12.9 oz

**Exhibit H** – Similac Go & Grow EarlyShield Milk-based infant formula, powder, 22.0 oz

Products observed during inspection of the production areas:

**Exhibit I** – Similac Early Shield Advance Infant Formula, powder, 23.2 oz

**Exhibit J** – Ensure Homemade Vanilla Shake, liquid, 8.0 fl oz

Products sampled during the inspection:

**Exhibit K** – Similac Early Shield Advance Infant formula, powder, 12.9 oz

**Exhibit L** – Vital HN Specialized Nutrition Vanilla, powder (product pouch), 2.79 oz

**Exhibit M** - Vital HN Specialized Nutrition Vanilla, powder (product 6-pack carton), 1.04 lb

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

Ms. Marlene R. Hernandez identified herself as the most responsible person for this facility with oversight of all of the facilities manufacturing operations. Managers of Manufacturing, Quality Assurance, and other areas report to Ms. Hernandez; an updated organization chart for the firm dated 2/22/10 was collected and will be included as **Exhibit # 3**. 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, Mr. Steven E. Cooper, Manager of Microbiology/Compliance Officer, and Ms. Susan M. Elgan, Plant Quality

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Systems Manager. Several other persons in various departments provided information and accompaniment during the inspection of their areas.

### FIRM'S TRAINING PROGRAM

The firm maintains a training program which includes training for new hires as well as on going training for existing employees. A packet of training information for (b) (4)

(b) (4) is included as

**Exhibit # 4.**

### MANUFACTURING/DESIGN OPERATIONS

The firm manufactures powdered infant formula (regular and exempt), one liquid infant formula, powdered and liquid medical foods, and nutritional products. This inspection covered all of the firm's operations. The firm's management reported no significant changes since the previous FDA inspection in the Manufacturing/Design Operations at this facility. The firm has however made several changes related to new products, formula, process, package, or shelf life extension. A copy of the summary of these changes was collected and will be included with this report as **Exhibit # 5.**

In addition to the physical inspection of the firm, records were reviewed for all areas of the firm's operation, including infant formula, medical foods, and nutritional products. The LACF portion of the operation was inspected, records reviewed, and the FDA Form 3511 "FDA LACF Inspection Report", and FDA Form 3511c "Processing in Steam in (b) (4)" were completed and will be included as Attachments to this report.

The infant formula batch records reviewed included the following:

1. Batch # 75841RB00 Similac Advanced Early Shield w/Iron, Stk # 55957
2. Batch # 76991T200 Isomil Advance Powder, Stk # 50825
3. Batch # 81803T200 Similac Sensitive w/Iron, Stk # 50817
4. Batch # 78284T300 Alimentum Advance Powder, Stk # 57663
5. Batch # 82028RB00 Alimentum Advance LCP RTF (Ready to Feed), Stk # 57508
6. Batch # 7716T200 Go & Grow Soy Powder Formula
7. Batch # 87831RB00 Similac Advance Early Shield for Immune Support, Stk # 55957

Review of the batch record files for the following lots of nutritional/medical foods was completed and the records appeared acceptable:

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1. Batch # 85630RB00 Ensure Vanilla 8 oz., Stk# 50460
2. Batch # 81902RB00 Glucerna Snack Shake Chocolate, Stk# 59859
3. Batch # 84369RB00 Ens Gluc Shk Choc Reform Inst, Stk # 54544
4. Batch # 79439RB00 Jevity w/Soy, Stk # 00143
5. Batch # 85433RB00 Vital HN Powder, Stk # 00766
6. Batch # 87813RB00 Two Cal HN Butter Pecan Reform, Stk # 54064
7. Batch # 85578RB00 Reform Pulmocare Vanilla, Stk # 00699

The following additional records were reviewed during the record review portion of the inspection:

1. Retort Thermometer Recorder
2. Calibration Sterilizer Recorder Records
3. Sterilizer Record
4. Filler Room Balance Scale and Can Weights
5. Weigh Room Scale Calibration Record
6. Pre-Heat Thermometer Calibration record
7. Balance <sup>(b) (4)</sup> Fill Weight Scale Calibration Record
8. Pest Control Records
9. Water Sample Records

The following items were included in the records reviewed and photocopies were requested and collected to be included as Exhibits with this report:

NOTE: Exhibits marked as "CONFIDENTIAL" by Abbott Laboratories, Inc. management staff.

**Exhibit # 6** <sup>(b) (4)</sup> Clinical Bulletin dated August 2008, 5 pgs

**Exhibit # 7** <sup>(b) (4)</sup> informational packet, 10 pgs

**Exhibit # 8** Exerpt from Federal Register, Vol. 59, No. 116 with comments on Chlorhexidine Gluconate solution similar to one used in the <sup>(b) (4)</sup> system, 3 pgs

**Exhibit # 9** Filed Process Filing for Ensure, Vanilla (retail), 8 oz, 6 pgs

**Exhibit # 10** Filed Process Filing for Ensure Plus, Vanilla (non-GMO), 8 oz, 4 pgs

**Exhibit # 11** Sterilizer Master Work Order: <sup>(b) (4)</sup> for Ensure Vanilla 8 oz., Batch No. 85630RB00, Product: 50460, 6 pgs

**Exhibit # 12** Weight Checks Master Work Order: <sup>(b) (4)</sup> for Glucerna Snack Shake Chocolate 8 oz., Batch No. 81902RB00, Product: 59859, 1 pg

**Exhibit # 13** Visual Can Inspection Master Work Order: <sup>(b) (4)</sup> for Glucerna Snack Shake Chocolate 8 oz., Batch No. 81902RB00, Product: 59859, 2 pgs

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**Exhibit # 14** Overcook Evaluation Instructions Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 856309RB00, Product: 50460, 2 pgs

**Exhibit # 15** Venting Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 85630RB00, Product: 50460, 1 pg

**Exhibit # 16** Double Seam Evaluation Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 85630RB00, Product: 50460, 3 pgs

**Exhibit # 17** 8 Ounce Isolation Line Clearance, Effective Date: 01-Sep-2009, 10 pgs

**Exhibit # 18** Overcook Evaluation Guideline, Effective By Date: 26-Mar-2009, 5 pgs

**Exhibit # 19** Calibration/Service Record for Sterilizer Thermometer, Temp. & Speed Recorder, Controller Sterilizer Display, and Sterilizer Recorder, 4 pgs

**Exhibit # 20** (b) (4) December 8, 1977, 2 pgs

**Exhibit # 21** Drawing of (b) (4) Ensure Vanilla Flowchart, 6/4/2008, 1 pg

**Exhibit # 22** Drawing of (b) (4) Similac Early Shield Powder Flowchart, 10/15/2008, 2 pgs

**MANUFACTURING CODES**

The manufacturing code break-down for the Similac Advanced Early Shield being produced during the inspection is as follows:

Code: 87831RB60

(b) (4)

The firm's coding also includes a time of packaging such as "0630" and the Julian date such as "074". The expiration date and product identification is also applied to the bottom of the can of powder products.

**COMPLAINTS**

A copy of the firm's SOP titled "Procedure for Handling Complaints" dated 02-Feb-2010 was received, reviewed during the inspection, and will be included with this report as **Exhibit # 23**.

One consumer complaint (#105372) dated 11/23/2009 was found by the inspection team to be located in FDA FACTS. The complaint status was "Awaiting Follow Up Disposition". The complaint received by DET-DO from the Michigan Department of Agriculture, involved a (b) (6) month old infant which had been hospitalized from 11/8/09-11/11/09. The reported symptoms were

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vomiting, fever, and diarrhea. The reported diagnosis was salmonella. The FDA Complaint Description included the statement "State investigator suspects cross-contamination may have occurred in home between lizard and preparation of formula". The formula identified in the Product and Labeling section of the complaint was Ross brand Similac Advanced Formula Powder, 23.2 ounce carton, Lot # 79367T2-0821, Exp/Use by Date 2/1/2011. The product was reportedly purchased at a (b) (4) retail store.

The management of Abbott Laboratories, Inc. stated they had been informed of this complaint by an FDA Investigator on 2/22/10. The firm's Summary of Complaint form was dated 3-19-09 and the Investigation Summary stated "Samples were not received on this complaint. A batch record review has been conducted and there were no unusual circumstances surrounding the production of this batch. The batch record showed that all finished product analytical testing and micro testing was acceptable". The report also includes a Medical Comments section which indicates a Medical Review was conducted by the firm. The Medical Comments section states "23-FEB-2010: A complaint review was conducted for ISO ADV 23.2oz. PWD LUXOR (Stock Code 50819, Batch 79367T200, and (b) (4) units) and showed no similar reports or a trend for any sign or symptom associated with this batch. Should additional information be received, this RPIC will be re-evaluated. (b) (6) RN".

The investigation of Complaint # 105372 revealed no process deviations. The consumer complaint file did not reveal a trend. Investigation found no product reworked and no production Exception Reports filed. Investigation closed and no root cause noted. Photocopies of the firm's records of the receipt, review and summary of the above consumer complaint were collected. Documents listed as **Exhibit # 24** in this report.

During the inspection information regarding another Consumer Complaint (# 113496) having been received by FDA FLA-DO was received by the inspection team leader via telephone from the FDA/GRRP ASCSO. This complaint involved a (b) (4) old infant who had been reportedly been diagnosed with Salmonella in the urinary tract and was currently hospitalized in Florida. The complaint information reported there are two dogs and one cat in the house, but no reptiles. The product indicated was Similac Advanced Powdered Baby Formula with Iron, 23.2 ounce size, Lot # 85500T2, Expiration/Use By Date of 08/01/2011. Samples of this product were collected by FDA staff from the firm's warehouse facility in Columbus, OH.

We reviewed the firm's Complaint Log entries from March, 2009 through March, 2010. The firm's records of the receipt, review, and summary of approximately fourteen of the Complaint Log entries were requested and reviewed by the inspection team. There were no related complaints, no associated complaints, no records of batch deviations, and no issues noted in the medical reviews. This complaint (# 113496) will be reported on in more detail by the Inspection Team in a related OP13 assignment Memo.

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**RECALL PROCEDURES**

The firm has a written recall procedure. No recent recalls have been conducted. The most recent mock recall (trace back-trace forward investigation) was completed by the firm on December 3, 2009. The firm conducts two trace back-trace forward investigations annually (every 6 months).

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

A close out meeting was held with Ms. Marlene R. Hernandez, Plant Manager; Mr. Matthew S. Painter, Plant Quality Assurance Manager; Mr. Steven E. Cooper, Manager of Microbiology, Compliance Officer; Ms. Mary Scott, Material Control Manager; Mr. Michael P. Collins, Plant Engineering Manager; Mr. Jeffrey Rasmussen, Manufacturing Manager; and Ms. Tracey Nielson-Trune, Human Resources Manager. No significant observations were made during the inspection and no FDA 483, Inspectional Observations list, was issued. See the General Discussion with Management section of this report for detail of the Discussion Items covered with the firm.

**REFUSALS**

There were no refusals encountered during the inspection.

**GENERAL DISCUSSION WITH MANAGEMENT**

Four discussion items were covered with the firm's management team during the inspection and at the closeout meeting with management on 3/24/10. The persons participating in the close out meeting from the firm were previously identified in the Objectionable Conditions section of this report. The firm promised correction to all four items.

1) The (b) (4) hand cleansing systems are located just prior to the (b) (4) main entrances to the production area. These are (b) (4)

(b) (4)

(b) (4) on 3/23/10 read "Empty". When asked to show us the empty bottles, Mr. Painter showed us the solution bottles that were in use. They were in fact not empty. There was some problem with the dial readings.

Response: Management is in contact with the (b) (4) Company regarding this problem.

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The efficiency of these (b) (4) systems was discussed with management. The first concern is that these machines do not allow the worker to scrub (wash) grease or heavy soil off their hands.

Response: The firm informed us that their employees are trained to wash their hands at a traditional hand washing sink before using the (b) (4) system if necessary.

The above practice was observed by FDA during the inspection.

Secondly, we asked for verification of the efficiency of this system.

Response: Management was in contact with the company that supplied them the (b) (4) and found out that they can test the (b) (4)

(b) (4) They are coming up with a new Standard Operating Procedure (SOP) for (b) (4) (b) (4) This will include a sign-off sheet as well. Management will include the new SOP in the firm's written response to FDA DET-DO.

2) During the 3/19/10 walk through, it was observed that the lid machine outside line (b) (4) had lids stacked and ready to be put on cans. However, this machine was not in use that day and the lids could potentially collect aggregate matter while left out. In addition, this machine was placed in a "common area" where it was not necessary to gown up in order to come in contact with the machine.

Response: On 3/22/10, Mr. Painter had informed us that they had moved the gowning station to the area immediately exiting the elevator. This in effect means the lid machine is now in a sterile area and not a common area. Also, they built a new structure to enclose this machine, in order to prevent contamination. They will no longer leave lids on the machine when they cease production. This was reiterated at the close-out meeting by Ms. Hernandez.

3) During the 3/22/10 walk through of the tanker bay area in building (b) (4) it was noticed some exposed insulation on the overhead piping. This room is where materials such as condensed skim milk, oils, and corn syrup are received from tankers. Discussion with management included how exposed insulation is not appropriate in an area where raw materials are handled.

Response: Management told us that there had been some repairs done recently on those particular pipes. They then informed us that this problem was fixed the morning of 3/23/10.

4) During the 3/22/10 walk through of the tanker bay area in building (b) (4) it was observed that the hand washing sink drains to the bare floor tile. The water exits through a pipe approximately 10 feet in length that starts at the sink and runs along the wall. We discussed with management our concerns about the drainage from the sink to the bare floor.

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Response: Ms. Hernandez said it will take some time to come up with corrective action plan. The firm will include the final plan in their written response to FDA DET-DO.

**ADDITIONAL INFORMATION**

The firm is licensed and inspected by the Michigan Department of Agriculture.

The firm had the air vent over the empty container conveyor to (b) (4) cleaned to remove apparent dust buildup, and placed the vent on a quarterly cleaning schedule.

The firm's pest control program is provided by (b) (4) The pest control notebook and the reports of the last two visits were reviewed.

The firm's water supply notebook titled "Sturgis Annual Water Testing 2009" was reviewed. This book and its contents, including well water testing and analysis reports, are maintained by the firm's Senior Quality Engineer. The most recent sample dates were dated 8/26-27/09. The firm samples from ports at wells (b) (4) as well as from Tank (b) (4) which is the plants drinking water source, and from the lines exiting tanks (b) (4) which is the plants ingredient water source. The firm's potable water supply is provided by the (b) (4) wells the firm maintains (b) (4) The firm also has (b) (4) wells which reportedly have been properly abandoned, and another well which is used for groundwater monitoring purposes.

According to the notebook and the engineer, the plants water supply has been issued one identification number which is (b) (4) The wells are located off site from the plant due to reported previous groundwater quality issues in this immediate area due to a manufacturing facility which had at one time been located in this area of Sturgis, MI.

The water samples were sent to (b) (4) (b) (4) Asbestos testing was done by (b) (4) (b) (4) All reports reviewed appeared to have acceptable results to have been reported.

**SAMPLES COLLECTED**

Investigational samples 444480, 444481, and 444482 of environmental swabs were collected on 3/16-18/10 and submitted to a FDA laboratory for Salmonella analysis.

In addition, the following official samples were collected on 3/24/10, to fulfill the CFSAN assignment request:

- 612563 - Similac Sensitive infant formula powder for nutrient analysis.

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- 612564 - Similac Sensitive infant formula powder for microbiological analysis.
- 614375 - Vital HN medical food powder for nutrient analysis.
- 614376 - Vital HN medical food powder for microbiological analysis.

**VOLUNTARY CORRECTIONS**

During the inspection the firm moved the gowning station for Line (b) (4) to the area immediately exiting the elevator. This in effect means the lid machine is now in a sterile area and not a common area. Also, the firm built a new structure to enclose the lid machine, in order to prevent contamination. Management stated the firm will no longer leave lids on the machine when they cease production.

**EXHIBITS COLLECTED**

1. Diagram of the floor plan of the facility, 1 pg
2. Up dated list of in-process and finished products, 28 pgs
3. Up dated organization chart for the firm dated 2/22/10, 1 pg
4. Packet of training information for (b) (4)  
(b) (4) 13 pgs
5. Summary of changes related to new products, formula, process, package, or shelf life extension, 3 pgs
6. (b) (4) Clinical Bulletin dated August 2008, 5 pgs
7. (b) (4) informational packet, 10 pgs
8. Exerpt from Federal Register, Vol. 59, No. 116 with comments on Chlorhexidine Gluconate solution similar to one used in the (b) (4) 3 pgs
9. Filed Process Filing for Ensure, Vanilla (retail), 8 oz, 6 pgs
10. Filed Process Filing for Ensure Plus, Vanilla (non-GMO), 8 oz, 4 pgs
11. Sterilizer Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 85630RB00, Product: 50460, 6 pgs
12. Weight Checks Master Work Order: (b) (4) for Glucerna Snack Shake Chocolate 8 oz., Batch No. 81902RB00, Product: 59859, 1 pg
13. Visual Can Inspection Master Work Order: (b) (4) for Glucerna Snack Shake Chocolate 8 oz., Batch No. 81902RB00, Product: 59859, 2 pgs
14. Overcook Evaluation Instructions Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 856309RB00, Product: 50460, 2 pgs
15. Venting Master Work Order: (b) (4) for Ensure Vanilla 8 oz., Batch No. 85630RB00, Product: 50460, 1 pg
16. Double Seam Evaluation Master Work Order: (b) (4) for Ensure Vanilla 8

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- oz., Batch No. 85630RB00, Product: 50460, 3 pgs
17. 8 Ounce Isolation Line Clearance, Effective Date: 01-Sep-2009, 10 pgs
  18. Overcook Evaluation Guideline, Effective By Date: 26-Mar-2009, 5 pgs
  19. Calibration/Service Record for Sterilizer Thermometer, Temp. & Speed Recorder, Controller Sterilizer Display, and Sterilizer Recorder, 4 pgs
  20. (b) (4), December 8, 1977, 2 pgs
  21. Drawing of (b) (4) Ensure Vanilla Flowchart, 6/4/2008, 1 pg
  22. Drawing of (b) (4) Similac Early Shield Powder Flowchart, 10/15/2008, 2 pgs
  23. SOP "Procedure For Handling Complaints", 02-FEB-2010, 28 pgs
  24. Firm's record of the receipt, review and summary of consumer complaint, 7 pgs

**LABEL EXHIBITS**

- A. Similac Isomil Advance Soy infant formula, powder, 8.0 oz
- B. Similac Sensitive w/iron infant formula, powder, 8.0 oz
- C. Similac Sensitive R.S. w/iron infant formula, powder, 8.0 oz
- D. Similac Sensitive R.S. w/iron infant formula, powder, 12.9 oz
- E. Similac Sensitive R.S. w/iron infant formula, powder, 23.2 oz
- F. Similac Advance EarlyShield w/iron infant formula, powder, 8.0 oz
- G. Similac Advance EarlyShield w/iron infant formula, powder, 12.9 oz
- H. Similac Go & Grow EarlyShield Milk-based infant formula, powder, 22 oz
- I. Similac Early Shield Advance Infant Formula, powder, 23.2 oz
- J. Ensure Homemade Vanilla Shake, liquid, 8.0 fl oz
- K. Similac Early Shield Advance Infant formula, powder, 12.9 oz
- L. Vital HN Specialized Nutrition Vanilla, powder (product pouch), 2.79 oz
- M. Vital HN Specialized Nutrition Vanilla, powder (product 6-pack carton), 1.04 lb

**ATTACHMENTS**

1. FDA 482, Notice of Inspection, issued 3/15/10 to Ms. Marlene R. Hernandez, Plant Manager
2. FDA 482a, Demand For Records, issued 3/22/10 to Mr. Matthew S. Painter, Plant QA Manager
3. FDA 482b, Request For Information, issued 3/22/10 to Mr. Matthew S. Painter, Plant QA Manager
4. FDA 484, Receipt for Sample, issued 3/24/10 to Mr. Matthew S. Painter, Plant QA Manager
5. FDA 3511, FDA LACF Inspection Report
6. FDA 3511c, Processing In Steam In (b) (4) Retorts

**Establishment Inspection Report**

Abbott Laboratories, Inc.

Sturgis, MI 49091

FEI:

**1815692**

EI Start:

03/15/2010

EI End:

03/24/2010

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*Tonnie L. Carter*

Tonnie L. Carter, Investigator

*Robert G. Taylor*

Robert G. Taylor, Investigator

*Margaret N. Persich*

Margaret N. Persich, Investigator