TABLE OF CONTENTS

SUMMARY

This comprehensive inspection was conducted as part of the Infant Formula Program and Medical Foods Program-FY21 Schedule of Inspections/Sample Collections under DFPG#21-04, FACTS#12071684, eNSpect ID#204136. This assignment was conducted pursuant to Compliance Programs 7321.006-Infant Formula Program-Import and Domestic, 7321.002-Medical Foods-Domestic and Import, 7303.803a-Domestic Acidified and Low-Acid Canned Foods, 7321.005 Domestic and Import NLEA, and 7303.040-Preventive Controls and Sanitary Human Foods Operations. Mead Johnson Nutrition is located at 2400 W. Lloyd Expressway Evansville, IN 47712. The firm manufactures powder and liquid infant formula products (exempt and non-exempt) and medical food products.

The previous inspection was conducted by FDA from 08/06/2018-08/09/2018 and was classified VAI. A 2-point Form FDA 483, Inspectional Observations, was issued to Arthur Pike, Site Director for the following:

- You did not a maintain a cold storage area for a final infant formula at a temperature not to exceed (b) (4) ^{0}C) for a defined period of time.

- You did not equip a cold storage compartment with a validated high temperature alarm.

See **Voluntary Corrections** for information regarding corrections to these observations.

Additionally, during the 08/06-08/09/2018 inspection, 5 items were discussed with management.

- The (b) (4) line is equipped with a dual element temperature recording device (b) (4) (b) (4) one of these sensors was recording temperatures higher than the (b) (4) temperature indicating device.
- System Operators and not management were conducting the first review of LACF records within (b) (4) (b) (4) and prior to distribution of completing a record.

See **Voluntary Corrections** section.

- The current audit SOPs/procedures used by the firm during their annual quality control and GMP audit are not maintained at the facility. They are maintained off-site by a separate audit group.

See **General Discussion with Management** section.

- The firm does not challenge critical factor alarms on the (b) (4) or (b) (4) aseptic processing and packaging lines.
- On the (b) (4) line, critical factors are not (b) (4) documented for the processor, aseptic surge tank, and filler between sterilization and the start of production.

See **Objectionable Conditions and Management's Response** section.

During this inspection, we covered the aseptic processing and packaging of Enfamil Gentlease NeuroPro Lot No. EA1HQU USE BY 01SEP22 on the firm's (b) (4) aseptic processing line. Additionally, we covered the firm's continuous agitating retort (13oz. can) line processes. Inspectional coverage included GMPs, complaints, recalls, training program, quality control procedures, environmental monitoring, product and nutrient testing programs, supply chain, calibrations, deviations, pest control, and record review.

At the conclusion of the inspection, Form FDA 483 Inspectional Observations was issued to Scott A. Fisher, Site Director, for the following:

- A temperature-indicating device was not installed where it could be accurately and easily read.
- A record was not made of a critical factor specified in the scheduled process.
- Observation and measurement of an operating condition was not recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product was being achieved.

See **Objectionable Conditions and Management Response** for details.

During the closeout meeting, **8** items were discussed with management:

1. For the continuous agitating steam retort, review of the document, "Critical Points Check- 13 oz. Can Line- CCP" indicated that (b) (4) bleeder checks are performed every (b) (4), yet these checks are grouped with (b) (4) other operational checks. Therefore, the Operator's initials pertain to all these checks and it cannot be determined if the Operator verified the function of each (b) (4) bleeder or not.
2. For the continuous agitating steam retort, the Operators record the proper function of the (b) (4) bleeder on the document, "Production Quality Audit Process Control 13 Ounce Line CCP"; any of the (b) (4) bleeders may be visually verified. However, the bleeder at the inlet end to the cooker is not readily visible to the Operator as it is obstructed by a metal sheet.

3. For the continuous agitating steam retort, the (b) (4) and (b) (4) cooler are partially filled with (b) (4) water; sanitizer is not added directly to the shells nor is the (b) (4) water (b) (4) by the firm when it enters the plant. For the (b) (4) cooler, residua (b) (4) levels are checked (b) (4) (b) (4) they are not verified for the (b) (4)
4. For the (b) (4) aseptic line, review of the documents, "Aseptic Sterilizer Production Log (UHT)-CCP" and "Aseptic Surge Tank (AST) Product Log- CCP" indicated that in addition to critical factors, several operational parameters are also documented, yet ranges are not identified for these parameters, which would allow an Operator to determine whether a reading is within specification or not.
5. For the 13 oz. retort line, in-house calibration records for the TID and the reference thermometer were reviewed; the calibration record for the TID did not identify the next calibration date as required by 21 CFR part 113.100(c).
6. During review of the firm's environmental monitoring results record for (b) (4), the firm obtained a composite positive *Cronobacter* sample in the (b) (4) Room. The firm completed the OOS report but did not re-sample each individual sampling site for *Cronobacter* prior to re-cleaning/sanitization in order to isolate the source of the positive result.
7. On 08/23/2021, during the walk-through of the (b) (4) Room, the (b) (4) Room Operator was observed not changing gloves when touching non-food contact surfaces and then touching food contact surfaces. Additionally, he was observed not washing hands between glove changes.
8. During review of aseptic tracking sheet records from February 2021 and May 2021, the firm did not record (b) (4) cleaning for the (b) (4) and (b) (4) on (b) (4) and the (b) (4) on (b) (4)

One additional item was discussed with the firm during the inspection.

The current audit SOPs/procedures used by the firm during their annual quality control and GMP audit are not maintained at the facility.

See **General Discussion with Management** for additional information.

The following samples, requested as part of this inspection and FY21 SCOPE sampling assignment, were collected from the firm's distribution center by FDA Investigators.

- 1145786-12 cans of Enfamil NeuroPro Non-GMO Infant Formula Powder 20.7oz. Batch Code (b) (4) for nutritional analysis
- 1145787-60 cans of Enfamil NeuroPro Non-GMO Infant Formula Powder 20.7oz. Batch Code (b) (4) for microbiological analysis
- 1145788-12 6-pack packages of Enfamil Enfalyte RTD Cherry 6oz. Batch Code (b) (4) for nutritional analysis

(b) (3) (A)

During this inspection, there was no evidence of rodent, insect, or avian activity.

No refusals were encountered.

Current Observations

Citation Text: A record was not was not made of a critical factor specified in the scheduled process.
Correction Status: Not Corrected
Citation Text: A temperature-indicating device was not installed where it could be accurately and easily read.
Correction Status: Not Corrected
Citation Text: Observation and measurement of an operating condition was not recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product was being achieved.
Correction Status: Not Corrected

ADMINISTRATIVE DATA

Inspected firm:	Mead Johnson Nutrition
Location:	2400 W Lloyd Expy Evansville, IN 47712-5095
Phone:	812-429-5000
FAX:	
Mailing address:	2400 W Lloyd Expy Evansville, IN 47712-5095
Email address:	Scott.Fisher@rb.com
Dates of inspection:	8/23/2021-8/26/2021
Days in the facility:	4
Participants:	**Daniel B Arrecis, Investigator** **Elizabeth P Mayer, National Expert**

On 08/19/2021, I, Investigator Daniel B. Arrecis, called Tom Fleming, Director of North America Quality Nutrition, to preannounce an inspection at the firm. Mr. Fleming agreed to an inspection date of 08/23/2021 at 9:00am. Mr. Fleming stated that we would meet with Scott A. Fisher, Site Director.

On 08/23/2021, Elizabeth P. Mayer, National Food Expert, and I arrived at the firm. We displayed our credentials to Mr. Fisher who stated he was the most responsible person at the firm at the time of the inspection. I issued Form FDA 482, Notice of Inspection, to Mr. Fisher (**Attachment 1**). During the initial meeting, we displayed our credentials to Mr. Fleming, Russell E. Roehr, QA Manager, and (b) (6) (b) (6) Associate Quality Manager of HACCP.

On 08/24/2021, I issued Form FDA 482a, Demand for Records (**Attachment 2**), and Form FDA 482b (**Attachment 3**), Request for Information, to Mr. Fisher.

At the conclusion of the inspection, a 3-point Form FDA 483, Inspectional Observations (**Attachment 4**), was issued to Mr. Fisher. Form FDA 484, Receipt for Samples (**Attachment 5**), was issued to Ryan P. Risinger at the conclusion of the sampling on 08/25/2021. An updated Form FDA 484, Receipt for Samples (**Attachment 6**), was issued to and signed by Scott A. Fisher, Site Director, at the conclusion of the inspection on 08/26/2021.

Per FMD-145, all correspondence should be addressed to:

Mr. Scott A. Fisher, Site Director
Mead Johnson Nutrition
2400 W. Lloyd Expressway
Evansville, IN 47712
(812)429-5209

This Establishment Inspection Report is written by National Expert Mayer and Investigator Arrecis. National Food Expert Mayer wrote the following sections: **Manufacturing/Design Operations**, **Objectionable Conditions and Management Response**, and **General Discussion with Management-Items 1-5**. She also completed Form FDA 3511-3, Aseptic Processing and Packaging Report (**Attachment 7**), and 3511c, Processing In Steam In Continuous Agitating Retorts (**Attachment 8**), during the inspection.

HISTORY

Mead Johnson Nutrition is located at 2400 W. Lloyd Expressway Evansville, IN 47712. The firm has been at this location for 115 years. This location houses the liquid (aseptic and multi-pack) and powder Bag-In-Box/Bag-In-Tub (BIBBIT) infant formula operations, liquid medical food operations, human milk fortifier operations (HMF), laboratories, ambient and temperature controlled storage, receiving areas (packaging, raw material, bulk), and administrative/management offices. The firm manufactures exempt and non-exempt infant formula products in powder and liquid forms, and medical food products.

Mead Johnson's additional domestic operations include Zeeland Specialty Products (ZSP) and Zeeland Integrated Powder Processing (ZIPP) at firm's the Zeeland, MI facility and Maple Island-Wanamingo Supply Center (Wanamingo, MN). The firm has international operations in Mexico, Singapore, Thailand, Philippines (dry base manufacturing), and the Netherlands.

Mead Johnson Nutrition LLC is a division of Reckitt. Reckitt is located at 103-105 Bath Road Slough Berkshire SL1 3 UH. Laxman Narasimhan is the CEO of Reckitt. Reckitt Benckiser changed its name to Reckitt in 2021.

The Evansville location has approximately (b) (4) employees. The firm also has approximately (b) (4) employees. The firms plant hours are (b) (4) with the following (b) (4)
(b) (4)
The firm uses an off-site warehouse, (b) (4)
(b) (4) This warehouse is used for packaging, ingredient, and finished product storage.

Since the last inspection the firm has made the following changes:

- Decommissioning and removal of the (b) (4) retort line in Q4 of 2018/2019
- Removal of building (b) (4) in 2018/2019
- (b) (4) of Maple Island-Wanamingo Supply Center (Wanamingo, MN).
- Contract filling and packaging of (b) (4) product to (b) (4)
  (b) (4)
  operations are planned to switch to the Evansville location, under (b) (4)
- Organic product launch in August 2021

(b) (3) (A)

During this inspection, there was no evidence of rodent, insect, or avian activity.
No refusals were encountered.

INTERSTATE (I.S.) COMMERCE

The firm receives approximately (b) (4) % of all its raw materials outside the state of Indiana. Suppliers include (b) (4) and (b) (4) The firm ships approximately (b) (4) % of its domestic finished product into interstate commerce from its distribution location, (b) (4) The firm's three biggest customers are (b) (4) and (b) (4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Mead Johnson Nutrition manufactures exempt and non-exempt infant formulas, toddler formulas and medical food products, which are subject to the FD&C Act. These products include powdered infant formulas under the Mead Johnson Enfamil brand names such as NeuroPro, Reguline, Enspire, Organic Infant, and AR, and liquid formulas under the Enfamil, Pregestimil, and Nutramigen brand names. Additionally, the firm manufactures an oral rehydration medical food, Enfalyte, and 32oz. water (retort).
The firm provided the Retort Product List **(Exhibit 1)**, the Aseptic Active Formulations Product List **(Exhibit 2)**, and the BIBBIT Product List **(Exhibit 3)**.
Liquid infant formulas are packaged in cans (13oz.) and plastic bottles (2oz. nursettes, 6oz., 8oz., 32oz.). Powder products come in bag in box form (14.7oz., 15oz., 15.2oz., 17.6oz., and 18.2oz.) or bag in tub (19.5oz., 20oz., 20.5oz., and 20.7oz.).
Approximately (b) (4) % of vitamin and mineral premixes are manufactured by the firm and the remainder come from (b) (4) and (b) (4)
Ms. (b) (6) provided us with labels for Enfamil Infant Formula 13oz. **(Exhibit 4)** and Enfamil NeuroPro Gentlease Infant Formula 32oz. **(Exhibit 5)** for review. No discrepancies were noted.
Mr. Roehr provided us with a copy of labels that are new or revised since the last inspection **(Exhibit 6)**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Scott A. Fisher, Site Director-Mr. Fisher stated he has been with the firm for 10 years. He has been in his current role since April 2021. Mr. Fisher's responsibilities include oversight of all operations, teams, operators, EHS (health & safety) programs, and maintenance. Mr. Fisher can make capital recommendations but requires corporate approval. Mr. Fisher is authorized to stop production if necessary. He reports to Alexander Gregorian, Senior Vice-President of Supply in North America (NJ).
Russell E. Roehr, Quality Assurance Manager-Mr. Roehr has been with the firm for 43 years and 10 years in his current role. He stated his main responsibility is product release, including Quality Control (QC) and Plant release. He stated his duties include product specifications verification, product deviations, planning group, distribution, and analytical testing for the Wanamingo products. He reports to Mr. Fleming.
(b) (6) Associate Quality Manager of HACCP-Ms. (b) (6) has been with the firm for 2 years. She stated she oversees all HACCP programs, plant sanitation, contract employees, employee training, installs of new equipment, maintenance, and support to QA Specialists. She reports to Mr. Fleming.
Thomas Fleming, Director North America Quality Nutrition-Mr. Fleming has been with the firm for 13 years and in his current role for 3.5 years. He has quality responsibilities at the Mead Johnson facilities located in Zeeland (MI), Evansville (IN), and Wanamingo (MN). He is also involved in some third-party quality. He reports to Naill Mullane, Director of Americas Quality (NJ).

During the inspection, we were accompanied by Ms. (b) (6) Mr. Roehr, Mr. Fleming, and Mr. Fisher, all of whom provided inspectional access, copies of records and reports, and information contained in this Establishment Inspection Report (EIR). The firm arranged for the following individuals to either call in or accompany us during department/operational specific inspectional tours and provide information in this EIR:

Chris Pilsbury, Processing Supervisor
Andrew Lindauer, Aseptic Workstream Manager
(b) (6) Room Operator
Ann S. Bartholomew, Manager of Product Information and Compliance
Matthew W. Smith, Automation Manager
(b) (6), Senior Engineer
(b) (6), Process Specialist
Aldo R. Gonzalez, America Regional Technical Manager

Reckitt Corporate Officer Reporting Structure
Alexander Gregorian, Senior Vice-President of Supply in North America (NJ) reports to Alexandre Grillet, Senior Vice-President of Supply and Nutrition (Slough U.K.). Mr. Grillet reports to Sami Naffakh, Chief Supply Officer (Slough U.K.). Mr. Naffakh reports to Laxman Narasimhan, CEO (Slough U.K.).

We were provided with a copy of the firm's facility organizational chart **(Exhibit 7)**.

FIRM'S TRAINING PROGRAM

The SOP, "ESC On-Boarding and Off-Boarding Procedure" was reviewed; this SOP applies to all plant personnel. When a new employee is hired, several topics are covered including GMPs, PPE, gowning, basic HACCP, reading and signing SOPs and good documentation practices. (b) (4) are given and the employee must score (b) (4) % or higher; approximately, (b) (4) are allowed. A log of employee training is maintained.
Training records for the following individuals were reviewed:

- Andrew Lindauer, Aseptic Workstream Manager
  Records from 2017-2021 including Better Processing School, Aseptic Processing, Sanitation, and SOP training
- (b) (6), Process Specialist
  Records from 2016-2021 including 13oz Filling Line, 13oz (b) (4) Room cleaning, Venting Procedure
- (b) (6) Room Operator
  Records from 2016-2021 including Weighing and (b) (4) . Retraining for ESC OPC training on (b) (6), which included review of the firm's SOP "EVV-SC-MFG-SOP-04393 Evansville Liquid Operations GMPs". See **General Discussion with Management Item #7**.

The records reviewed indicated that all three employees have received training for their specific job duties. Firm records were dated and recorded for each employee.

MANUFACTURING/DESIGN OPERATIONS

Production

The firm manufactures infant and toddler formulas; most of the products are liquid and the remaining

items are powders. Infant formulas are soy or milk-based and include liquid concentrate, liquid ready-to-use (RTU), human milk fortifier (HMF) and powder. Exempt infant formulas are also manufactured, which are milk-based or hypoallergenic. Milk-based exempt formulas include Enfamil NeuroPro EnfaCare, Enfamil Human Milk Fortifier, Enfamil Premature Iron Fortified (20/24 Cal), Enfamil Premature High Protein (24 Cal), Enfamil Premature 30 Calorie and Enfaport; hypoallergenic formulas include Nutramigen and Pregestimil.

Several protein sources are used including (b) (4) milk powder, whey protein concentrate (b) (4) %, whey protein concentrate, whey protein-lipil concentrate, hydrolyzed whey protein isolate, low lactose milk protein isolate, milk protein partial hydrolysate, milk protein concentrate, lactoferrin milk protein, (b) (4) soy protein isolate with calcium phosphate and protein hydrolysate (hypoallergenic). Partially hydrolyzed base powders are received from Mead Johnson Zeeland (ZIPP plant) for use in powder products; extensively hydrolyzed base powders are also received from Mead Johnson Zeeland (ZSP plant) and partially hydrolyzed base powders are from (b) (4) for use in liquid formulas. No hydrolysis of proteins is performed on-site.

Products are labeled under the firm's brands, Enfamil and Enfagrow (powdered toddler formula). Pre-mixes are produced on-site; they are also purchased from (b) (4) and (b) (4) The firm is Kosher, Halal and organic certified.

Below is a summary of the firm's manufacturing lines:

- Powder operation including dry blending (14.0-20.7 oz. pouches of powdered infant formula)
- (b) (4) retorts (2 oz. nursettes of RTU infant formula and water)
- (b) (4) retort-(b) (4) shells (13 oz., two-piece metal cans, infant formula concentrates)
- (b) (4) aseptic line-(b) (4) processor and portable aseptic tanks (PATs) of(b) (4)
- (b) (4) aseptic line-(b) (4) processor and aseptic surge tank and(b) (4) filler (8 oz. and 32 oz. plastic bottles of RTU infant formula)

Since the previous inspection, the (b) (4) retort was decommissioned and physically removed from the facility; Building (b) (4) which housed this retort was also torn down. In the future, the(b) (4) aseptic line will be decommissioned.

During this inspection, the product, Enfamil NeuroPro Gentlease RTU milk-based infant formula with iron was covered for the (b) (4) aseptic line (b) (4) FDA Form 3511-3 (Aseptic Processing and Packaging Report) was completed and is attached to this Establishment Inspection Report (EIR). **(Attachment 7)**. The 13 oz. continuous agitating steam retort was also reviewed for the product, Enfamil concentrate milk-based infant formula with iron (b) (4) The line was not running, yet the (b) (4) room and retort were reviewed in-depth. The 13oz. line runs (b) (4) (b) (4) product is mainly for the (b) (4) and (b) (4) customers. FDA Form 3511c (Processing in Steam in Continuous Agitating Retorts) was completed and is attached to this EIR **(Attachment 8)**. Flow diagrams were provided **(Exhibits 8, 9, 10, & 11)**.

Raw Material Receiving and Weighing

The following raw material receiving and weighing procedures pertain to all products.

Incoming ingredients are received at the warehouse, (b) (4) upon arrival, the electronic inventory system, (b) (4) generates an internal lot number, and the raw materials are tagged. Sampling is performed and the ingredients are placed on-hold pending results; the electronic laboratory system, (b) (4) is used to track all specifications and testing results. Once released, they are transported to the Evansville facility. At the plant, the electronic inventory control system, (b) (4) is used for the receipt of ingredients and production. Incoming ingredients are tagged with a (b) (4) label, which identifies the material #, product name, weight of container, net weight, batch #, internal lot # and allergen identification. (b) (4) and (b) (4) are linked with (b) (4) they are add-ons to (b) (4) Operators use (b) (4) which are username and password protected. Ingredients are stored in room (b) (4) on the (b) (4) floor; there are separate rooms for the storage of milk, soy and hypoallergenic ingredients.

Bulk oils and corn syrup are received; the firm has (b) (4) bays. Oils are received (b) (4) (b) (4) ; corn syrup is received (b) (4) haulers are typically used; if not, food grade items are carried, and the firm is aware of loads that were previously hauled. Tankers are not CIP'd on-site. Upon receipt, tanker seals (upper and lower ports) and the wash ticket are compared to the bill of lading; certificates of analysis are also received. Samples are obtained from the (b) (4) Employees are responsible for unloading the tankers. Dedicated lines pump the product to the storage tanks; the (b) (4) lines are equipped with a (b) (4) -micron filter. The tanks are (b) (4) and have a (b) (4) . Temperatures are electronically monitored; an analog thermometer is also present. There are (b) (4) GMO oil tanks (b) (4) gallons each), which are maintained at (b) (4) °F with a (b) (4) There are (b) (4) tanks for (b) (4) GMO oils (b) (4) gallons each), which are maintained at (b) (4) °F and have a (b) (4) There are (b) (4) corn syrup tanks (b) (4) gallons each), which are maintained at (b) (4) °F; they have a (b) (4) (b) (4) and filter. The (b) (4) are changed every (b) (4) the HEPA filter is (b) (4) microns and changed (b) (4)

Ingredients including liquid vitamin pre-mixes and drums of DHA/ARA oil are stored in the walk-in cooler, (b) (4) on the (b) (4) floor. The cooler is equipped with a (b) (4) chart; the system also alarms at (b) (4) °F and plant personnel are notified. There is also a pre-mix cooler, which hold liquid and powder pre-mixes.

In the (b) (4) Room (room (b) (4) minor ingredients including vitamin and mineral pre-mixes are weighed. There are (b) (4) scales (b) (4) with different accuracies, which are connected to (b) (4) . The scales are calibrated (b) (4) in-house; the previous calibration was done on 8/10/21. For each batch, the barcode on the Weight Sheet is scanned, which is linked to a specific process order. The Operator scans the ingredient label with a (b) (4) unit; if the wrong ingredient is scanned, the Operator cannot proceed. White plastic tubs ((b) (4) kg) are used to hold weighed ingredients; they are cleaned and tared prior to use. The Operator uses the (b) (4) reading on the scale to ensure the exact amount is added; if too much or too little is added, the Operator cannot proceed. (b) (4) generates an error code, and a ticket is not printed. If the correct amount is weighed, a ticket is printed, which the Operator applies to the tub. The ingredient bag is also scanned again, and a new label is printed for the bag with the current weight. The tubs are staged on a pallet for production and stored on the (b) (4) floor. For the weighing of major ingredients, the process is similar to weighing minor ingredients. Major ingredients are staged on pallets on the (b) (4) floor; the

Weigh Sheet is scanned along with the ingredient label. In the (b) (4) Room, major ingredients are not weighed yet tickets are printed for full and partial bags, which are applied to the ingredient container. (b) (4) production, each ingredient is scanned to ensure the correct amount is present; (b) (4) the ingredients are scanned again. For metered ingredients, the process is more (b) (4) The Operator scans the Weigh Sheet and enters the amount of bulk ingredient to be consumed into the (b) (4) the amount is also (b) (4) documented on the Weigh Sheet. Bulk tanks are not equipped with load cells; flow meters are used. For all ingredients, the lot number is tracked; double verification procedures are also in place, which are documented on the batch records.

Enfamil NeuroPro Gentlease Infant Formula – (b) (4) Aseptic Line
Please see FDA Form 3511-3 for more information **(Attachment 7)**.

In the (b) (4) Processing Center, minerals and water at (b) (4) °F are added to the (b) (4) tank, which is equipped with an agitator and holds (b) (4) gallons; the tank (b) (4) In the (b) (4) gallon (b) (4) , proteins, carbohydrates and water at (b) (4) °F are added. The (b) (4) from the (b) (4) tank and the (b) (4) are pumped to the (b) (4) tanks (b) (4) no (b) (4) mixing is performed. Each (b) (4) tank holds (b) (4) gallons and is (b) (4) with (b) (4) ; an agitator is present. The mineral (b) (4) is added directly; the (b) (4) from the (b) (4) is (b) (4) with the (b) (4) tank. The (b) (4) are added to (b) (4) and when that tank is emptied, the (b) (4) are added to (b) (4) followed by (b) (4) The product is held for (b) (4) after (b) (4) , the pH is verified. (b) (4) or (b) (4) (b) (4) are added to the (b) (4) tanks if a pH adjustment is necessary.

In the (b) (4) tank, oils, emulsifiers and oil soluble vitamins are added; the tank holds (b) (4) gallons and is (b) (4) with (b) (4) at (b) (4) °F. Product from the (b) (4) tanks and the (b) (4) tank is pumped to the main mix tank, (b) (4) which holds (b) (4) gallons and (b) (4) . After which, the product is pumped to the (b) (4) system; not all products are run through this system. The flow is as follows:

(b) (4)

Flow through the system is controlled by the (b) (4) pump; the flow rate is (b) (4) gallons (b) (4) The (b) (4) flow meter (b) (4) sends a signal to the (b) (4) which alters the pump speed via a (b) (4) (b) (4) The (b) (4) is in a locked cabinet. The (b) (4) flow meter is calibrated (b) (4) in-house; the previous calibration was performed on 4/29/21. There is a temperature sensor (b) (4) at the (b) (4) steam controller for the (b) (4) unit; the temperature is read by the (b) (4) which opens and closes the (b) (4) steam control valves. The sensor (b) (4) is calibrated (b) (4) in-house; the previous calibration was done on 6/19/21. At the end of the (b) (4) , there is a temperature sensor (b) (4) which is calibrated (b) (4) in-house; the previous calibration was conducted on 6/19/21. If temperature or flow limits are exceeded, the product is (b) (4) followed by a (b) (4) with water. There are two (b) (4) -micron strainers; only (b) (4) as their use (b) (4) (b) (4) tanks. As product travels from (b) (4) to the refrigerated finished product tanks,

initial and random checks are done including a "(b) (4) test" of the product line to verify it is cool and that the (b) (4) valve (b) (4) is open signaling forward flow. Product enters the finished product tanks at (b) (4) °F.

Water soluble vitamins are added to the (b) (4) tank and pumped to the finished product tank. There are (b) (4) finished product tanks, which hold (b) (4) gallons; they are (b) (4) with (b) (4) and the temperature is electronically monitored. Product is held at (b) (4) °F; the alarm set-point is (b) (4) °F. On 5/2/19, a software change was implemented, and the set-point was lowered from (b) (4) °F to (b) (4) °F for all the tanks. The product is held for a maximum of (b) (4) ; a (b) (4) extension (b) (4) may be added on a case-by-case basis if evaluation indicates that the temperature, pH, vitamin (b) (4) color and odor are within specification. The temperature sensors are calibrated (b) (4) in-house; the alarms are also challenged at the (b) (4) If a tank alarms, the quality and maintenance groups are notified to address the issue and physical samples are also obtained. The tank is monitored and if the temperature reaches (b) (4) °F, filling of current product is completed; if the temperature reaches (b) (4) °F, filling is stopped.

Since the previous inspection, the firm performed two studies to support (b) (4)

(b) (4)

From the finished product tanks, the product is pumped through an (b) (4) to the (b) (4) aseptic processor. The flow through the processor is as follows:

(b) (4)

Prior to production, the processor is CIP'd followed by sterilization. The processor is sterilized with (b) (4) water at (b) (4) °F for (b) (4) at a minimum (b) (4) psi; non-product pipes are also sterilized. The sterilization (b) (4) is (b) (4) . The (b) (4) valve cluster is sterilized with the processor and the aseptic surge tank; the (b) (4) chamber is sterilized with the processor and the (b) (4) chamber is sterilized with the surge tank. The cluster has steam barriers, which protect the processor from the tank and vice versa when sterility is lost. During sterilization, the (b) (4) location, "(b) (4) " is measured at the water tank of the processor. During production, water (b) (4) between the (b) (4) (b) (4) and the (b) (4) coolers (b) (4) The (b) (4) is (b) (4) and there are (b) (4) options: (b) (4)) or (b) (4) for this product, (b) (4) are used. (b) (4) cannot be utilized

alone. The flow rate is fixed; a flow meter is present to record the flow but not regulate the flow. The maximum flow rate is (b) (4) gpm, but the system (b) (4) at (b) (4) gpm; the (b) (4) is set at (b) (4) % to ensure the residence time is achieved. There is no minimum flow rate. The flow rate was verified via a "(b) (4) test" when the system was commissioned but has not been performed since; the firm relies upon the calibrated flow meter.

The (b) (4) aseptic surge tank holds (b) (4) gallons and is (b) (4) with (b) (4) which is only used for cooling; product from the processor never bypasses the tank. Product is discharged through the (b) (4) a temperature sensor is present. The tank is also equipped with an agitator, which has a steam seal. The tank is sterilized with (b) (4) steam at (b) (4) °F for (b) (4) with an (b) (4) of (b) (4) psi; the (b) (4) location is measured (b) (4) of the (b) (4) filler at the (b) (4) valve cluster, which is sterilized with the tank. (b) (4) air is used to provide sterile air (b) (4) filters are used to sterilize the air. The filters are changed after (b) (4) sterilization (b) (4) A (b) (4) is installed, and the (b) (4) filter is moved to the (b) (4) ; the (b) (4) is disposed of. The filters are (b) (4) % efficient at (b) (4) microns. Filter integrity is also verified (b) (4) and was previously conducted on 7/21/21. After sterilization, the tank is vented of air and cooled.

Product is pumped from the aseptic surge tank to the (b) (4) Asep (b) (4) filler where it is filled in 32 oz. plastic bottles with a (b) (4) seal. The filler runs at (b) (4) bottles (b) (4) . The filler is sterilized with a combination of (b) (4) and (b) (4) % minimum); (b) (4) valve with a steam barrier protects the filler from the aseptic surge tank and vice versa if sterility is lost. During production, a sterile air (b) (4) via HEPA filters is maintained in the sterile cabinet. The HEPA filters are (b) (4) microns; the (b) (4) and (b) (4) filters are (b) (4) and (b) (4) microns, respectively. Filters are changed (b) (4) sterilization (b) (4)

At the time of production, the bottles are (b) (4) and rinsed with (b) (4) there are (b) (4) filters (b) (4) The bottles are conveyed in the filler via a (b) (4) system; they are freely suspended to the neck in the bottle carriers. The filler is divided into (b) (4) sections. The bottles are sterilized with (b) (4) (b) (4) for (b) (4) the (b) (4) is (b) (4) into the bottle and subsequently flows out of the bottle over the top to the outside of the neck. The bottles are dried by evacuating the (b) (4) and replacing it with (b) (4) sterile air; the air is flushed in (b) (4) . The empty bottles are flushed with (b) (4) and filled with product via a (b) (4) filling process (b) (4) filling heads) under a (b) (4) each filling head has a flow meter to control the fill level. A continuous reel of (b) (4) is fed to a (b) (4) where the (b) (4) caps are cut and shaped; both sides of the caps are sterilized with (b) (4) and placed on top of the bottle. The (b) (4) sealing heads contact the (b) (4) cap; the (b) (4) causes a (b) (4) of the cap with the bottle.

The bottles are discharged from the filler and pass through the (b) (4) vision system and fill level detector. After which, they are conveyed through a (b) (4) leak detection system, which pulls a (b) (4) at (b) (4) (b) (4) to check for micro-leaks; the system is challenged (b) (4) , every (b) (4) and the (b) (4) . After the leak detection system, the over-cap is applied followed by the (b) (4) vision system. The bottles are labeled with pre-coded labels and conveyed past the (b) (4) vision system, which is challenged when transitioning to (b) (4) . They are conveyed through the (b) (4) to the (b) (4) detector (gross leaks), which is challenged with (b) (4) at (b) (4) every (b) (4) and at the

(b) (4) . The bottles are cased, palletized and stored at (b) (4) pending (b) (4) release in (b) (4) .

For the aseptic system, recipes identifying critical factors are entered in the (b) (4) which is password protected; the (b) (4) also monitors and records critical and operational parameters. IT verification procedures are also in place to ensure that all timing devices associated with the (b) (4) are accurate. If sterility is lost, (b) (4) and product is (b) (4)

Enfamil Concentrate Infant Formula- 13 oz. Continuous Agitating Steam Retort
Please see FDA Form 3511c for more information **(Attachment 8)**.

Prior to use, empty cans are (b) (4) and pass through the (b) (4) vision system, which removes any cans with defects. After which, they are (b) (4) and rinsed with (b) (4) water. Product from the finished product tanks passes through the filter bank, which consists of (b) (4) each with a (b) (4)-micron (b) (4), which is changed (b) (4) . From there, the product is pumped to the surge tank, which feeds the filler. Product is filled into the cans via a (b) (4) head, (b) (4) filler, which fills at (b) (4) containers (b) (4) . After filling, the cans are conveyed to the (b) (4) seamer where a vacuum is pulled (b) (4) Hg) and the cans are seamed; lids are received in a sleeve. They are run past a (b) (4) detector to ensure a vacuum is present; the detector is verified (b) (4) and (b) (4) with "(b) (4)" cans. After which, they are conveyed past the fill height detector and washed via the can washer. After washing, they are conveyed to the retort.

The (b) (4) continuous agitating steam retort has (b) (4) shells: (b) (4) (b) (4) . Most of the retort controls are (b) (4) including the vent (b) (4) critical parameters, and alarms such as low temperature, water and pressure are (b) (4) controlled. Changes to the retort speed are password protected.

The (b) (4) is partially filled with (b) (4) water, which is re-used but there is no recirculation pump. (b) (4) water is added based on temperature and water level. Sanitizer is not added nor are free residual (b) (4) levels verified. **Please See Discussion with Management Item #3.** A (b) (4) glass is present. Steam enters the (b) (4) of the shell via (b) (4) different zones; the temperature increases as the cans move from zone (b) (4) to zone (b) (4) Each zone is equipped with an (b) (4) steam controller. For both the (b) (4) and cooker, each (b) (4) steam controller has a temperature sensor, which charts the temperature on a (b) (4) chart recorder; based on temperature, the steam control valve opens or closes. The system operates in a (b) (4) with ar (b) (4) signal. The sensors are calibrated (b) (4) and were previously calibrated in-house on 7/3/21.

(b) (4) , the cooker is vented for (b) (4) to (b) (4) °F through the (b) (4) vent located at the (b) (4) of the shell. Steam is fed in the (b) (4) through a steam (b) (4) to a steam (b) (4) an (b) (4) steam controller is present (b) (4) which is located (b) (4)" from the west end of the shell and (b) (4)" from the (b) (4) of the vessel. There are ((b) (4) bleeders; due to the set-up of the cooker, they are not readily visible under the cooker itself. Therefore, (b) (4) is a (b) (4) drain-pipe, which is piped from the cooker to under the cooler where it drains; (b) (4) considers this the (b) (4) bleeder. The other (b) (4) bleeders have a (b) (4) trap and are located at opposite ends of the cooker. The bleeder located at the inlet end of the cooker is obstructed by a metal sheet and therefore, not readily

visible to the Operator. The (b) (4) bleeder at the outlet end is piped from the cooker to under the (b) (4) (b) (4) where it drains. Operators may view and document the proper function of any of the (b) (4) bleeders when performing their visual checks **(Exhibit 14– page 1)**. **Please See Discussion with Management Item #2.** A high level alarm is also present, which is calibrated (b) (4) in-house and was previously conducted on 6/21/21. There are (b) (4) bleeders, which are piped to a bleeder (b) (4) with water; each bleeder line is identified and the water (b) (4) when the bleeders are functioning. All (b) (4) shells are equipped with (b) (4) thermometers at the inlet and outlet, which are replaced every (b) (4) and calibrated in-house at the time of removal and again (b) (4). On the cooker, the (b) (4) thermometers (temperature indicating device- TID) are not easily readable as they are located behind the reel arms and positioned in an area that is not well lit. **Please See FDA 483 Observation #1**.

The (b) (4) cooler is partially filled with water, (b) (4) water is added at the (b) (4) and flows (b) (4) with the cans. Water is (b) (4) and sanitizer is not added. Residual chlorine levels are verified (b) (4) using a (b) (4) and a (b) (4) water sample; a (b) (4). **Please See Discussion with Management Item #3**.

After retorting, the cans are run past a (b) (4) detector and (b) (4) detector; from there, they are labeled and conveyed past a (b) (4) detector. The cans are cased, palletized and stored at (b) (4) (b) (4) pending shipment.

Major and Minor (Before First Processing) Changes

During this inspection, major and minor (Before First Processing) submissions, which were submitted to the Infant Formula and Medical Foods Staff (IFMFS) at CFSAN were reviewed as identified in the Plant Report for this facility **(Attachment 9)**. FDA Form, Reporting Changes in Processing and Formulation for Infant Formulas (Attachment A) was completed for each major submission **(Attachment 10)**. There were no additional requests from the IFMFS. No deficiencies were noted.

Record Review

During this inspection, records were reviewed for the product, Enfamil NeuroPro Gentlease RTU milk-based infant formula with iron packaged in a 32-oz. bottle on the (b) (4) aseptic line. The following batches were reviewed:

(b) (4)

Critical factors are captured via the (b) (4) chart and Operator's Logs (every (b) (4)); visual checks of steam barriers and seals are also performed. The following was noted during review of these records.

Critical factors were not (b) (4) documented for the processor, aseptic surge tank and filler between the sterilization of equipment and the start of production; in addition, critical factor alarms are not routinely challenged. **Please See FDA 483 Observation #3**. In addition to critical factors, several operational parameters are documented on production records, yet ranges are not identified for these parameters, which would allow an Operator to determine whether a reading is within specification or not **(Exhibit 15–**

pages 2 and 3). **Please See Discussion with Management Item #4**.

Records were also reviewed for the product, Enfamil concentrate milk-based infant formula with iron packaged in a 13oz. can on the continuous agitating steam retort line. The following batches were reviewed:

(b) (4)

Critical factors are captured via (b) (4) charts and the Operator's Logs (b) (4) checks); visual checks of critical and operational parameters are also performed every (b) (4) and documented with the Operator's initials only. The following was noted during the review of these documents.

Process temperature is a critical factor, yet readings of the temperature recording device (TRD) are (b) (4) documented at the start of production only; this frequency does not ensure that the TRD does not read higher than the TID **(Exhibit 14–page 1)**. Venting is critical to the process; however, the vent temperature is not (b) (4) documented at the start or end of the venting process **(Exhibit 14-page 2)**. **Please See FDA 483 Observation #2**. (b) (4) bleeder checks are performed every (b) (4), yet these checks are grouped with (b) (4) other operational checks. Therefore, the Operator's initials pertain to all these checks and it cannot be determined if the Operator verified the function of each (b) (4) bleeder or not **(Exhibit 14 -page 3)**. **Please See Discussion with Management Item #1**. In-house calibration records for the TID and the reference thermometer were reviewed; the calibration record for the TID did not identify the next calibration date. **Please See Discussion with Management Item #5**.

Per the requirements of 21 CFR Part 106.6, the firm has implemented a system of production and in-process controls that covers all stages of processing from raw material receipt to distribution of finished product. The written Manufacturing Batch Record is the firm's "Master Manufacturing Order"; written Standard Operating Procedures (SOPs) are also in place for all areas of production. All employees have access to these documents.

Allergens

The firm has control measures in place to minimize the potential carry-over of allergens in products manufactured at the plant; there are only two allergens handled: soy and milk. The firm also identifies hypoallergenic products, which do not contain soy or milk. In the warehouse, allergen-containing ingredients are stored in designated areas, which are identified; (b) (4) also identifies the raw material as an allergen. Employees wear color-coded uniforms in allergen containing areas. A scheduling matrix is in place; products with the same allergens are grouped together and for example, run the (b) (4) of the (b) (4) Cleaning is performed between different allergen runs; however, the scheduling matrix is used to minimize the frequency of cleaning. After cleaning, product lines are swabbed for allergen proteins, (b) (4) or both depending on the production schedule. Finished products are analyzed in-house; hypoallergenic products are tested for soy and milk protein and soy items are analyzed for milk protein. Milk-based products are not tested for soy protein as they contain soy lecithin. All ingredient and finished product labels are properly identified with any allergen containing sub-ingredients or ingredients. Employees receive allergen training.

Microbiological, Nutrient and Stability Testing

Testing is done in-house. A (b) (4) program is in place; product is electronically held and released for distribution once all testing is completed. Testing protocols were reviewed for Enfamil NeuroPro Gentlease RTU milk-based infant formula with iron and Enfamil concentrate milk-based infant formula with iron; FDA Form, Nutrient Reporting Form (Attachment B) was completed for both products **(Attachment 11)**.

Incoming ingredients are tested per (b) (4) and (b) (4) a risk-based sampling protocol is in place. Testing includes microbiological, analytical and physical parameters. Most products are analyzed but identity testing is performed at a minimum. Certificates of analysis are received for all raw materials. For Enfamil NeuroPro Gentlease, in-house COAs were reviewed for the ingredients, corn syrup solids and fat blend (non-GMO); for Enfamil concentrate, COAs were also reviewed for whey protein concentrate (b) (4)% and (b) (4) syrup. No deficiencies were noted.

Nutrient testing is conducted for raw materials, in-process product and finished product; please see Attachment B for more information. For Enfamil NeuroPro Gentlease, (b) (4) pre-mixes are used including a dry vitamin pre-mix (b) (4) the dry vitamin pre-mix is provided by (b) (4) and the others are manufactured in-house. A certificate of analysis is provided by (b) (4) . All (b) (4) pre-mixes are analyzed to ensure the presence of each nutrient. For the dry vitamin pre-mix, the indicator nutrient is vitamin(b) (4) and is analyzed at the finished product tank; (b) (4) indicator nutrient is vitamin (b) (4)and is tested at the finished product tank (b) (4) (b) (4) or (b) (4) is the indicator nutrient and is analyzed at the finished product tank. For Enfamil (b) (4) pre-mixes are utilized including dry vitamin iodide pre-mix(b) (4) (b) (4) all (b) (4) pre-mixes are manufactured in-house. For the dry vitamin pre-mix, the indicator nutrient is vitamin(b) (4) and is analyzed at the finished product tank; (b) (4) the indicator nutrient is vitamin (b) (4)and is tested at the finished product tank (b) (4) or (b) (4) is the indicator nutrient and is analyzed at the finished product tank. Certificates of analysis were reviewed; no deficiencies were noted.

Individual nutrients are also added to the product formulations. For Enfamil NeuroPro Gentlease, individually added nutrients include (b) (4) For Enfamil concentrate, individually added nutrients include (b) (4) . Individually added ingredients are tested in-process or at the finished product stage.

At the finished product stage, vitamins (b) (4) are tested again for (b) (4) A full label claim is done (b) (4) for an existing product batch unless that item was not produced; this includes testing for nutrients such as (b) (4) and (b) (4) that are not declared on the nutrient panel. Otherwise, (b) (4) testing is done for minerals and vitamins that were not previously analyzed. If the bulk formula is shared between (b) (4)batches, a full label claim will only be conducted on (b) (4) batch; reduced testing is done on the (b) (4) batch. Certificates of analysis for both products were reviewed for October 2019-July 2021; no

deficiencies were noted.

The shelf-life of Enfamil NeuroPro Gentlease and Enfamil concentrate is (b) (4) and (b) (4), respectively. Stability testing is performed for (b) (4) at (b) (4) and at the (b) (4). For a new formulation, testing is done at (b) (4) every (b) (4) thereafter, and (b) (4); a full label claim is conducted for the (b) (4) batches. If a full label claim is conducted for an existing product, extended stability testing is done every (b) (4) over the shelf-life of the infant formula. The number of samples pulled is product dependent and is outlined in (b) (4) samples are held at room temperature. Stability data was reviewed for both products including full label claims for October 2019-May 2020; no deficiencies were noted.

Incubation testing is performed for aseptically processed and retorted product to determine the presence of (b) (4) or (b) (4) spoils. For Enfamil NeuroPro Gentlease, a minimum of (b) (4) packages (b) (4) are analyzed for (b) (4) growth ((b) (4) °C) and a minimum of (b) (4) packages (b) (4) are tested for (b) (4) growth (b) (4) to (b) (4) °C). Shortened incubation times may be implemented in certain situations. At the end of incubation, the product is visually inspected and opened for (b) (4). For a (b) (4) or (b) (4) spoil, (b) (4) plating on a (b) (4) or general purpose (b) (4) is performed; plates are held up to (b) (4) at (b) (4) °C and (b) (4) is held up to (b) (4) at (b) (4) °C. The plates are examined for mixed cultures and isolates. Isolates are further characterized via (b) (4) (b) (4) profiling and/or (b) (4) analysis. A new product, process or manufacturing site and a spoilage/atypical event require additional incubation samples. Certificates of analysis dated March-May, 2020 were reviewed; no deficiencies were noted.

Water and Boilers

Water is received from the (b) (4) Of the water lines entering the facility, (b) (4) are for product contact. Each line is equipped with a (b) (4) device, which is serviced every (b) (4) by (b) (4) units are also located at several points (b) (4). (b) (4) water is used as an ingredient in product formulations; the flow of the (b) (4) water line is as follows:

(b) (4)

The (b) (4) are sampled (b) (4) for coliforms; per testing results, the (b) (4) is changed. The (b) (4) system is meter-based; a sensor reads the set-point. On the (b) (4) system, the sample port is cleaned (b) (4) and the hoses and tubes are changed (b) (4). The (b) (4) system consists of (b) (4) stages; each stage has (b) (4). Parameters are reviewed (b) (4) and include pressure, flow rate, conductivity, pH, (b) (4) and chlorine; (b) (4) are changed based on these results. The (b) (4) unit is not CIP'd. The process water tanks are CIP'd (b) (4) At the surge tank, the pH, conductivity, chlorine, (b) (4) and (b) (4) are also measured (b) (4) and (b) (4) Microbiological testing of water is done (b) (4) for coliforms and total aerobic count (TAC); specifications are in place for coliforms (b) (4) ml.) and TAC (b) (4) ml.). Samples are pulled at the product water tanks (b) (4) and (b) (4) and at a port after the (b) (4) system. Results for 9/2/20-8/25/21 were reviewed and no

deficiencies were noted. Chemical testing including general chemistry, metals, disinfection by-products, semi-volatile organic chemicals and volatile organic chemicals is performed (b) (4) by (b) (4) (b) (4) The previous report dated 12/28/20 was reviewed; no deficiencies were noted. Radiological testing for radionuclides is also done every (b) (4) by (b) (4) . The previous report dated 12/18/19 was reviewed and no deficiencies were noted.

There are (b) (4) which are (b) (4) feed the central distribution system. They are equipped with (b) (4) and (b) (4) and are used (b) (4) and (b) (4) Chemicals are added and include (b) (4) (b) (4) and (b) (4) (b) (4) they are provided by (b) (4)

The firm has (b) (4) water (b) (4) boilers (b) (4) which use (b) (4) gas and (b) (4) gas. Additives are FDA approved and include (b) (4) (boiler water treatment) and (b) (4) (boiler water treatment); they are provided by (b) (4)

MANUFACTURING CODES

The firm utilizes a batch code system.

(b) (4)

COMPLAINTS

The firm has a written complaint SOP. The firm's Product Information and Compliance (PIC) department receives customer communications via email, phone, social media, letter, and verbal. Complaints are routed to PIC Associates or PIC Specialists for medical events. The program defines the following medical events: Medical Event-sign, symptom or illness associated with product and experience where medical case was received; Serious Medical Event-death, life-threatening, inpatient hospitalization, or persistent incapacity; Hazard to Health-probable occurrence of injury, illness, or adverse health consequences. Information from medical events are recorded on the firm's "Global Quality and Medical Events" reporting form.

Ann S. Batholomew, Manager of Product Information and Compliance provided a filtered report, “All

Medical ESC Manufactured Infant Formula Products" from (b) (4) I reviewed three products with the highest complaints that undergone a reformulation, processing or packaging change since the last inspection: Enfamil NeuroPro Infant Powder 20.7oz bag-in-tub (BIT) (316 complaints); Enfamil NeuroPro Gentlease 19.5oz BIT (205 complaints); and Enfamil NeuroPro Infant RTU 2oz nursettes (100 complaints). Mr. Fleming provided summary reports for all batch numbers for these products. This included complaint history for the products before and after any reformulation, process, or packaging change. Additionally, he provided "Global Quality and Medical Event" reports for the three aggregates with the highest number of complaints:

- Enfamil NeuroPro Infant Powder 20.7oz (b) (4)
- Enfamil NeuroPro Gentlease 19.5oz (b) (4)
- Enfamil NeuroPro Infant RTU 2oz (b) (4)

Most complaints on both the liquid and powder products were spit-up, gassiness, vomiting, diarrhea, cramping, and fussiness. In some cases, MD's were consulted. The reports included information on whether the baby was still on product, any product defects, change in formula, resolved symptoms, and any customer fulfillment; concluding with a summary indicating the basis for no health hazard.

The firm had one complaint involving an infant death, (b) (4) on (b) (6), (b) (7)(C) (**Exhibit 16**). This complaint (b) (7)(E) the death of an infant from (b) (6), (b) (7)(C) (b) (7)(E) The firm documented that ingredients were within guidelines and that there is not a reasonable possibility of a causal relationship between the baby's death and the formula. Report summary identified this complaint under "serious" assessment.

FDA Complaints

A review was conducted of the following FDA complaints logged in OSAR/FACTS.

FACTS ID 168456/MJN EVNT 631856: On 06/02/2021, a complaint was received from a complainant reporting mixing Enfamil NeuroPro Sensitive Infant Formula (EE1B2J) with water and seeing yellow-orange specks in the liquid congealed in the bottle nipple. No illness reported. Initial disposition remarks indicated that there was one similar complaint regarding this same lot code and that no illness was associated with that complaint.

NA Quality Director spoke to FDA. Mr. Fleming stated he sent the firm's event report to the Global Brand Protection Team. The firm issued product replacement and a check.

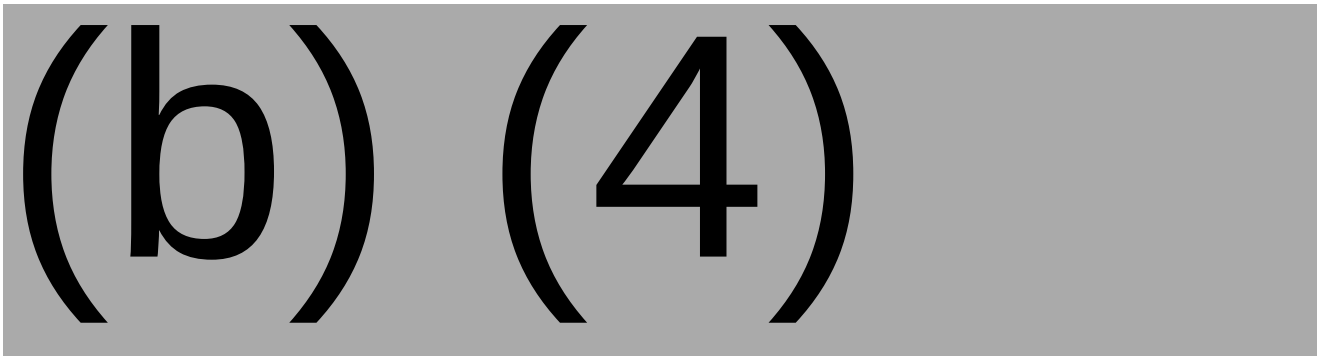
FACTS ID 161910/MJN EVNT 581721: On 04/22/2020, a report was received from a complainant reporting that Enfamil NeuroPro RTU Infant Formula (EV9JDG) turned pink in unrefrigerated bottles left out for 6-8 hours overnight. Additional products also included Enfamil NeuroPro RTU Infant Formula (EV9MHE) and Enfamil NeuroPro Gentlease (EA9J5Q & PP9JRK).

This complaint was reviewed in a separate FDA investigation on 04/24/2020-08/24/2020. See OSAR for detailed report and memorandum.

(b) (4)

FACTS ID 159189/NO MJN EVNT: On 10/17/2019, a complaint was received indicating that a melted piece of

plastic, pink with black lines ½" long, wider than a piece of string found in a can of Enfamil Gentlease Powdered Infant Formula (ZP9H3V).
This product is not manufactured at the firm's Evansville facility. This will be covered at the next inspection at the firm's Zeeland, MI facility.
FACTS ID 159025 MJN EVNT 555978 & 556711: On 10/02/2019, a complaint was received reporting that 7 month-twin boys were hospitalized after experiencing an anaphylactic reaction after mixture of Enfamil Infant Formula (EV9EPF) and Enfamil Neuro Pro 32oz (EA9D2S). Both children experienced lip swelling, vomiting, and urticaria. Children were taken to ER and admitted to hospital. MD believe this to be an allergic reaction. Initial disposition remarks include communication with Mr. Fleming.
The firm reviewed records for reports received on batch, no other medical events of any type have been received, appears isolated.



RECALL PROCEDURES

The firm has a written recall program, "Critical Events and Product Recall Procedure All Products" and conducts (b) (4) mock recalls. The program identifies execution of actions, roles and responsibilities, recall effectiveness, product disposition, and communication with customers, consumers, and suppliers.
The last mock recall was conducted for (b) (4) on (b) (4) . The mock recall was completed in (b) (4) with (b) (4) % accuracy for raw material and finished product.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

A temperature-indicating device was not installed where it could be accurately and easily read.

Specifically, on the cooker shell of your continuous agitating steam retort (13oz line), the temperature indicating devices (b) (4) and (b) (4) located at the shell inlet and outlet, are not easily readable due to being obstructed by the reel arms, and positioned in an area that is not well lit.

Reference: 21 CFR 113.40(c)(1)(v)

Supporting Evidence and Relevance:
On the cooker shell, the (b) (4) located at the shell inlet (b) (4) and outlet (b) (4) are the "official" thermometers, which ensure that the critical factor, process temperature as identified in the firm's

scheduled process is achieved and maintained during the retort (b) (4) The (b) (4) are located behind the shell screen and reel arms in an area that is not well lit as the temperature column and calibration tag were not readable during this inspection **(Exhibit 17–Photographs DSC02936 & DSC02937** (b) (4) **and Exhibit 18-Photographs DSC02939 & DSC02940** (b) (4) .

Discussion with Management:
We discussed with management that the (b) (4) must be easily readable to ensure that the process temperature is achieved and maintained during the retort (b) (4) In the current location, it is very difficult for the Operator to read these devices and obtain accurate temperature values.

Mr. Fisher stated that management is currently brainstorming to determine a solution to this issue. He further explained that options include improved lighting, installation of an advanced temperature device or the use of a video camera; he also stated that the firm will work with (b) (4) Mr. Fisher stated that a solution will be implemented within 30 days.

Observation Correction Status: Not Corrected

OBSERVATION 2
A record was not was not made of a critical factor specified in the scheduled process.

Specifically, review of the record, "Production Quality Audit Process Control 13 Ounce Line CCP", dated (b) (4) indicated that readings of the temperature recording device (TRD) are only (b) (4) documented at the start of production. As such, you do not ensure that the process temperature charted on the TRD does not read higher than the temperature indicating device (TID). Process temperature is a critical factor according to your scheduled process.

In addition, review of the record, "Venting Procedure Checklist 13 Ounce Can Line CCP", dated (b) (4) (b) (4) , and (b) (4) indicated that the vent temperature is not (b) (4) documented at the start or the end of the venting process.

Reference: 21 CFR 113.100(a)

Supporting Evidence and Relevance:
During record review for the continuous agitating steam retort (13oz. line), it was determined that temperature readings of the TRD are only (b) (4) documented at the start of production on the record, “Production Quality Audit Process Control 13 Ounce Line CCP” **(Exhibit 14 – page 1)**. Process temperature is a critical factor per the firm’s scheduled process and is captured via the TID and TRD. The TID is the “official” thermometer and the TRD provides a continuous record. Temperature readings of the TID are (b) (4) documented (b) (4) therefore, temperature readings of the TRD must also be recorded concurrently to ensure that the TRD temperature is not higher than the TID temperature. If so, adjustments to the TRD must be made.

(b) (4), the retort is vented for (b) (4) to (b) (4) °F to remove air from the retort; this process is critical to ensure that production critical factors including process temperature are achieved and maintained during the retort (b) (4) During record review, it was determined that the vent temperature is not (b) (4) documented at the start or end of the venting process **(Exhibit 14 – page 2)**. The vent (b) (4) is captured on the (b) (4) chart, yet it is impossible to decipher if the vent temperature was met; during this inspection, we also spoke with one of the record reviewers who agreed that the vent temperature is difficult to determine from the chart **(Exhibit 14 – page 4)**.

Discussion with Management:
We discussed with management that temperature readings of the TRD must be (b) (4) documented (b) (4) along with temperature readings of the TID; this ensures that the TRD temperature is not higher than the TID temperature. We also explained that the venting process is critical to the operation of the retort and that if the vent temperature is not recorded, how does the Operator know that the temperature was met.

Mr. Fisher stated that the above records will be updated immediately to capture temperature readings of the TRD, and the vent temperature at the start and end of the venting process. Operators will also be retrained to (b) (4) document these values. This will be done within 15 days.

Observation Correction Status: Not Corrected

OBSERVATION 3
Observation and measurement of an operating condition was not recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product was being achieved.

Specifically, on the aseptic (b) (4) line, critical factors, which identify the maintenance of commercial sterility, are not (b) (4) documented for the processor, aseptic surge tank and filler between the sterilization of equipment and the start of production.

For example, review of the records, "Aseptic Filler Pre-sterilization Log CCP" and "32oz. Aseptic Filler Production Log CCP" dated (b) (4) respectively, indicated that critical factors were not documented between the end of sterilization at (b) (4) on (b) (4) and the start of filling at (b) (4) on (b) (4)

In addition, critical factor alarms for the processor, aseptic surge tank, and filler are not routinely challenged; they were previously challenged in 2017 when the system was commissioned.

Reference: 21 CFR 113.40(g)(2)(ii)(C)

Supporting Evidence and Relevance:
Review of the above production records for the filler indicated that critical factors as identified in the firm's supplemental filing were not (b) (4) documented between the end of sterilization and the start of

production; on (b) (4) , there was an approximate, (b) (4) gap **(Exhibit 15–pages 4 and 5)**. Review of production records for the processor and aseptic surge tank also indicated that critical factors were not (b) (4) recorded between sterilization and production.

When critical instruments are calibrated, the associated alarms are not challenged since all utilities are powered off. The previous alarm challenges were four years ago.

Discussion with Management:
We discussed with management that the aseptic system must be actively monitored by the Operator to ensure that sterility is maintained and that it is not running on "(b) (4) ". The firm relies upon alarms if a critical factor is not within specification or commercial sterility is lost; however, these alarms are not routinely challenged. We further stated that these critical factor alarms associated with the processor, aseptic surge tank and filler must be routinely challenged to ensure they are functioning properly; these challenges should be documented.

Mr. Fisher stated that Operators will (b) (4) document critical factors between the end of sterilization and the start of production; retraining of Operators will also be done. Regarding alarm challenges, Mr. Fisher explained that he will consult with (b) (4) and (b) (4) to determine how to proceed with these challenges using the current engineering design. This will be accomplished within 15 days.

Observation Correction Status: Not Corrected

ADDITIONAL OBSERVATIONS

Observations not listed on form FDA 483

There were no additional observations during this inspection.

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT
On 08/26/2021, a closeout meeting was held with Scott A Fisher-Site Director Thomas Fleming-Director North America Quality Nutrition, (b) (6) -Associate Manager of HACCP, Russell E. Roehr-Quality Assurance Manager, Andrew Lindauer-Aseptic Workstream Manager, and Aldo R. Gonzalez-America Regional Technical Manager. A 3-point Form FDA 483, Inspectional Observations, was issued to Mr. Fisher. During the meeting, the following items were discussed with management:

1. For the continuous agitating steam retort, review of the document, "Critical Points Check- 13 oz.

Can Line- CCP" indicated that (b) (4) bleeder checks are performed every (b) (4) , yet these checks are grouped with (b) (4) other operational checks. Therefore, the Operator's initials pertain to all these checks and it cannot be determined if the Operator verified the function of each (b) (4) bleeder or not **(Exhibit 14-page 3)**. We discussed with management that the document be modified so each bleeder is identified separately; this would allow the Operator to initial or place a checkmark next to each bleeder verifying that it was functioning.

Mr. Fisher stated that the form will be updated and the Operator's retrained; this will be done within 15 days.

2. For the continuous agitating steam retort, the Operators record the proper function of the (b) (4) bleeder on the document, "Production Quality Audit Process Control 13 Ounce Line CCP"; any of the (b) (4) bleeders may be visually verified **(Exhibit 14-page 1)**. However, the bleeder at the inlet end to the cooker is not readily visible to the Operator as it is obstructed by a metal sheet. We discussed with management that the "main" bleeder be identified; this bleeder will be routinely checked by the Operators to provide consistency. We further explained that the bleeder at the inlet end of the cooker is not a feasible option since is not readily visible to the Operator.

Mr. Fisher stated that changes will be implemented within 15 days.

3. For the continuous agitating steam retort, the (b) (4) and (b) (4) cooler are partially filled with (b) (4) water; sanitizer is not added directly to the shells nor is the (b) (4) water (b) (4) by the firm when it enters the plant. For the (b) (4) cooler, residua (b) (4) levels are checked (b) (4) (b) (4) they are not verified for the (b) (4) We discussed with management that the free residual (b) (4) levels should be checked for both shells (b) (4) to (b) (4) to ensure the water is of sanitary quality. We also discussed adding sanitizer directly to the shells to further reduce the potential for microbial contamination.

Mr. Fisher stated that (b) (4) levels will be verified more frequently; they will also work with (b) (4) to determine the most effective method to add sanitizer to the (b) (4) and (b) (4) cooler.

4. For the (b) (4) aseptic line, review of the documents, "Aseptic Sterilizer Production Log (UHT)-CCP" and "Aseptic Surge Tank (AST) Product Log- CCP" indicated that in addition to critical factors, several operational parameters are also documented, yet ranges are not identified for these parameters, which would allow an Operator to determine whether a reading is within specification or not **(Exhibit 15 – pages 2 & 3)**. We discussed with management that ranges be identified on these documents; therefore, if a value is not within specification, the Operator can act.

Mr. Fisher stated that the documents will be updated within 15 days.

5. For the 13 oz. retort line, in-house calibration records for the TID and the reference thermometer were reviewed; the calibration record for the TID did not identify the next calibration date as required by 21 CFR part 113.100(c).

Mr. Fisher stated that the record will be updated within 15 days.

6. During review of the firm's environmental monitoring results record for (b) (4), the firm obtained a composite positive *Cronobacter* sample in the (b) (4) Room. The firm completed the OOS report but did not re-sample each individual sampling site for *Cronobacter* prior to re-cleaning/sanitization in order to isolate the source of the positive result, as required by the firm's SOP, "ESC Powder Operations Environmental Monitoring Program" **(Exhibit 19)**.

Mr. Fleming stated that the firm's micro lab broke down each individual sample in the composite sample and obtained a negative result for each. Mr. Fleming stated that the firm will review the wording in the SOP. He stated this review would take place in 30 days.

7. On 08/23/2021, during the walk-through of the (b) (4) Room, the (b) (4) Room Operator was observed not changing gloves when touching non-food contact surfaces and then touching food contact surfaces. Additionally, he was observed not washing hands between glove changes. The (b) (4) Room hand sink was observed inaccessible by an equipment table and without any hand-towels in the hand-towel dispenser.

The firm provided documentation that the operator was retrained on 08/25/2021. The retraining consisted of a review of the firm's "EVV-SC-MFG-SOP-04393 Evansville Liquid Operations GMPs". The content of the training covered glove changes and hand-washing. Mr. Fisher stated that the retraining would be shared with the entire campus. He stated this would be accomplished within 15 days.

8. During review of aseptic tracking sheet records from February 2021 and May 2021, the firm did not record (b) (4) cleaning for the (b) (4) and (b) (4) on (b) (4) and the (b) (4) on (b) (4). Additionally, the corresponding comment section was left blank. This form was signed by a supervisor. Ms. (b) (6) stated that the comment section should be filled in if there is an omission in the record.

Ms. (b) (6) stated that the firm would be discussing the importance of completed entries on forms. She stated this would be completed in 15 days.

One additional item was discussed with management prior to closeout:

The current audit SOPs/procedures used by the firm during their annual quality control and GMP audit are not maintained at the facility. They are maintained off-site by a separate audit group. We discussed that 21 CFR 106.94(b) specifies that the audit plan shall set out the methods the manufacturer use to determine whether the facility us operating in accordance with GMP and quality control procedures in accordance with sections 412(b) and (i) of the FD&C Act.

In response to a request for the firm's onsite audit procedures, Mr. Fleming provided the firm's SOP, "Global Auditing Process," which indicates audit ratings, classification, and CAPA plan target dates and follow-up schedule. He also provided the firm's document, "Pre-Audit Questionnaire Nutrition Manufacturing Site Appendix C," used to plan the internal audit. Mr. Fleming stated the documents are global documents and assessable. However, he stated he does not have access to make changes to the

documents. Mr. Fleming stated there is no additional document for the audit procedure used during the audit.

ADDITIONAL INFORMATION

Pest Control

Pest control is provided by (b) (4) ; personnel are on-site (b) (4) inspections of the facility are conducted to address sanitation and structural issues. In the liquid and powder areas, interior rodent traps, insect light traps (ILTs), pheromone traps and air curtains are serviced (b) (4) insect and pest monitors are inspected (b) (4) and exterior rodent stations are serviced (b) (4) All chemicals are EPA approved.

Records for (b) (4) for powder, liquid and warehouse operation locations were reviewed. Reports include (b) (4) and (b) (4) trending. No discrepancies were noted.

IT Programs/Automatic Equipment

The firm's IT program, validation procedures, and periodic system review (PSR) were covered. Matthew W. Smith, Automation Manager, provided information and records relating to the firm's IT programs. Mr. Smith stated that (b) (4) comprises approximately (b) (4) % of the software and hardware used. These systems consist of (b) (4) . The firm uses (b) (4) to maintain a list of all hardware and software, including program and version control.

Since the last inspection, a (b) (4) main host server has been added (2020), all of which are backed-up (b) (4) (b) (4) and (b) (4) Data is maintained for (b) (4) in the (b) (4) . The firm backs up (b) (4) data to the (b) (4) with access controlled through the firm's legal and on-site IT resource departments. Servers require badge access. The firm's written procedure "Critical System Backup and Restore Testing Procedure" describes the firm's backup procedures and frequencies.

The firm has a procedure for validating systems including equipment, controller type, controller name, IP address, version, and model. The firm conducts a PSR every (b) (4) . The validation for the (b) (4) UHT was performed in 2016, with PSR's performed in (b) (4) and (b) (4) . The PSR includes any changes made to the system, mechanical electrical programs/process, user security & access accuracy, configuration of hardware/software, operations (stability/reliability), and software/data backups. Non-production validations are completed off-site, and production validations are conducted on-site. Using a (b) (4) authentication and monitored by the firm's automation engineers, (b) (4) can now perform off-site remote changes.

Environmental Monitoring

The firm has an environmental monitoring program covering the powder and liquid Operations. The firm's documents, "ESC Powder Operations Environmental Monitoring Program" and "Environmental Program for ESC Liquid Operations excluding LHMF Operations", provide guidance for environmental sample type, hygienic zones (b) (4) location frequency, and number of swabs. Additionally, the documents provide instruction for out-of-specification (OOS) results. The firm uses (b) (4) Air Sampler for air samples and (b) (4) for (b) (4) air sampling. All swab locations are tracked in (b) (4)

For the powder operations, the program includes BIBBIT and premix operation locations. Powder operation environmental monitoring records from 08/25/2020-08/23/2021 were reviewed. The firm had no record of any OOS *Salmonella* findings. The firm had six OOS findings for *Cronobacter* in (b) (4) hygiene zones. For five of

the OOS findings, the firm's reports indicated that the firm followed their SOP, determined root cause, and completed corrective actions. On (b) (4) the firm obtained a composite positive *Cronobacter* sample in the (b) (4) Room. The firm completed the OOS report but did not re-sample each individual sampling site for *Cronobacter* prior to re-cleaning/sanitization in order to isolate the source of the positive result, as required by the firm's SOP. See **General Discussion with Management Item #6** for the firm's response. The firm completed five re-samples of the area after cleaning and obtained all negative results.
Liquid operation environmental monitoring results from 09/01/2020-08/17/2021 were reviewed. The firm did not have any OOS findings for *Salmonella*.

Supplier Qualification
The firm has a supplier approval/audit program. The firm's supplier audit SOP provides audit criteria, rating system, risk tier, audit schedule, and CAPA requirements for suppliers. Audit programs include cover foreign material management, micro-contamination controls (ingredients, finished products, and packaging), and processing facility controls (air/water/environmental monitoring). Suppliers not meeting requirements can be discontinued as an approved supplier or suspended until CAPA items are completed. The program identifies provisions for removing a supplier from the firm's inventory programs.
Supplier audits for (b) (4) on 11/11/2020 and (b) (4) on 06/09/2021 were reviewed. The audits covered items in the SOP, revealed any potential areas of concern, and introduced proposed corrective actions. No discrepancies were noted.

Internal GMP/Quality Control Audits
Internal audits covering GMPs and quality control procedures are conducted annually by a team of auditors. The most recent audit was 07/19-07/23/2021, led by Lead Auditor (b) (6) Regional Compliance-Canada. Mr. Fleming stated that Mr. (b) (6) conducts audits for all of the firm's facilities. Mr. Fleming provided a memo documenting that the audit provided a review of compliance with the applicable regulations including 21 CFR 106, 107, 113, and 117. The firm's SOP, "Global Auditing Process", indicates audit ratings (i.e. unacceptable, needs improvement), classification (critical, major, minor), and CAPA plan target dates and follow-up schedule.
The firm's "Pre-Audit Questionnaire Nutrition Manufacturing Site Appendix C" is used to plan the internal audit. Areas include facility and process (pest control, hygiene zones, equipment cleaning, maintenance, calibration, validation), supplier audits, warehouse/storage practices (including temperature control and excursions), traceability, laboratory functions, batch release, change control, deviations, and management review.
See **General Discussion with Management** section for discussion during the inspection.

Master Sanitation
The firm has a master sanitation schedule and SOP for the individual operation locations. The "Aseptic Master Sanitation Schedule" covering the (b) (4) aseptic filling and packaging areas was reviewed. Locations within in the aseptic processing operation such as the (b) (4) room, WIP lab, (b) (4) and capper, (b) (4) room, and (b) (4) packer are on a (b) (4), and (b) (4) schedule. Cleaning operations include sanitizing of floors, overhead platforms, and specific exterior and interior components, which are recorded on the firm's "Aseptic FMS Tracking Sheet".
Aseptic tracking sheet records from February 2021 and May 2021 were reviewed. The firm did not record (b) (4) cleaning for the (b) (4) and (b) (4) on (b) (4) and the (b) (4) or (b) (4) Additionally, the corresponding comment section was left blank. This form was signed by a supervisor. Ms.

(b) (6) stated that the comment section should be filled in if there is an omission in the record. See **General Discussion with Management Item #8** for management response.

The facility is divided into hygienic zones: (b) (4) . The firm has a (b) (4) policy and gowning is zone specific. The powder and liquid operations have their own respective ante rooms.

Photographs from Establishment Inspection
The officially sealed original copy disc containing photographs taken during the inspection are filed with the unlabeled exhibits and attachments.

SAMPLES COLLECTED

The following samples, requested as part of this inspection and FY21 SCOPE assignment, were collected from the firm's distribution center, (b) (4) by FDA Investigator Jennifer R. Johnson:
-1145786 12 cans of Enfamil NeuroPro Infant NonGMO Powder 20.7oz, batch code (b) (4) for nutrient analysis
-1145787 60 cans of Enfamil NeuroPro Infant NonGMO Powder 20.7oz, batch code (b) (4) for microbiological analysis
-1145788 12 6-pack packages of Enfamil Enfalyte RTD Cherry 6oz, batch code (b) (4) for nutrient analysis
Form FDA 484, Receipt for Samples, was issued to Ryan P. Risinger at the conclusion of the sampling on 08/25/2021. An updated Form FDA 484, Receipt for Samples, was issued to and signed by Scott A. Fisher, Site Director, at the conclusion of the inspection on 08/26/2021.
(b) (4)

VOLUNTARY CORRECTIONS

The following corrections to observations from the previous FDA inspection dated 08/06-08/09/2018 were reviewed.
Observation 1-You did not a maintain a cold storage area for a final infant formula at a temperature not to exceed (b) (4) ^{0}F (b) (4) ^{0}C) for a defined period of time.
Correction-Verified: The firm provided the following documents: (b) (4)

(b) (4)

Results for both studies indicated that (b) (4) .
Observation 2-You did not equip a cold storage compartment with a validated high temperature alarm.
Correction-Verified: The firm provided the following documentation **(Exhibit 20**): "MJN ESC Automation System-Software Change Request Form" (dated 05/02/2019), "Bulk Product Storage Temperature NA-SC-QA-SOP-04077", and "Bulk Product Storage Temperature Communication Plan for High Temp Alarms". The software request document describes the change as mandating the (b) (4) high temperature set points from (b) (4) ^{0}F to (b) (4) ^{0}F. The SOP refers to (b) (4) temperature verification steps taken by (b) (4) personnel when temperatures reach (b) (4) ^{0}F, (b) (4) ^{0}F, and (b) (4) ^{0}F and reference to the communication plan. The communication plan describes supervisor notification and lab personnel action and sampling. Additionally, the communication plan provisions for (b) (4) and (b) (4) notification procedures.

The following corrections to discussion items from the previous FDA inspection dated 08/06-08/09/2018 were reviewed

Discussion Item 1-The (b) (4) line is equipped with a dual element temperature recording device (b) (4) and (b) (4) one of these sensors was recording temperatures higher than the (b) (4) (b) (4) temperature indicating device.

Correction-Verified: Review of the document, "Aseptic Sterilizer Production Log (UHT)- CCP" dated 4/10/21, 4/13/21 and 4/14/21 indicated that the temperature recording device (TRD) did not read higher than the (b) (4) or temperature indicating device (TID).

Discussion Item 2-System Operators and not management were conducting the first review of LACF records within (b) (4) and prior to distribution of completing a record.

Correction-Verified: Batch records reviewed showed management reviewed the records within (b) (4) (b) (4)

EXHIBITS COLLECTED

1(DBA) Retort Product List, 2 pages
2(DBA) Aseptic Active Formulations Product List, 1 page
3(DBA) BIBBIT Product List, 1 page
4(DBA) Label-Enfamil Infant 13oz Concentrate, 1 page
5(DBA) Label Enfamil NeuroPro Gentlease 32oz, 2 pages
6(DBA) Product Labels, 68 pages
7(DBA) Facility Organizational Chart, 1 page
8(DBA) Process Flow-ESC Liquid Processing, 1 page
9(DBA) Process Flow-ESC Aseptic Processing and Packaging 8oz&32oz, 1 page
10(DBA) Process Flow-Aseptic , 3 pages
11(DBA) Process Flow-ESC 13oz Operation, 1 page
12(DBA) (b) (4) 12 pages
13(DBA) (b) (4) 10 pages
14(DBA) Retort Records-Enfamil Infant Concentrate 13oz, 4 pages
15(DBA) Aseptic Records-Gentlease NeuroPro 32oz, 5 pages
16(DBA) (b) (4) , 16 pages
17(DBA) Photographs DSC02936 & DSC02937-(b) (4) 2 pages
18(DBA) Photographs DSC02939 & DSC02940-(b) (4) , 2 pages
19(DBA) ESC Powder Operations Environmental Monitoring Program, 6 pages
20(DBA) Alarm Setpoint Change Documentation, 10 pages

ATTACHMENTS

1(DBA) FDA 482, Notice of Inspection, issued to Scott A. Fisher, Site Director, 3 pages
2(DBA) FDA 482a, Demand for Records, issued to Scott A. Fisher, Site Director, 1 page
3(DBA) FDA 482b, Request for Information, issued to Scott A. Fisher, Site Director, 1 page
4(DBA) Issued 483, 3 pages
5(DBA) FDA 484 Receipt for Samples issued to Ryan Risinger, 1 page

6(DBA) FDA 484 Receipt for Samples issued to Scott Fisher, Site Director, 2 pages
7(DBA) FDA 3511-3 MJN Evansville, 9 pages
8(DBA) FDA 3511c MJN Evansville, 8 pages
9(DBA) Plant Report, 15 pages
10(DBA) Attachment A for B73/B85/B74/B75/B78/B81/B66, 60 pages
11(DBA) Attachment B for Enfamil Concentrate 13oz & NeuroPro Gentlease, 6 pages

X Daniel B Arrecis
Investigator
Signed By: Daniel B. Arrecis -S
Date Signed: 09-15-2021 13:35:29

X Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer -S
Date Signed: 09-15-2021 13:41:12