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SUMMARY

This was a limited inspection of a large infant formula and medical foods manufacturer, according to CFSAN assignment DFP&G 08-31, "Infant Formula/Other Milk Products Surveillance" and FACTS # 969621. The inspection was limited to sampling milk-based components and finished infant formula using these components, for melamine and melamine analog testing, and obtaining information related to these components and products.

The previous infant formula/medical foods inspection was 3/18-20/08. Follow-up was also conducted for two testing issues. An FDA 483 was not issued, and the inspection was classified NAI. Verbal comments were discussed with management concerning the lack of backflow prevention at a wash sink and powder spillage above a filling area. A limited inspection was also conducted 6/4/08 related to a recall of Calcilo XD powder exempt infant formula. This was also classified NAI.

The current inspection found no deficiencies and an FDA 483 was not issued. Answers and information were obtained related to assignment questions or requests.

Samples 451424 – 451426, 488918 – 488932, 489653 – 489657 were collected from milk-based ingredients. Samples 489658 – 489662 and 492140 – 492141 were collected from finished infant formula products using one or more of these ingredients. Samples are described further under the Samples Collected section and in Attachment D with this report.

Note: this report contains or refers to confidential information. This includes raw materials and suppliers.

ADMINISTRATIVE DATA

Investigators Carter and Tingley showed their credentials and issued a Notice of Inspection to Ms. Marlene R. Hernandez, Plant Manager on 9/24/08. Ms. Hernandez identified herself as the most responsible person at the firm. An opening meeting was held with Ms. Hernandez, Matthew Painter, Plant Quality Assurance Manager, and Thomas Darrington, Manager, Analytical Laboratory.

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:	9/24/2008, 9/25/2008, 9/26/2008
Days in the facility:	3
Participants:	William D. Tingley, Investigator (9/24 & 25/08 only) Tonnie L. Carter, Investigator (9/24-26/08)

HISTORY

Refer to the March 2008 EIR for previous history. No changes have been made. The Divisional management is located in Columbus, OH, and Abbott corporate headquarters in North Chicago, IL.

The firm has had one recall since the previous inspection. They had notified FDA of this recall in May 2008. This was for two Calcilo XD powdered exempt infant formula lots, due to off-aroma and oxidation. A follow-up inspection was performed on 6/4/08.

Please direct correspondence to Marlene R. Hernandez, Plant Manager at the above address.

JURISDICTION & INTERSTATE COMMERCE

The firm continues to make a variety of powdered infant formulas, both regular and exempt; one liquid infant formula; powdered and liquid medical foods and nutritional products as reported previously. This includes milk-based and soy-based infant formulas under Similac® and Isomil® brands, respectively. Approximately (b) (4) of products are sent to customers or distribution centers outside Michigan, in the U.S. and world. Most components are also received in I.S. commerce.

This assignment focused on milk-based ingredients, infant formulas and other products using the ingredients. The ingredients and products are described in the Assignment Coverage section below, Exhibits 1 & 2, and Attachment D.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Ms. Hernandez is the most responsible person at this plant, overseeing daily operations. Most information or accompaniment was provided by the following individuals currently:

- Matthew Painter, Plant Quality Assurance Manager
- Thomas Darrington, Manager, Analytical Laboratory
- Susan Elgan, Manager, Quality Systems

Several persons from Incoming QA also assisted with sampling.

MANUFACTURING OPERATIONS & CODES

Manufacturing operations were not covered currently. Refer to the March 2008 EIR for manufacturing and code information. Manufacturing dates and codes for finished products sampled currently are also noted in the Samples Collected section below.

ASSIGNMENT COVERAGE

The following information relates to questions or requests in the attached assignment DFP&G 08-31:

1.) Obtain invoices or other records to document the firm's milk component suppliers used in infant formulas. The firm provided lists of all milk-based ingredients used in formulas and other products. A list of U.S. – sourced ingredients is shown in Exhibit 1, and foreign-sourced ingredients are shown in Exhibit 2. The lists also show which finished products the ingredients are used in, including infant formulas, medical foods, and nutritional products. They also include which of the Abbott plants use the ingredients. The Sturgis plant is indicated by "ST."

Each of the (b) (4) ingredients was sampled currently. Exhibit 3 includes invoices, shipping documents, certificates of conformance, and other records documenting suppliers for each ingredient. A copy of applicable records was also included with each Collection Report. Ingredients and lot numbers are included in the Samples Collected section below, and additional details are included in the assignment Attachment D with this EIR. According to the firm's information, no milk-based ingredients are coming from China or other countries of interest. Some are received from New Zealand, Australia, Germany, and Ireland.

Two clarifications for the Exh. 1 & 2 lists are as follows, determined during follow-up telephone calls with the firm after the EI:

• Commodity no. (b) (4) enzymatically hydrolyzed casein is listed in Exh. 1 p. 4 as a U.S. sourced product. It is received from (b) (4) Another commodity from (b) (4) no (b) (4) (lactalbumin hydrolysate or enzymatically hydrolyzed whey protein and casein) is listed in Exh. 2 p. 3 as sourced from Denmark. Follow-up with the firm and (b) (4) by phone indicated that the milk used in both of these products comes from New Zealand and/or Australia. The milk is initially processed at the firms identified in Attachment D for these commodities, then is sent to (b) (4) (b) (4) for final processing.

2.) Determine if the firm uses the same components in products exported to Canada as they use for the U.S. market.

Some of the same milk-based ingredients are used in (b) (4) infant formula products going to Canada. This information was provided by the firm in a chart, Exhibit 4, and this is also reported in Attachment D. Exh. 4 shows the ingredient commodity number (can be cross-referenced in Exh. 1 and 2) and finished product using the ingredient or ingredients.

3.) Obtain a list of additional finished products the firm manufactures using the same milk components as used for infant formula. Refer to Exhibits 1 and 2, which list the ingredients and all finished products.

4.) Determine rejected components, reasons, and country of origin.

Exhibit 5 is a list of rejected components from the past 12 months. Eight lots of milk-based commodities have been rejected in that period: six for failed flavor/aroma; one for torn bags; and one for lot tested out-of-specification for microbiological quality. None of the lots were rejected for chemical or related concerns. Four of the lots rejected for flavor/aroma were commodity (b) (4) whey protein hydrolysate (lactalbumin hydrolysate in Exh. 2). The other four lots were different commodities.

5.) Determine if the firm is currently testing for melamine and melamine analogs.

Mr. Painter said that the firm is not currently testing for melamine or analogs, but the Division is looking into developing a method for this in the future.

6.) Collect representative samples of milk-based components and finished products.

Components and finished products sampled are described in the following section. All milk-based components used by the firm were sampled, whether or not they are used in infant formulas. Exhibit 6 is a chart provided by the firm, showing which milk-based components are used in which infant formulas. Only 11 of the (b) (4) components sampled are used in infant formulas. Seven of the infant formulas were sampled, to bracket the use of the 11 components.

SAMPLES COLLECTED

The following ingredients and finished products were sampled for melamine and melamine analog testing. The firm collected companion samples at the same time as our collection. Additional details about suppliers are included in the assignment Attachment D included with this EIR.

Milk-based Components

- 451424: Whey Protein Concentrate, commodity no (b) (4) lot (b) (4) – (b) (4)
- 451425: NZMP Sodium Caseinate, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 451426: Low Calcium Whey Protein Concentrate, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488918: IMP 1220 Milk Protein Isolate, commodity no. (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 488919: Whey Protein Concentrate, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488920: CE90 HM Enzymatically Hydrolyzed Casein, commodity no. (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 488921: 8200 Heat Stable/Gelling Whey Protein Concentrate, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488922: Lactose, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488923: Lactose, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488924: Lactose, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488925: NZMP Calcium Caseinate, commodity no (b) (4) lot (b) (4) – (b) (4)
- 488926: Ultranor 9060 Milk Protein Isolate, commodity no (b) (4) lot (b) (4) – (b) (4)
- 488927: Organic Nonfat Dry Milk, commodity no. (b) (4) lot (b) (4) – (b) (4)

- 488928: NZMP Milk Protein Isolate, commodity no. (b) (4) lot (b) (4) – (b) (4)
- 488929: Soluble UF Whey Protein Concentrate, commodity no. (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 488930: Sodium Caseinate, commodity no (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 488931: TMP 1100 Milk Protein Isolate, commodity no (b) (4) lot (b) (4) (b) (4)
- 488932: Sodium Caseinate, commodity no. (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 489653: Whey Protein Hydrolysate, commodity no. (b) (4) lot (b) (4) – (b) (4) (b) (4)
- 489654: Natra Pro Milk Protein Concentrate MPC 80, commodity no. (b) (4) lot (b) (4) (b) (4)
- 489655: NZMP Acid Casein, commodity no (b) (4) lot (b) (4) – (b) (4)
- 489656: LE80H Enzymatically Hydrolyzed Whey Protein and Casein, commodity no. (b) (4) lot (b) (4)
- 489657: Condensed Skim Milk, commodity no. (b) (4) lots (b) (4) (b) (4)

Finished Infant Formula

- 489658: Similac Alimentum lot 67313T300 – manufactured in July '08.
- 489659: Calcilo XD lot 69639RB60 – manufactured in September '08.
- 489660: Similac PM 60/40 lot 68411RB60 – manufactured in August '08.
- 489661: Provimin lot 69648RB60 – manufactured in September '08.
- 489662: Similac Human Milk Fortifier lot 68624T300 – manufactured in August '08.
- 492140: Similac Advance lot 68621RB60 – manufactured in August '08.
- 492141: Similac Sensitive lot 68471RB60 – manufactured in August '08.

EXHIBITS COLLECTED

1. List of U.S. sourced milk-based components & finished products used in – 6 pp.
2. List of foreign sourced milk-based components & finished products used in – 8 pp.
3. Invoices, shipping documents, certificates of conformance, and other records for sample ingredients – 83 pp.
4. List of milk-based components & finished products manufactured for Canada – 1 p.
5. List of rejected milk-based components in past 12 months – 1 p.

6. List of milk-based components & finished infant formula products – 1 p.

ATTACHMENTS

Notice of Inspection
Assignment DFP&G 08-31 (amended 9/23/08)
Assignment Attachment D
Collection reports and attachments for 451424/426, 488918/932, 489653/662 & 492140/141

William D. Tingley

William D. Tingley, Investigator, KA/RP, DET-DO

Tonnie L. Carter

Tonnie L. Carter, Investigator, GR/RP, DET-DO