

Establishment Inspection Report

Abbott Laboratories, Inc.

Sturgis, MI 49091

FEI:

1815692

EI Start:

10/15/2008

EI End:

10/16/2008

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SUMMARY

This was a limited inspection of a large infant formula and medical foods manufacturer according to CFSAN 10/10/08 Expanded Infant Formula Assignment and FACTS 983371. It was limited to sampling soy-based components and finished infant formula for melamine and melamine analog testing, and obtaining related information.

A previous similar inspection and sample collection was done 9/24-26/08 for milk-based formulas and components, according to CFSAN DFP&G 08-31. The previous infant formula and medical foods inspection was in March 2008, classified NAI. A limited EI was also performed 6/4/08 to cover a recall of Calcilo XD powder exempt infant formula; this was NAI.

No deficiencies were found during the current inspection and an FDA 483 was not issued. Answers to requested information were obtained. Samples 493963 through 493972 were collected, consisting of 8 soy ingredients, 1 amino acid ingredient, and 1 finished soy-based infant formula. Samples are described in a later section.

Note: This report contains or refers to confidential information, including raw materials and suppliers.

ADMINISTRATIVE DATA

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My credentials were shown and a Notice of Inspection issued to Matthew Painter, Plant Quality Assurance Manager. Marlene R. Hernandez, Plant Manager and most responsible person, was not available during the inspection.

Inspected firm: Abbott Laboratories, Inc.
Location: 901 N Centerville Rd
Sturgis, MI 49091
Phone: 269-651-0600
FAX: 269-651-
Mailing address: 700 West Lafayette
Sturgis, MI 49091
Dates of inspection: 10/15/2008, 10/16/2008
Days in the facility: 2
Participants: William D. Tingley, Investigator, KA/RP, DET-DO

HISTORY

Refer to the March 2008 EIR for previous history. No changes have been made. The firm has had one recall since the prior inspection, and this was for Calcilo XD exempt infant formula. This is described in the 6/4/08 EIR.

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

INTERSTATE COMMERCE & JURISDICTION

The firm continues to make a variety of powdered regular and exempt infant formulas, one liquid infant formula, powdered and liquid medical foods and nutritional products, as previously reported. Approximately (b) (4) are distributed outside Michigan in the U.S. and world. Most components are also received in I.S. commerce.

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:

- Matthew Painter, Plant Quality Assurance Manager

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- Steven Cooper, Manager, Plant Microbiology
- Thomas Darrington, Manager, Analytical Lab
- Susan Elgan, Manager, Quality Systems
- Lonnie Nickell, Supervisor, Incoming Material Acceptance

Other personnel assisted with sampling.

MANUFACTURING OPERATIONS & CODES

Manufacturing was not covered currently. Refer to the March 2008 EIR for manufacturing and code information.

ASSIGNMENT COVERAGE

The following relates to questions and requests in the attached CFSAN assignment:

1.) Obtain records to document suppliers for soy-based and other protein ingredients. Exhibit 1 is a list of soy-based ingredients and the infant formulas and other products in which they are used. Management noted no other protein sources are used, other than milk-based sources. Exhibit 2 includes shipping documents, certificates of analysis, and other records that document the 9 ingredients sampled. This includes 8 soy ingredients and 1 amino acid premix. Refer also to Attachment C – tracking form for the assignment, which includes other details about ingredients.

According to the firm’s information, no soy-based ingredients are coming directly from China or other countries of interest. One ingredient is received from Denmark.

2.) Determine if the same components are used in products exported to Canada. Exhibit 3 is a listing of the 3 ingredients used in products destined for Canada. This includes two soy protein isolates and an amino acid premix. The finished products are Vital and Optimal medical foods, and Elecare exempt infant formula.

3.) Obtain a list of additional finished products containing the soy ingredients used in infant formulas. Exhibit 1 includes this information.

4.) Determine rejected components, reasons, and country of origin. Exhibit 4 includes the soy protein ingredient rejections from the past 2 years. (b) (4)

(b) (4)
(b) (4)

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5.) Determine if the firm is testing for melamine and analogs. Mr. Painter said the firm has begun testing for melamine in the milk-based samples that were collected in September. The firm plans to perform routine testing in the future. Other microbiological, chemical, and physical testing is performed on components, as described in previous EIRs. The firm also receives a certificate of analysis with components, as shown in Exh. 2.

6.) Collect representative official samples of ingredients and finished products. All soy-based ingredients were sampled, whether used in infant formulas or other products. The following samples were collected:

Soy-based Ingredients

- 493963: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493964: Soy & gelatin protein, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493965: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493966: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493967: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493968: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493969: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493971: Amino acid premix, commodity no. (b) (4) lot (b) (4) from (b) (4)
- 493972: Soy protein isolate, commodity no. (b) (4) lot (b) (4) from (b) (4)

Soy-based Infant Formula

Exhibit 5 shows which soy-based ingredients are used in infant formulas and other products. The only soy-based commodity used in soy formulas is (b) (4) a soy protein isolate from (b) (4). One representative soy-based infant formula, Isomil Advance with Iron lot 68459RB6 was sampled as 493970. This product was manufactured in August 2008.

GENERAL DISCUSSION WITH MANAGEMENT

No additional discussion was held with management.

SAMPLES COLLECTED

Samples 493963 through 493972 were collected as described above.

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EXHIBITS COLLECTED

1. List of soy-based ingredients and products used in – 3 pp.
2. Shipping and other records for ingredients – 47 pp.
3. Soy and amino acid ingredients and products for Canada – 1 p.
4. List of soy-based ingredient rejections in past 2 years – 1 p.
5. Additional list of soy-based ingredients and products used in – 2 pp.

ATTACHMENTS

FDA 482 Notice of Inspection

CFSAN assignment

Attachment C – tracking sheet

C/Rs and records for samples 493963 through 493972

William D. Tingley

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