

Establishment Inspection Report

Abbott Nutrition
Sturgis, MI 49091-9302

FEI: **1815692**
EI Start: 9/20/2021
EI End: 9/24/2021

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SUMMARY

This comprehensive inspection was conducted as part of the Infant Formula Program and Medical Foods Program-FY21 Schedule of Inspections/Sample Collections under DFIG#21-04, FACTS#12071684, eNSpect ID#204137. This assignment was conducted pursuant to Compliance Programs 7321.006-Infant Formula Program-Import and Domestic, 7321.002-Medical Foods-Domestic and Import, 7321.005 Domestic and Import NLEA, and 7303.040-Preventive Controls and Sanitary Human Foods Operations. Abbott Nutrition is located at 901 N. Centerville Road Sturgis, MI 49091. 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 09/16/2019-09/24/2019 and was classified VAI. A 1-point Form FDA 483, Inspectional Observations, was issued to Patrick A. Cooper, Site Director, for the following:

- You did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production

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aggregate meets the required microbiological quality standards.
Additionally, during the closeout meeting, the following items were discussed with management:

- On 09/16/2019, we observed a window screen located on floor (b) (4) of (b) (4) Dryer (b) (4) building with accumulated dust-like debris collected on the exterior of the screen.
- On 09/18/2019, we observed that the firm does not obtain water samples for radiological testing from a point in the system in which water is in the same condition as when used in infant formula manufacturing.

See **Voluntary Corrections** section for corrections to observations and discussion items.

During this inspection, we covered the Line (b) (4) powder filling operations for Similac Alimentum Batch Code- (b) (4). Additionally, we observed receiving, storage, vitamin/mineral weigh operations, liquid processing, dry-blending, and (b) (4) Dryer (b) (4) operations. Inspectional coverage included GMPs, non-conformance reports, complaints, recalls, training program, quality control procedures, environmental monitoring, finished product testing, stability/nutrient testing programs, supply chain, maintenance, water, (b) (4), calibrations, pest control, and record review.

At the conclusion of the inspection, a 5-point Form FDA 483, Inspectional Observations, was issued to TJ Hathaway, Site Director, for the following:

- You did not maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition.
- You did not install a (b) (4) capable of (b) (4) or smaller when (b) (4) is used at a product filling machine.
- Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a handwashing facility at a suitable temperature after the hands may have become soiled or contaminated.
- An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.
- You did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control.

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

During the closeout meeting, 6 items were discussed with management:

- For the temperature-controlled storage areas, ingredient bulk tanks and finished product tanks, temperatures are electronically monitored; alarms are in place, but they not challenged to ensure they are functioning properly.
- (b) (4) is equipped with a backflow prevention unit (b) (4) which is inspected (b) (4) (b) (4). The inspection dated 6/4/21 indicated that the (b) (4) not open and therefore, the (b) (4) did not pass the inspection. The (b) (4) remained on-line during this time.
- In the South cooler, the overhead fan was blowing directly on a (b) (4) of stage two metabolic powder, which was stored on the top storage rack.
- Review of both the Line (b) (4) Room (b) (4) Wash and the Line (b) (4) Filler (b) (4) Wash records dated 07/17-07/18/2021 indicated that a (b) (4) was required for both. The entry for the (b) (4)

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was not signed off by the operator but signed by reviewers.

- During the walk-through, a screen in the ceiling directly above the (b) (4) Dryer (b) (4) was observed with trapped dust-like debris.
- In the Cool Room/Flavor Room, (b) (4) drums of (b) (4) Sanitizer Lot (b) (4) (b) (4) were stored next to (b) (4) premixes, vitamin D₃, E, & K₁ in (b) (4).

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 by FDA Investigators Danny Tuntevski and Micmarie Ramos:

1033049-60 cans Similac Pro-Advance 34oz. Lot 32669SH0 1358 228 USE BY 1SEP2023 SIMESPWD for microbial analysis

1033050-12 cans Similac Pro-Advance 34oz. Lot 32669SH0 1358 228 USE BY 1SEP2023 SIMESPWD for nutrient analysis

1033051-60 cans of ProViMin 5.3oz. Lot 31393K0 1050 USE/BY 1 MAY2022 196 PROVIM for microbial analysis

1033052-12 cans of ProViMin 5.3oz. Lot 31393K0 1050 USE/BY 1 MAY2022 196 PROVIM for nutrient 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: An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

Correction Status: Not Corrected

Citation Text: You did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control.

Correction Status: Not Corrected

Citation Text: You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

Correction Status: Not Corrected

Citation Text: You did not install a (b) (4) capable of (b) (4) when (b) (4) is used at a product filling machine.

Correction Status: Not Corrected

Citation Text: Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

Correction Status: Not Corrected

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ADMINISTRATIVE DATA

Inspected firm: Abbott Nutrition
Location: 901 N Centerville Rd
Sturgis, MI 49091-9302
Phone: 269-651-0600
FAX: 269-651-0959
Mailing address: 901 N Centerville Rd
Sturgis, MI 49091-9302
Email address: keenan.gale@abbott.com
Dates of inspection: 9/20/2021-9/24/2021
Days in the facility: 5
Participants: **Daniel B Arrecis, Investigator**
Elizabeth P Mayer, National Expert

On 09/16/2021, I, Investigator Daniel B. Arrecis, called Susan M. Elgan, Global Food Safety Director, to preannounce an inspection at the firm. Ms. Elgan agreed to an inspection date of 09/20/2021 at 10:00am. Ms. Elgan stated that a negative COVID-19 test would be required if we would be at the firm for more than (b) (4). She stated this test could be administered by the firm's third-party, (b) (4), or a test administered within no greater than 10 days prior to inspection. Upon arriving at the firm on 09/20/2021, I provided Ms. Elgan with documentation of a negative COVID-19 test result, dated 09/18/2021. National Expert Elizabeth P. Mayer took a COVID-19 test at the firm on 09/21/2021.

On 09/20/2021, Elizabeth P. Mayer, National Expert, and I arrived at the firm. We displayed our credentials to TJ Hathaway, Site Director, 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. Hathaway (**Attachment 1**). During the initial meeting, we displayed our credentials to Ms. Elgan, Keenan Gale, Director Quality Assurance, Penny Nichols, Sturgis Site QA Project Leader, and Megan M. Fry, Manager Site Quality Systems.

At the conclusion of the inspection, a 5-point Form FDA 483, Inspectional Observations (**Attachment 2**) was issued to Mr. Hathaway. During the closeout meeting, an amended 483 was also issued to Mr. Hathaway (**Attachment 3**).

Form FDA 484, Receipt for Samples, was issued to Mr. Hathaway at the conclusion of the inspection (**Attachment 4**). Per company policy, Mr. Hathaway did not sign the 484.

This Establishment Inspection Report was written by National Expert Mayer and Investigator Arrecis. Sections written by National Food Expert Mayer are denoted by initials (EPM). Co-written sections are also denoted with Investigator initials.

Per FMD-145, all correspondence should be addressed

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to:

Mr. Keenan Gale, Director Quality Assurance
Abbott Nutrition
901 N. Centerville Road
Sturgis, MI, 49091 (269)651-
0330
keenan.gale@abbott.com

HISTORY

Abbott Nutrition (AN-Sturgis) is located at 901 N. Centerville Road Sturgis, MI 49091. The firm manufactures powder and liquid infant formula products (exempt and non-exempt) and medical food products. This location houses the powder and liquid infant formula operations, powder and liquid medical food operations, human milk fortifier operations (HMF), ^{(b) (4)} laboratories, ambient and temperature-controlled storage, receiving areas (packaging, raw material, bulk), and administrative/management offices.

Abbott Nutrition additional domestic operations include locations in Columbus, OH, Tipp City, OH, Casa Grande, AZ, Altavista, VA, and Fairfield, CA. The firm provided a list of registered domestic and international Abbott locations (**Exhibit 1**).

Abbott Nutrition is a division of Abbott Laboratories. Abbott Nutrition Division (AN Division) headquarters is based in Columbus, OH. Abbott Laboratories World Headquarters is located at 100 Abbott Park Road Abbott Park, IL 60064. Robert Ford is the CEO of Abbott Laboratories.

AN-Sturgis employs approximately ^{(b) (4)} employees, of which ^{(b) (4)} ^{(b) (4)}. The firm's plant hours ^{(b) (4)} ^{(b) (4)}. Office hours are 8:00am to 5:00pm.

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

- 2019 ^{(b) (4)} modification around ^{(b) (4)}, replace ^{(b) (4)} r after filler ^{(b) (4)}
- 2020-Additional ^{(b) (4)} from ^{(b) (4)} the plant, replaced ^{(b) (4)} tanks that service ^{(b) (4)}. and Dryer ^{(b) (4)} replaced Energy Center Boiler Controls, replaced ^{(b) (4)} for Dryer ^{(b) (4)} ^{(b) (4)}, provide better access to hopper valves-Line ^{(b) (4)} filler, replaced bulk ^{(b) (4)} hopper covers for ^{(b) (4)} filler
- 2021-Roof replacement in building ^{(b) (4)} room and ^{(b) (4)} ^{(b) (4)} room

^{(b) (3) (A)} ^{(b) (4)}

There have been no recalls since the last inspection. Recall 83807 initiated prior to the last inspection was closed out on 04/30/2020. See **Recall Procedures** for details.

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

No refusals were encountered.

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INTERSTATE (I.S.) COMMERCE

The firm receives approximately (b) (4) of all its raw materials outside the state of Michigan. Suppliers include (b) (4). The firm ships approximately (b) (4) of its domestic finished product into interstate commerce from the firm location or the Abbott Nutrition Network Warehouse located at (b) (4). The firm's three biggest customers are (b) (4).

The firm provided a Packing List (Identified with (b) (4)) and Bill of Lading (b) (4) (referencing Packing List identified with (b) (4)) documenting the shipment (b) (4) cases of Similac Pro Advance Batch (b) (4) 34oz. PWD from the firm to Atlanta Distribution Center (GA) (**Exhibit 2**).

The firm also exports finished product infant formula worldwide.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Abbott Nutrition manufactures exempt and non-exempt infant formulas, toddler formulas, human milk fortifier (HMF), and medical food products, which are subject to the FD&C Act. These products include powdered infant formulas under the brand names Similac, Calcilo, Phenex, and ProViMin. Liquid products include brand names such as Glucerna and PediaSure.

The firm provided an infant formula product list (**Exhibit 3**), medical foods product list (**Exhibit 4**), and a dry-blend product list (**Exhibit 5**).

Powdered infant formulas are packaged in metal cans (7oz. gratis size, 14.1oz.), composite cans (7oz. gratis size, 19.8oz.), and plastic tubs (20oz., 22oz., 23.2oz., 30oz., 34oz., and 40oz.). Liquid retorted products come on 8oz. cans.

Product is (b) (4), with some product distributed as "gratis" packs.

The firm provided us with a label for Similac Alimentum 12.1oz. for review (**Exhibit 6**). No discrepancies were noted.

Megan M. Fry, Manager Site Quality Systems, provided us with a copy of labels that are new or have been revised since that last inspection (**Exhibits 7 and 8**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Keenan S. Gale, Director of Quality Assurance-Mr. Gale stated he has been with the firm for 14 years. He has been in his current role since August 8, 2021. He stated he is responsible for the firm's quality programs including analytical and microbiological laboratories, compliance, food safety, and sanitation. Additionally, he stated he is responsible for CAPA and quality systems such as manufacturing records, auditing, and document management. The follow personnel report to Mr. Gale: Site QA Project Lead, Sanitation Manager, Manager Site Quality Systems, Analytical Lab Manager, Micro Lab Manager, and CAPA Coordinator. Mr. Gale reports to Lesa Scott-Director of Quality Assurance-Operations North America.

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Susan M Elgan, Global Food Safety Director-Ms. Elgan has been with the firm for 20 years and in her current position since 09/2021. She stated her position involves the food safety program strategy for Abbott Nutrition. She stated a primary function is to standardize when applicable. This includes standardizing networks throughout AN, including regulatory considerations, equipment usage, and food safety. She supports (b) (4) AN locations. She reports to Dana Limpert-Director of Global Food Safety.

Penny R. Nichols, Site QA Project Lead-Ms. Nichols stated she has been with the firm for 15 years. She has been in her current position for 9 months. She is involved with planning for a (b) (4) te. This includes the (b) (4) (b) (4). She reports to Mr. Gale.

TJ Hathaway, Site Director-Since the last inspection, Mr. Hathaway became the Site Director for AN Sturgis. He previously held the position of Manufacturing Manager. Mr. Hathaway stated that he is the most responsible person at this location.

During the inspection, we were accompanied by Mr. Gale, Ms. Fry, Ms. Nichols, and Ms. Elgan, who provided inspectional access, copies of records and reports, and information included in this EIR. The firm arranged for the following individuals to either call-in or accompany us during department/operation-specific inspectional tours and provide information:

- Deanna L. Denton, Analytical/IMI Lab Manager
- (b) (6) Front Line Leader
- (b) (6), Front Line Leader Packaging
- (b) (6) -Operator Tech
- John M. Lucht, Operations Manager-Processing & Drying
 - (b) (6), Business System Analyst
 - (b) (6), Senior Manager Client Services
 - (b) (6) Validation Specialist
 - (b) (6) Senior System Analyst
 - (b) (6), Building Engineer
 - (b) (6) Dryer Coordinator
 - (b) (6), Quality Engineer
- Eric Bower, Energy Center Manager
 - (b) (6) Micro Lab Frontline Leader
 - (b) (6) Principle Process Engineer and Calibration Coordinator
 - (b) (6), Reliability Engineer
 - (b) (6), Reliability Engineer
- Rob Stauffer, Plant Sanitation Manager
 - (b) (6), Interior Front-Line Leader

The firm's CEO is Robert Ford, based at the firm's world headquarters in Abbott Park, IL.

We were provided with a copy of the firm's facility organizational chart (**Exhibit 9**)

FIRM'S TRAINING PROGRAM

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The firm conducts new-hire and recurrent employee training. The firm uses (b) (4) new hire training, (b) (4) formats. Training is plant-wide and job-specific. The firm's document, "Training in Curriculum ANST_Plantwide Requirements", lists plant-wide training, including GMP Work Habits, Line Clearance, Dress Code & Personal Hygiene, Food Defense, Documentation Guidelines, and Safety Trainings. The firm documents and monitors employee training. Review of the firm's document, "Training Process", identifies training needs and establishes competency and training effectiveness requirements. Competency is demonstrated through successful completion of training, which can include assessments, performance, and/or qualification or certification.

Training records for the following individuals were reviewed:

- (b) (6) Front Line Leader

Records from 09/23/2019-09/08/2021 included the following: BLDG (b) (4) start-up, microbial events, GMPs, process production control standards, CAPA, CIP monitoring, and (b) (4) temperature (b) (4) status.

- (b) (6) Senior Process Operator Tech

Records from 09/25/2019-09/18/2021 included the following: food safety and GMPs, ingredient control, extraneous matter, allergens, and production/process control. (b) (6) also participated in a group sanitary glove retraining on 09/22/2021 and a management one-on-one conversation regarding sanitary glove use. See **Objectable Conditions and Management's Response-Observation 3**.

- (b) (6), Operator Tech

Records from 09/25/2019-09/20/2021 included the following: GMPs, powder operations, packaging material control, fill weight, cleaning and sanitation, and Line filling.

The records reviewed indicated that the all three employees have received training for their specific job duties.

MANUFACTURING/DESIGN OPERATIONS

Manufacturing/Design Operations

Production (EPM)

This firm manufactures both exempt and non-exempt infant formulas and medical foods. (b) (4) products are powder; the firm does have (b) (4) for 8 oz. liquid ready-to-use (RTU) products in two-piece metal cans with (b) (4) lids. Non-exempt infant formulas are milk-based and consist of intact proteins; (b) (4), Similac Total Comfort contains partially hydrolyzed milk protein. Several milk protein sources are used including whey protein concentrate (WPC), low calcium WPC, milk protein concentrate, milk protein isolate, whey protein hydrolysate, concentrated skim milk and non-fat dry milk. Exempt formulas and medical foods include intact milk protein, hypoallergenic and amino acid based (elemental/metabolic formulas). (b) (4), Pediasure contains highly refined soy lecithin. A product list for infant formulas and medical foods was provided (**Exhibit 3 & 4**). The firm is Kosher, Halal and organic certified.

This (b) (4) houses liquid and powder manufacturing operations, administrative and management offices, (b) (4) laboratories, ambient and temperature-controlled warehousing, and bulk receiving and storage. Manufacturing consists of wet processing areas, evaporators, heat treatment, and (b) (4) dryers (b) (4) there are (b) (4) powder filling/packaging lines (# (b) (4) (b) (4)). Powder filling lines (b) (4) are for (b) (4) and lines (b) (4) are for (b) (4) dryers (b) (4) were (b) (4). The

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plant is divided into (b) (4) areas based on the potential risk of contamination; (b) (4) areas are (b) (4)

During this inspection, the process flow for Similac Alimentum hypoallergenic powdered infant formula with iron, which the firm referred to as Similac Advance was reviewed; a flow diagram was provided (**Exhibit 10**). The powder (b) (4) system, (b) (4) pasteurizer (b) (4) dryer (b) (4) and powder filling line (b) (4) were covered. The product is filled and packaged in two-piece metal cans (7.0 oz. and 12.1 oz.). The largest batch size for Similac Alimentum (b) (4) of powder.

Raw Material Receiving (EPM)

In Building (b) (4) raw materials are received and stored in the ambient warehouse; there are (b) (4) receiving docks. Both full and LTL loads are received; a trailer inspection is performed. The ingredient is entered in the electronic inventory system, (b) (4) a Pallet Identification Label (PIL) is applied to the pallet with the following information: product name, commodity item number, date received, quantity, internal lot number and vendor lot number. (b) (4) are used to scan pallet labels; (b) (4) through (b) (4) for incoming ingredients and production; (b) (4), (b) (4) is used for finished product distribution. Manual records are also in place.

All ingredients are initially placed on-hold (b) (4); sampling plans and procedures based on ingredient risk and supplier qualification status are outlined (b) (4). Some raw materials do not undergo testing; certificates of analysis are received for all ingredients. Incoming ingredient testing was reviewed for corn maltodextrin and casein hydrolysate, which are ingredients in Similac Alimentum; no deficiencies were noted. Ingredients and finished product, which are out of specification are placed on-hold; larger quantities are flagged in (b) (4) while smaller quantities are stored in a "hold" cage on the (b) (4) of Building (b) (4)

In Building (b) (4) there are (b) (4) coolers (b) (4), (b) (4) -freezer (b) (4) cool room (b) (4) and (b) (4) room (b) (4) for all areas, the temperature (b) (4) monitored; there are no (b) (4) thermometers present. Alarms are in place, but they are not challenged. **Please See Discussion with Management Item #1.** The temperature (b) (4) are calibrated (b) (4) and were previously done as follows: 1/28/21 (freezer) and 5/6/21 (b) (4) coolers, cool room and (b) (4) room). During this inspection, in the (b) (4) cooler, the overhead fan was blowing directly on a (b) (4) of stage two metabolic powder, which was stored on the top storage rack. **Please See Discussion with Management Item #3.** Also, in the cool room, drums of cleaning chemicals were stored adjacent to food items. **Please See Discussion with Management Item #6.**

Labels are stored in a label cage.

Bulk Receiving (EPM)

There is (b) (4) tankers; (b) (4) (b) (4) and (b) (4) (b) (4) are received. Approximately, (b) (4) loads are received (b) (4), (b) (4) At the time of arrival, the presence of seals on the lower and upper ports are verified and compared to the bill of lading; a wash ticket is also received. Samples are pulled and analyzed in-house. Testing records were reviewed for recent loads of (b) (4); no deficiencies were noted. Once analysis is

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completed and the load passes, the tankers are unloaded by employees; bulk chemicals are unloaded by the driver. Tankers are not CIP'd on-site.

There is (b) (4) for condensed skim milk; (b) (4) is present, and it is CIP'd after (b) (4). There are (b) (4) transfer lines: (b) (4) r (b) (4) is present (b) (4) e, which is cleaned every (b) (4). The lines are flushed with (b) (4). There are (b) (4) additional lines for (b) (4) (b) (4); a (b) (4) is not present on these lines and they are CIP'd as necessary. There are (b) (4) transfer lines, (b) (4).

Condensed skim milk and in-process refrigerated infant formula are stored interchangeably in (b) (4) finished product storage tanks, which hold (b) (4) and are (b) (4); they are (b) (4) h (b) (4). There are (b) (4) tanks, which range from (b) (4) and are (b) (4) (b) (4) is also present. Oils are stored at the following temperatures: canola oil (b) (4) (b) (4), coconut oil (b) (4), GMO and non-GMO soy oil (b) (4) MCT oil (b) (4) and high oleic safflower oil (b) (4). There are (b) (4) liquid sugar tanks, which each hold (b) (4) and are at (b) (4) they are (b) (4). The sugar tanks are equipped with a (b) (4) and a (b) (4). The (b) (4) are replaced as needed. The (b) (4) were previously cleaned in (b) (4) and the (b) (4) was changed in (b) (4). There are (b) (4) corn syrup (b) (4) bulk tanks; the (b) (4) (b) (4). The tanks are (b) (4) and (b) (4).

Lots are co-mingled. Temperatures for the bulk tanks are electronically monitored; there are no analog thermometers present. Alarms are in place but are not challenged. **Please See Discussion with Management Item #1.** Calibration records of temperature sensors for tank (b) (4) (safflower oil), (b) (4) (b) (4) sugar tanks, tanks (b) (4) (corn syrup tanks) and tank (b) (4) (condensed skim milk) were reviewed along with the pressure sensor for tank (b) (4) no deficiencies were noted.

Rail Car Receipt (EPM)

In Building (b) (4), there is one receiving area for rail cars; (b) (4) are received. Each rail car holds (b) (4) and they are not temperature-controlled. Approximately, (b) (4) loads are received (b) (4); the rail company e-mails the firm the bill of lading and other paperwork. At the time of arrival, the presence of seals on the (b) (4) and discharge valve are verified and compared to the bill of lading; a wash ticket is also received. Samples are pulled and analyzed (b) (4) Once analysis is completed and the load passes, the cars are unloaded by employees. (b) (4) d transfer lines with (b) (4) (b) (4) are used to pump the oils to the bulk tanks; the line is attached to the belly of the rail car. The (b) (4) is changed (b) (4) The rail company is responsible for bringing in full cars and removing empty cars.

Both bulk tankers and railcars must be food-grade and only transport food items per the firm's written SOP, Ingredient Supplier Expectations.

Ingredient Weighing (EPM)

There are (b) (4) for weighing minor ingredients: Mineral Weigh Room (Building (b) (4) and Weigh Room (Building (b) (4)); the Mineral Weigh Room is for weighing minerals and the Weigh Room is for weighing vitamins and other ingredients. For each batch, a Work Order is generated (b) (4), which

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identifies the required major and minor ingredients and the corresponding weight. Warehouse personnel are responsible for pulling major and minor ingredients for each batch.

(b) (4) is used for weighing ingredients; each Operator has a username and password. At the time of weighing, the Operator selects the first ingredient per the Work Order and the Operator uses (b) (4) to scan the barcode on the Pallet Identification Label (PIL). If the wrong ingredient is scanned, the Operator cannot proceed. Clear plastic bags are used for weighed ingredients; after which, they are stored in a white tub. The tub is cleaned (b) (4) and the plastic bag is single use. The scale and bag are tared, and the ingredient is weighed.

In the Mineral Weigh Room, there are (b) (4) scales (b) (4) with different accuracies, which are calibrated every (b) (4); the previous calibration was done on (b) (4). In the Weigh Room, there are (b) (4) weighing (b) (4) which each have (b) (4) with different accuracies and are calibrated every (b) (4). The (b) (4) scales were previously calibrated on 9/14/21 and 9/7/21, respectively. The scales are directly linked to (b) (4).

The Operator (b) (4) scoops ingredients from the “parent” container into the clear plastic bag. During this inspection, the Operator did not sanitize nor change his gloves after touching non-food contact surfaces; immediately afterwards, he touched food contact surfaces. **Please See FDA 483 Observation #3.** As the ingredient is added to the tub, (b) (4) are measured; a (b) (4) to (b) (4) once the correct amount is weighed and a ticket is printed. If too little ingredient is added, (b) (4) remains (b) (4) too much ingredient is added, (b) (4) in either case, a ticket cannot be printed. Exact weights are required for minor ingredients. The ticket is applied to the container and includes the ingredient name and weight. The ingredient container is also scanned again; (b) (4) automatically deducts the amount used. A new label is not applied to the ingredient container. Once the ingredient is weighed, it is removed from the Work Order (b) (4). Designated scoops are utilized for each ingredient and are washed afterwards.

For the weighing of major ingredients, (b) (4) is also used; the process is similar to the procedure utilized for weighing minor ingredients and includes the scanning of bulk containers to ensure the correct ingredient is used. For metered ingredients, the Operator must manually enter the bulk tank identification number and the amount consumed.

Double verification procedures by the Operator (b) (4) are in place to ensure that ingredients are properly weighed. All ingredients are scanned again prior to addition at the production tanks; (b) (4) alerts the Operator if the wrong ingredient is scanned or if too little or too much ingredient is added. If so, the Operator cannot proceed. All verification procedures are documented on the batch records along with manual signatures. Electronic signatures are also utilized (b) (4).

Wet Processing (EPM)

For Similac Alimentum, the liquid process time is approximately (b) (4). At the start of production, in the Powder Processing (b) (4) Room (b) (4), powdered ingredients for the (b) (4) are scanned. After which, ingredient tubs and (b) (4) bags are (b) (4) via a (b) (4) and (b) (4) are dumped (b) (4) to tank (b) (4), which is

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partially (b) (4). Tank (b) (4) holds (b) (4) and is maintained at (b) (4) (b) (4) and (b) (4) also present. The temperature sensor for tank (b) (4) is calibrated (b) (4) (b) (4) and was previously done on 4/11/21; the (b) (4) is calibrated (b) (4) and was previously conducted on 11/1/21. The (b) (4) is mixed for approximately, (b) (4) and pumped to tank (b) (4). The (b) (4) bypasses tank (b) (4) and is pumped directly to the (b) (4) balance tank.

Tank (b) (4) and is maintained (b) (4) are present. The temperature sensor for tank (b) (4) is calibrated in-house every (b) (4) and was previously done on 4/11/21; the pressure sensor is not calibrated. **Please See FDA 483 Observation #4.** For the (b) (4) bulk oils including (b) (4) are pumped from the bulk tanks and blended in tanks (b) (4). A flow meter is present on the transfer line from the bulk tanks to tanks (b) (4) which is calibrated in-house (b) (4); the previous calibration was performed on 6/26/21. Tanks (b) (4) each hold (b) (4) and are (b) (4); a (b) (4) is also present. The temperature sensors for tanks (b) (4) are calibrated in-house every (b) (4) and were previously done on 9/14/21; the pressure sensors are not calibrated. **Please See FDA 483 Observation #4.** Additional oils, (b) (4) and oil-soluble vitamins are added to the (b) (4) tank, which holds (b) (4) and is equipped with (b) (4). The (b) (4) tank is maintained (b) (4); (b) (4) is present. The pressure sensor is calibrated in-house every (b) (4) and was previously conducted on 8/28/21; the calibration record for the temperature sensor was requested but not provided. From tanks (b) (4) are pumped to tank (b) (4) and with the (b) (4). Once the (b) (4) "complete" it is held (b) (4) before homogenization is started.

From tank (b) (4) the (b) (4) is pumped to the (b) (4) tank, which is the feed tank for the homogenizers. While product is pumped from the (b) (4) tank to the homogenizers, (b) (4) are added (b) (4) are (b) (4) added and mixed in the (b) (4) tank, which holds (b) (4) and is maintained (b) (4). The (b) (4) tank has a (b) (4) (b) (4) and (b) (4). The temperature sensor and (b) (4) for the (b) (4) tank are calibrated (b) (4) every (b) (4) and were previously done on 7/10/21 and 8/20/21, respectively.

The product is pumped to the homogenizers; product (b) (4) and then through (b) (4). All (b) (4) have (b) (4) is a (b) (4) stage (b) (4) and (b) (4) are (b) (4). After homogenization, the product is (b) (4), which use (b) (4) are not monitored. A (b) (4) "test" is performed (b) (4) to ensure there are no (b) (4) ks present in the (b) (4) and was previously done on 7/21/21.

After cooling, the product is pumped to the refrigerated finished product tanks (b) (4) and (b) (4). The (b) (4) tanks each hold (b) (4) and the (b) (4) tanks each hold (b) (4). The tanks are (b) (4) and are maintained (b) (4) the set-point (b) (4). The temperature is (b) (4) monitored; graphs are printed and reviewed (b) (4) and the entire report is printed for each batch record. The tanks alarm (b) (4) they are not challenged. **Please See Discussion with Management Item #1.** If a tank alarms, management is notified immediately, and maintenance is contacted. If the temperature is above (b) (4) a Plant Information Report (PIR) is completed. We discussed with management that one written SOP be developed to outline the handling of alarms and

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temperature excursions for the bulk ingredient tanks and finished product tanks; currently, this information is captured in two different SOPs.

The temperature sensors for the (b) (4) finished product tanks are calibrated in-house every (b) (4), respectively. (b) (4) temperature points are measured: (b) (4).
Please See Discussion with Management Item #1. The pressure sensors are calibrated in-house every (b) (4). Calibration dates vary for each tank.

Additions consisting of nutrients (minerals, water-soluble vitamins and amino acids) and (b) (4) are added to the standardization tank, (b) (4), which (b) (4) is equipped with (b) (4). The temperature sensor for the (b) (4) tank is calibrated in-house every (b) (4) and was previously conducted on 8/18/21. The pressure sensor is not calibrated as weight in this tank is not considered critical and instead, the finished product tank weight is relied upon. From the (b) (4) tank, the nutrient (b) (4) are added to the refrigerated finished product tank. At the finished product tank, samples are pulled; analysis includes (b) (4) nutrients, ratios (fat, protein and (b) (4) and homogenizer efficiency. (b) (4) is adjusted as necessary with (b) (4). (b) (4) is also performed as necessary. (b) (4) to release to the (b) (4) pasteurizer, (b) (4) and vitamin C level are verified again. Product is typically (b) (4), (b) (4) is monitored every (b) (4) per the firm's written SOP, FP Tank Hold Time Monitoring (**Exhibit 11**).

During this inspection, documents regarding the storage of in-process infant formula in the refrigerated finished product tanks were provided as justification for holding product (b) (4) and included: interoffice memorandum, "Tank Temperature Monitoring Study-(b) (4)" dated 5/4/20 and the Abbott wide assessment titled, "Potential Impact of Temperature Excursions Exceeding (b) (4) on the Growth of Pathogenic Bacteria during Refrigerated Storage of Infant Formula" dated 6/25/19 (**Exhibit 12**). The interoffice memorandum further supports the 6/25/19 study. This memorandum stated that in-process product is not held for more than (b) (4) days at (b) (4) and (b) (4) days at (b) (4). Ms. Deanna Denton, Analytical/IMI Manager stated that these hold times are guidelines and that no maximum hold time is in place; however, she further explained that batches are not scheduled to be held for longer than (b) (4) days and are never held longer than (b) (4) days.

After the refrigerated finished product tanks, the product is pumped to the (b) (4) pasteurizer. The flow through the pasteurizer is as follows:

(b) (4)

For the (b) (4), pressure differentials are not monitored; (b) (4) (b) (4) test is performed to ensure there are (b) (4) present in the (b) (4) (b) (4) are used. The previous test was done on 8/26/21 by an outside service. For Similac Alimentum, the operating temperature range (b) (4).
At the end of the (b) (4) sensors; (b) (4) for the (b) (4) recorder-controller (b) (4) chart) and the other for the digital indicating thermometer. The temperature sensors are calibrated (b) (4) every (b) (4) and were previously done on 9/9/21. Flow through the system is

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initially controlled by the (b) (4) flow meter; however, after start-up, flow through the (b) (4) pasteurizer is controlled by (b) (4), which is a (b) (4) cement pump associated with the (b) (4) dryer. (b) (4) flow meter is also present on the (b) (4) dryer. Readings of (b) (4) are compared, and the Operator (b) (4) as necessary. The (b) (4) flow meter on the pasteurizer is calibrated with the (b) (4).

The (b) (4) on the (b) (4) pasteurizer also (b) (4) valve; the system diverts if the minimum temperature is not achieved, or the flow rate is too fast. Temperature and flow diversions are controlled by the (b) (4) and the PLC, respectively. A (b) (4) is performed (b) (4) to ensure the (b) (4) is functioning properly; a (b) (4) are not done for flow due to the potential of running (b) (4) into the (b) (4) dryer. However, a complete assessment of the pasteurizer (b) (4) is performed (b) (4) in-house and was previously conducted on 9/9/21; it includes conducting a (b) (4).

Temperature and flow rate are continuously charted along with the position of the (b) (4) valve; the temperature of the indicating thermometer is (b) (4) documented nor is the flow rate. **Please See FDA 483 Observation #5.**

From the (b) (4) pasteurizer, product is pumped into (b) (4) dryer (b) (4) via the (b) (4); (b) (4) (b) (4) the product (b) (4) prior to the (b) (4) dryer. The (b) (4) sensor is not calibrated; instead, the firm relies upon the bulk density of the powder and adjusts the flow rate as necessary. **Please See FDA 483 Observation #4.** A (b) (4) is present, which (b) (4) and is changed (b) (4); (b) (4) the point-of-use. A backflow prevention device is also present on the line to ensure that the bulk (b) (4) tank is not potentially contaminated.

(b) (4) Dryer (b) (4) - Please See FDA 483 Observation #1 (EPM)

The firm has (b) (4) dryers for powdered infant formula and medical food production. (b) (4) dryer (b) (4) was installed in (b) (4) and manufactured (b) (4); it has (b) (4) and operates at approximately, (b) (4) a maximum flow rate (b) (4). (b) (4) dryer (b) (4) was manufactured by Abbott and installed in (b) (4); it has (b) (4) Dryer (b) (4) to (b) (4) and is (b) (4) run. Dryer (b) (4) levels and is primarily for specialty products but also runs milk-based items.

(b) (4) y dryer (b) (4) is in Building (b) (4) and consists of a (b) (4) with (b) (4). The dryer is (b) (4) is present. The (b) (4); the (b) (4) pressure. (b) (4) are located at several points in the (b) (4) dryer. An (b) (4) system is a component of the dryer and was recently replaced due to a crack. (b) (4) introduced into the dryer at start-up and shut-down and after an event.

Product is pumped via the (b) (4) to the (b) (4) dryer; the feed rate is approximately, (b) (4) which is less than the rated capacity. The product flow rate is not controlled by the air exhaust temperature of the dryer. A (b) (4) flow meter is present and the speed of the (b) (4) is (b) (4) changed as necessary; samples for (b) (4) and moisture are pulled (b) (4) and depending on the results, the (b) (4) speed is altered. The (b) (4) flow meter is calibrated in-house (b) (4) and was previously performed on

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11/16/20.

Primary air from the roof enters the dryer (b) (4) and is (b) (4), which are changed (b) (4); after which, the air passes through a dehumidifier. The air is (b) (4) via (b) (4) which were previously changed on 9/9/21. After which, (b) (4) enters the top of the (b) (4) dryer. For the (b) (4) air from the building passes through (b) (4) (b) (4) are changed (b) (4) filters are tested (b) (4) by (b) (4) and changed every (b) (4). (b) (4) with its (b) (4) is utilized for product transport.

At the top of the (b) (4) dryer, there is (b) (4) with a (b) (4); (b) (4) is (b) (4). A (b) (4) is also present. The (b) (4) ure is (b) (4); the (b) (4) is released down (b) (4) (b) (4) the particles. The powder falls onto the (b) (4) and is further (b) (4) the (b) (4) has (b) (4). At the exit of the (b) (4), the powder temperature is (b) (4) the (b) (4), the powder is packaged in (b) (4).

The (b) (4) of the (b) (4). The bottom of (b) (4) is equipped with (b) (4); the (b) (4) do not (b) (4) but if they do, the (b) (4) powder removed. The (b) (4); (b) (4) the (b) (4), which is equipped with a cap.

Operating parameters including dryer inlet air temperature (b) (4) dryer outlet air temperature (b) (4) - (b) (4), dryer (b) (4) pressure, dryer outlet powder temperature and dryer feed flow are (b) (4) captured; graphs are printed for each batch. An Operator's Log is also maintained; parameters including (b) (4) Samples are also obtained throughout the (b) (4) drying process and analyzed for (b) (4), moisture, (b) (4).

(b) (4) Dryer Inspection

An inspection of the (b) (4) dryers to determine the integrity of the interior (i.e., micro-cracks and pitting) is performed (b) (4); for dryer (b) (4) the previous inspection was performed on 8/24-8/25/21 and for dryer (b) (4) the previous inspection was done on 8/30-9/1/21 (**Exhibit 13 & 14**). The inspection procedures for each dryer were also provided (**Exhibits 15 & 16**). Individuals with (b) (4) are (b) (4) and the workers (b) (4). When working in the main chamber, a (b) (4) is used to isolate the (b) (4) and vice versa to prevent potential cross-contamination.

For dryer (b) (4), the main chamber, (b) (4) and (b) (4) were inspected; the following defects were found.

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Main Chamber:

- “small ¼” long crack repaired, upper left door frame corner”
- “small ¼” long crack repaired, upper right door frame corner”
- “small ½” long crack repaired, south east under (b) (4) near (b) (4)
- “pit welded on (b) (4) frame, east side”
- “crack 6” long on South side under (b) (4) at duct outlet”
- “east (b) (4) duct crack 2” long under the (b) (4)”

For dryer (b) (4) the main chamber, (b) (4) exhaust (b) (4) fan and duct to (b) (4), duct up to (b) (4) and (b) (4) the following defects were found.

Main Chamber:

- “southeast side top of head on side wall, small pitting repaired”
- “west side under (b) (4) ” diameter section replacement”
- “mid-lower (b) (4) west side, repaired small pit”
- “middle lower (b) (4) east side, repaired 1/8” crack”

Fluid Bed:

- “cracked braces under screen”

(b) (4)

- “crack on transition to (b) (4) and crack on (b) (4) nozzle repaired”

For both (b) (4) dryers, all defects were repaired (welded and polished); (b) (4) was also performed to prevent future corrosion. The inspection of (b) (4) dryer (b) (4) was more extensive than for (b) (4) dryer (b) (4); we discussed with management that they speak with (b) (4) about conducting a more thorough inspection of dryer (b) (4) in the future. We also suggested that (b) (4) provide photos of the defects before and after repair.

(b) (4) Filling and Blending (EPM)

In the (b) (4) Filling Room, powder (b) (4) from the (b) (4); (b) (4) compressed air (b) (4) are present, which are changed (b) (4) All sifter (b) (4), the powder (b) (4) filler hoppers situated on (b) (4) The powder is filled into approximately, (b) (4) filling process. After which, (b) (4) or filling and packaging.

In the Dry Blending Room, (b) (4) nto the base powder for Similac Alimentum. A list of products, which are dry blended was provided (**Exhibit 5**); ingredients that are dry blended include amino acids, rice starch and flavorings. (b) (4) is utilized, which has one shaft with 12 plows total; there are (b) (4). There are (b) (4) stations (b) (4) the bags are scanned prior to use. The (b) (4) blender runs (b) (4). Both the speed and time are (b) (4) documented on the batch record for each batch. The speed sensor is calibrated (b) (4) (b) (4) and was previously done on 7/20/21; review of the report indicated that the speed was calibrated at the CIP speed (b) (4) and not the operating (b) (4) as is expected per the calibration

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instructions. However, review of the calibration record dated 1/22/21 indicated that the sensor was calibrated at the operating speed. It was discussed with management that the sensor calibration be routinely performed at the operating speed.

The blended powder is released into (b) (4) of the blender. Employees do not enter the blender; (b) (4) powder towards the ports as necessary. Samples are analyzed for viscosity throughout the batch to ensure powder homogeneity. The (b) (4) stored again in Warehouse (b) (4) pending filling and packaging. Blender studies are performed when a new product is launched, after a formulation change or per request to ensure homogeneity. (b) (4) in a minimum blender load and nominal blender loading using (b) (4). This was done to better understand the (b) (4) and therefore, to help (b) (4). Samples were pulled across the batch and analyzed for viscosity; based on the results, there was potentially a small portion of the blends that were out of specification per Health Canada's requirements. The powder was non-commercial and discarded after testing.

The blender parameters for Similac Alimentum were developed in the 1990s and have remained unchanged. For all products, (b) (4).

Line (b) (4) Filling and Packaging (EPM)

At the (b) (4) dump stations, (b) (4) Similac Alimentum are scanned and the powder (b) (4) a (b) (4) sifter; after which, the powder is (b) (4). The (b) (4) verified every (b) (4) (b) (4) using a (b) (4) meter. The product is fed (b) (4) filler on line (b) (4).

Empty cans are de-palletized and visually examined. At the (b) (4) they are (b) (4) (b) (4) there is a (b) (4) at the inlet and discharge end, which is changed every (b) (4) and was previously done on 8/22/21. (b) (4) are (b) (4) dumped into the (b) (4) that (b) (4) (b) (4), which (b) (4) to each can. (b) (4) are in place to ensure that the (b) (4) (b) (4) is (b) (4) and that each (b) (4); both systems are routinely challenged.

The (b) (4) filler has (b) (4), and each (b) (4) hoppers; during (b) (4), approximately, (b) (4) the can is (b) (4) (b) (4) of the can is filled. There is a (b) (4) fill hoppers. Cans that are grossly underweight or overweight are "kicked out" and the powder is reclaimed and run through (b) (4) again. Offline weight checks are done (b) (4) cans are pulled. The offline scale is calibrated (b) (4) in-house and was previously done on 9/10/21. The (b) (4) filler scales are not calibrated instead the offline scale is utilized to standardize the filler scales prior to the start of each batch and after any maintenance; they must be within (b) (4) of each other.

The (b) (4) fill hoppers are (b) (4); the can conveyor from the filler to the seamer also has (b) (4). The cans are (b) (4) with (b) (4) seamer prior to seaming; the seamer (b) (4). Lids are received in a sleeve and fed into the seamer. There are (b) (4) (b) (4) are present on the (b) (4) lines. **Please See**

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FDA 483 Observation #2. The (b) (4) are approximately, (b) (4) from the point of use; the (b) (4) are changed (b) (4).

The cans are seamed; the lid end is applied. A (b) (4) seamer inspection is performed. The cans are conveyed to the video jet coders where redundant codes are applied consisting of the batch number, Julian date and time and expiration date. The cans are labeled; the label scanner reads the barcode on the label to ensure the correct label is used. At (b) (4), the scanner is challenged with an unlabeled can and one with an incorrect barcode. The cans pass through the (b) (4) checkweigher; which is routinely challenged. The checkweigher is calibrated in-house (b) (4) and was previously done on 9/10/21. After which, they are conveyed to the (b) (4) system, which ensures that the (b) (4) is intact; it is challenged at (b) (4). The overcap is applied to the cans and they are cased, palletized and stored in the warehouse pending shipment. A positive release program is in place.

Headspace testing (b) (4) is performed; (b) (4) are pulled at the discharge of the filler (b) (4) (b) (4) and for the (b) (4). (b) (4) are verified at the start of the batch (b) (4) and after an event; (b) (4) cans are pulled from each seamer head. (b) (4) analysis (b) (4) is done (b) (4) and (b) (4); seamed can samples for oxygen testing are also used for (b) (4) testing. (b) (4) testing is performed at (b) (4), every (b) (4), after an event and within (b) (4) of the (b) (4) cans are pulled from each seamer head and a failure is defined as more than (b) (4).

(b) (4) examinations are performed at (b) (4), (b) (4) and after a seamer adjustment; (b) (4) cans are pulled from the seamer. A can seam teardown is performed every (b) (4) and prior to the start of filling if the line has been down for (b) (4) or more. Teardowns are conducted in a well-lit room; a poster of seam defects is also present. Seam Technicians are trained (b) (4). The computer software program, (b) (4) is used, which is password protected; (b) (4) is utilized for the equipment. The thickness gauge and optic piece are calibrated by Abbott Nutrition Division (Columbus, OH) (b) (4) and were previously done on 9/10/21. Critical measurements include seam height, cover hook, body hook, seam thickness, overlap, tightness and pressure ridge. Minimum and maximum specifications are in place, which were provided (b) (4) but Abbott Nutrition Division performs updates. If a value is out of specification, it is highlighted red; the line is stopped and a recheck is conducted on (b) (4) cans per the affected seamer head. Management and maintenance are also notified; actions may include a PIR or CAPA and the isolation of product. Records are (b) (4) lly signed.

Non-Major/Before First Processing Changes (EPM)

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 5**). FDA Form, Reporting Changes in Processing and Formulation for Infant Formulas (Attachment A) was completed for each major submission; the firm also provided documentation for each Before First Processing submission (**Attachments 6 & 7**). There were no additional requests from the IFMFS. No deficiencies were noted.

Record Review (EPM)

During this inspection, the following batch records were reviewed for Similac Alimentum hypoallergenic powdered infant formula with iron:

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-batch (b) (4)
-batch (b) (4)
-batch (b) (4)
-batch (b) (4)
-batch (b) (4)

The batch record consists of a Master Work Order, which outlines all production steps including ingredient weighing, liquid base processing, pasteurization and (b) (4) drying, blending and filling/packaging; a copy of the finished product label and in-process and finished product testing results are also included. There are (b) (4) of record review, which are performed by quality personnel; (b) (4) " and the (b) (4). The manufacturing section must be reviewed (b) (4) (b) (4) and the entire batch record (b) (4) from the completion of filling and packaging; certain records also require a signature.

Per 21 CFR Part 106.6, written procedures are in place, which cover all aspects of manufacture from incoming raw materials to finished product distribution.

Non-Conformance Reports- NCRs (EPM)

Non-Conformance Reports (NCRs) were requested for powdered product and for any finished product, which tested positive for pathogens since the previous inspection in August 2019. There were five NCRs for powdered product:

-#766048 (3/11/21)- potential flange defect
-#769241 (4/6/21)- short fill, empty case
-#769885 (4/12/21)- potential seal integrity issue
-#771581 (4/22/21)- out of specification result for *B. cereus*
-#778975 (6/17/21)- out of specification result for SPC

During this inspection, NCRs #771581 and #778975 were reviewed; a thorough investigation was conducted, and corrective actions were implemented including destruction of the affected batches.

There were two NCRs for finished product, which tested positive for *Cronobacter*:

-#697464 (9/25/19)
-#732675 (6/22/20)

During this inspection, both NCRs were reviewed (**Exhibits 17 and 18**). For NCR #697464, the root cause was determined to be environmental; corrective actions were implemented, and the affected batch was destroyed. For NCR #732675, a thorough investigation was conducted yet the root cause was not determined; however, sanitation, structural, personnel and record-keeping deficiencies were noted. Corrective actions were implemented, and the affected batch was destroyed.

Allergens (EPM)

The firm has control measures in place to minimize the potential carry-over of allergens in products manufactured at the plant; (b) (4). Milk protein is present in several products. The medical food, Pediasure contains (b) (4); the firm does not currently manufacture any infant formulas, which contain soy. Several hypoallergenic and non-allergen

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products are also produced.

In the warehouse, soy protein ingredients are stored in designated areas; milk protein ingredients cannot be stored above or adjacent to ingredients or work-in-progress product, which does not contain milk. The firm's electronic inventory system (b) (4) also identifies the raw material as an allergen. Protein-free, in-process (b) (4) stored in a designated warehouse in Building (b) (4).

Most milk and soy protein ingredients are bulk ingredients and are not dispensed in weigh rooms; full container quantities are used. For hypoallergenic products, dry blended ingredients are weighed in a (b) (4) room. Dedicated areas and equipment are used including powder filling lines (b) (4) and (b) (4), which are for non-allergen and hypoallergenic products only. For shared areas and equipment, master control schedules and product-to-product changeover grids are used to prevent cross-contact and minimize the frequency of sanitation between different allergen runs. Dress code requirements are also in place. Allergen testing including (b) (4) is used to verify cleaning effectiveness.

All ingredient and finished product labels are properly identified with any allergen containing sub-ingredients or ingredients; procedures are in place to ensure the correct label is used. Employees receive annual allergen training. A written SOP, Allergen Control is maintained.

Sanitation (DBA)

The firm's document, "Cleaning and Sanitation" (**Exhibit 19**) provides guidance for AN Sturgis standards for manufacturing locations, warehouse, laboratories and other areas. The document addresses training, self-inspection, cleaning procedures, documentation, monitoring, and includes maximum cleaning intervals for equipment.

The firm employs (b) (4) to supply and maintain cleaning chemicals used throughout the firm. A list of chemicals and specifications was provided (**Exhibit 20**). (b) (4) performs (b) (4) and the firm tests the concentrations. (b) (4) records for 02/21 and 05/21 were reviewed; no discrepancies were noted.

(b) (4) Dryer System (EPM)

The (b) (4) dryer, (b) (4) and (b) (4) are CIP'd at a (b) (4) to control (b) (4) and the microbial load in the product. For some products including Similac Alimentum Advance, a CIP cycle is conducted (b) (4) batches; (b) (4)

A CIP cycle includes (b) (4); only the (b) (4) receives a (b) (4). After the (b) (4), an (b) (4) which allows the Operator to (b) (4) inspect the main (b) (4) and (b) (4) with a (b) (4) via the (b) (4). If product build-up still exists, the area is (b) (4) cleaned, and a second (b) (4) wash is performed. The CIP cycle is (b) (4) " (b) (4). During the CIP cycle, the product (b) (4) the top of the (b) (4) dryer is removed and replaced (b) (4). There are also (b) (4) (b) (4) in the main chamber, (b) (4) and (b) (4) during drying, (b) (4) th (b) (4). The (b) (4) is CIP'd with the dryer; it also has a (b) (4) (b) (4)

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Prior to running a (b) (4) campaign, plant employees and individuals from (b) (4) enter (b) (4) dryer to (b) (4) verify that the equipment is clean and that no deficiencies exist.

Hose connections and the sifter are (b) (4) cleaned. No dry scraping is performed.

Filler Operations (DBA)

Powder packaging lines can run for a maximum (b) (4) with (b) (4) interruption during production. Line are area specific, using either wet wash and sanitize, advanced dry cleaning, extended cleaning and/or protein-free cleaning. Cleaning is recorded on a "Cleaning Work Order Review Summary" which accompanies the manufacturing record. This document indicates whether (b) (4) is required before and/or after cleaning. This document is signed by the individual performing the work and as part of a packaging review and quality systems review.

Line (b) (4) Wet Wash and Line (b) (4) Wet Wash records dated 01/11/2021, 05/02/2021, 07/17-07/18/2021 and 09/08-09/09/2021 were reviewed. See **General Discussion with Management Item #4**.

Master Sanitation (DBA)

The firm has a master sanitation program that covers production areas and locations throughout the firm. Master sanitation is conducted at intervals of (b) (4).

Building (b) (4) Dryer (b) (4) area records were reviewed for the following periods: (b) (4), (b) (4). Areas included are main floor, stairways, mezzanine, cabinets, wall vents, overhead piping and walls. No discrepancies were noted.

Master sanitation also includes the following for the warehouse:

- The dock plates are cleaned (b) (4) and are also maintained via a preventive maintenance program.
- The walls, ceilings and racks are cleaned (b) (4).
- The warehouse floor is cleaned (b) (4) with a floor scrubber; the floor scrubber is cleaned (b) (4).

Zoning and Traffic (DBA)

The facility is divided into hygienic zones: low care, medium care, and high care (**Exhibit 21**). The firm has a (b) (4) policy and gowning is zone specific. The firm uses (b) (4) at all high care areas and high traffic zones. The mats are replaced once they show wear. A (b) (4) representative conducts a (b) (4) test on the mat to indicate suggested replacement. Three of four mats reviewed indicated "past due."

IT Programs/Automatic Equipment (DBA)

The firm's IT program, validation procedures, data preservation, periodic review, and personnel access were covered. The following individuals provided information regarding the firm's IT systems and accessibility: (b) (6), Business System Analyst Operating Technology, (b) (6), Senior System Analyst (b) (6), Senior Manager Client Services and (b) (6), Validation Specialist/System Life Cycle. Systems include (b) (4).

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(b) (4)

The firm conducts routine data backups (b) (4) to the Corporate Data Center (Columbus, OH). All backups are held at (b) (4) (b) (4) which include automatic and scheduled backups. Access to changes must be requested through the firm's (b) (4) Requesting Process. There is a separate Administrator Level and Engineer Level access. Administrator access is separate from the owner of the data.

The firm has a procedure for validating systems. Validations involve control engineers developing screen-sets and associated functionality, testing procedures and approval. These are conducted in-house and can be vendor assisted. The review of AN Sturgis Evaporator (b) (4) was reviewed. No significant issues were identified in the firm's testing review, which included evaporator start-up, MPC controller, evaporator effects and feed, (b) (4) modes and (b) (4) functions. The review concluded that (b) (4) was approved.

Animal Feed/Segregation (DBA)

(b) (4) can be used in animal feed. The firm applies an orange tag to the product (**Exhibit 22**). The product is placed inside a white cart and loaded on a trailer staged at Building (b) (4). The product is then delivered offsite to the Abbott Recycle Center for further processing.

Quality Assurance/Control

Environmental Sampling (EPM)

Environmental sampling is conducted for EB, SPC, *Salmonella* and *Listeria* in low, medium and high care areas; samples include product contact and non-product contact surfaces, air, water, steam and compressed air. Additional environmental sampling may also be performed in response to a water event in the (b) (4) dryer towers.

EB samples are obtained (b) (4) in medium and high care areas of non-product contact surfaces; EB and SPC samples are obtained (b) (4) in low, medium and high care areas of product contact surfaces. If an EB swab of a non-product contact surface in a high care area is positive, isolates are analyzed for *Salmonella* and *Cronobacter*. However, further testing is not done for an EB positive sample of a product contact surface as finished product is analyzed for *Salmonella* and *Cronobacter*. Sampling for *Salmonella* is conducted (b) (4) static non-product contact surfaces are swabbed in low, medium and high care areas. *Listeria* samples are obtained (b) (4) of random non-product contact surfaces in low, medium and high care areas. Samples are obtained (b) (4) from low care sample points and non-production areas; swabbing is also done for SPC in medium care areas that are typically swabbed for EB (b) (4). For product contact and non-product contact surfaces, (b) (4) (b) (4) are utilized, respectively.

Air samples are obtained (b) (4) in medium and high care areas and (b) (4) in low care areas for SPC and EB; open "drop" plates and (b) (4) are used. (b) (4) samples are obtained and tested (b) (4) for SPC and EB; samples are pulled throughout the facility.

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Analysis is done in-house except for *Listeria* samples, which are analyzed (b) (4). Any speciating is performed by the Abbott Nutrition Division Laboratory or by (b) (4). EB and SPC are indicator organisms of sanitation practices; if results are not within specification, the affected department is notified to implement corrective actions followed by resampling. Areas that test positive for *Salmonella* and *Listeria* undergo vector swabbing and cleaning followed by additional swabbing. (b) (4) of monitoring are required after a positive result. Written SOPs are maintained.

Records were reviewed for any positive *Salmonella*, *Listeria* and *Cronobacter* results from January 2019 to August 2021. There were no positive *Salmonella* samples. There were four positive *Listeria* and five positive *Cronobacter* samples in medium and high care areas. Corrective actions were implemented, and all follow-up testing was negative.

Water (EPM)

Water is received from (b) (4) are located (b) (4). (b) (4) were inspected on 7/28/21 and no deficiencies were noted. (b) (4) The inspection for (b) (4) ated 6/4/21 indicated that the (b) (4). The (b) (4) on 9/23/21. **Please See Discussion with Management Item #2.**

From the (b) (4) system, which consists (b) (4) were previously changed on 5/5/16 by an outside service. (b) (4) (b) (4) is also verified (b) (4) and recorded on the (b) (4) log. The (b) (4). (b) (4) tank holds (b) (4).

Water testing is done (b) (4) and at sites in the facility including the drinking fountain. Samples are pulled (b) (4) for SPC and EB, which are analyzed (b) (4); results for 6/1/21-9/21/21 were reviewed and no deficiencies were noted. Testing is also conducted (b) (4) *E. coli* and coliforms by (b) (4) (b) (4) the previous report dated 7/22/21 was reviewed and no deficiencies were noted. Chemical analysis is done (b) (4) by (b) (4); the previous reports dated 6/18/21 and 8/3/21, respectively were reviewed; some results were out of specification. However, a summary is routinely sent to the Michigan Department of Health and the results were normal per that agency's specifications. Radiological testing is performed every (b) (4) by (b) (4); the previous report dated 11/5/19 was reviewed and no deficiencies were noted.

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An in-house program is maintained for backflow prevention units used throughout the facility; they are serviced and changed as needed.

There are (b) (4) cooling towers, which are outside the plant; they are (b) (4). The (b) (4) is used for the (b) (4) system, (b) (4) and (b) (4). (b) (4) is (b) (4) added based on the (b) (4) (b) (4) to the system; (b) (4) checks are performed (b) (4). (b) (4) is utilized for the cooling towers and they are CIP'd (b) (4).

(b) (4) (EPM)

The firm has two (b) (4) (b) (4) which produce (b) (4) they are (b) (4) (b) (4) (b) (4). (b) (4) are provided (b) (4) and include (b) (4) ment (b) (4) and (b) (4) (b) (4) are also received from (b) (4) and include (b) (4) additives are FDA approved; letters of guarantee are on-file.

Pest Control (EPM)

The firm utilizes pest control services from (b) (4); a Technician is on-site (b) (4). On (b) (4) exterior bait stations and exterior pheromone traps are serviced and on (b) (4), interior rodent traps and interior pheromone traps are serviced. Exterior spot spraying for insects is done (b) (4) in the (b) (4); there is no avian program presently. The Technician also reviews any sanitation or structural issues. Pest control service records from June-September 2021 were reviewed. Extensive warehouse beetle activity was noted; Mr. Rob Stauffer, Plant Sanitation Manager stated that activity was more prevalent than usual this summer. No pest activity was observed during this inspection.

Microbiological, Nutrient and Stability Testing (DBA)

The firm conducts microbiological, nutrient, and stability testing. Analysis are completed (b) (4) (b) (4) Abbott Analytical Research Services (ARS) (Columbus, OH) or in-house. The firm uses (b) (4) hold and release finished product, (b) (4) to hold and release ingredients. Product is released once all testing is completed meeting specifications, in accordance with the firm's positive release program. The firm provided a product form for X292 Alimentum Powder (**Exhibit 24**). This form replicates the information requested on FDA Form, Infant Formula Nutrient Reporting Form (Attachment B). Information provided identified testing protocols for each nutrient.

Nutrient Testing

Nutrient testing is performed; samples are pulled in-process and at finished product stages. (b) (4) were reviewed: (b) (4) vitamin (b) (4) (b) (4) Vitamin A/D₃/E/K₁ (b) (4) (material ID (b) (4) and (b) (4) vitamin (b) (4)). Certificates of analysis are provided for each lot. (b) (4) conducts testing (b) (4) premix and (b) (4) tests the (b) (4) e vitamin (b) (4). The indicator nutrients for the (b) (4) are (b) (4) which are tested at the (b) (4) the finished product stage. The indicator nutrients for the (b) (4) vitamin (b) (4) (b) (4) are (b) (4). These are tested in-process, (b) (4) again at finished product. Indicator nutrients are tested (b) (4). Selenium is tested at Eurofins.

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Individually added major minerals include calcium carbonate, potassium chloride, sodium chloride, magnesium chloride, potassium citrate, choline chloride, tricalcium phosphate, ferrous sulfate, potassium iodide and ascorbic acid. Additional individually added ingredients include amino acids, fat, and xanthan gum (b) (4). Amino acids are analyzed (b) (4). Vitamin C is tested at (b) (4). All remaining vitamins and minerals not previously analyzed are tested at the finished product stage per 21 CFR 107.100 panel. Vitamins A,C,E and thiamin (B₁) are tested (b) (4) at finished product stage.

Alimentum in-process lot (b) (4) finished lot (b) (4) and (b) (4) full test certificates of analysis were reviewed. No discrepancies were noted.

Stability Testing

The firm provided a copy of a document packet, which includes the following: a letter dated 11/25/2019 from FDA to Debra K. Rooney, PhD., Associate Director, Regulatory Affairs; firm document "Detailed Outline from the Current to the Proposed Infant Formula Compositing Procedure (b) (4)"; document "Infant Formula Compositing Procedure"; firm document "End of Shelf Life Stability Samples"; and SOP entitled "Commercial U.S. Infant Formula Stability Data Review and Testing Program" (2 versions) (**Exhibit 25**). Included in the letter are remarks that the FDA intends to exercise enforcement discretion for Abbott with respect to the portion of 21CFR 106.91(b)(2) provided conditions are met described in the letter.

The SOP describes the test frequencies and the test frequency level selection of formulas. As an example, Alimentum (b) (4) qualifies for a (b) (4) stability testing frequency (b) (4) Testing Frequency). (b) (4) batches were reviewed with results compared to the label, bill of materials, and (b) (4). Samples were taken at B/M/E of shelf life. No discrepancies were noted.

Microbiological Testing

Ingredients are placed on hold (b) (4). Microbiological sampling is based on ingredient risk and supplier qualification. See **Manufacturing/Design Operations**-Raw Material Receiving subsection.

The firm conducts finished product microbiological testing for *Salmonella*, *E. coli*, *B. cereus*, *Cronobacter* spp. (*E. sakazakii*), EB, and SPC. Since the last inspection, the firm had two NCRs (#697464 & #732675) for finished product which tested positive for *Cronobacter* (**Exhibits 17 & 18**). See **Manufacturing/Design Operations**-Non-Conformance-NCRs subsection.

Supplier Qualification (DBA)

The firm has a supplier qualification, approval and audit program. The programs were discussed with Deanna L. Denton, Analytical/IMI Lab Manager. The firm's document, "Ingredient/Supplier Qualification Process", provides the minimum qualifications for new and existing product ingredients and suppliers. Supplier qualification is designed as a phased project with established roles at the global and AN level, evaluation and testing sequences and reporting. A risk-based approach is applied. The firm uses a separate qualification for premixes, described in the firm's "Premix Qualification and Maintenance Procedure." Premix evaluation is dependent on type of premix (powder/liquid) and the change implemented (i.e. new premix manufacturer/nutrient level change). Evaluations include uniformity and stability evaluations. The firm's SOP "Supplier Qualification and For-Cause Audit Procedure", provides guidance for ingredient/packaging supplier qualification audits or event/quality concern audits. The guidance also provides rating information and acceptance criteria. The SOP, "Supplier Quality Compliance Audits" provides

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the audit types (AN onsite, onsite, self-assessment), site-based audit frequency (third-party, supplier-high, medium, low risk), audit criteria, procedure, reporting, CAPA and certification.

Supplier audit certificates for audits were reviewed:

(b) (4) supplier of (b) (4) -dated 01/23-02/18/2020
(b) (4) supplier of (b) (4) -dated 01/16-04/9/2019

The issuance of an audit certificate demonstrates that the firm is an approved supplier.

Internal GMP/Quality Control Audits (DBA)

The firm conducts internal GMP and quality systems audits. The firm's SOP, "AN-Sturgis Internal Audit Program" provides scope, qualifications, responsibilities, reporting and frequency of audits. This document includes the requirement that the site lead auditor have no direct responsibility for areas or systems audited. Additionally, this document lists the planning procedures and the different quality systems/processes/departments to be audited. (b) (4) cGMP audits are conducted (b) (4) with rotating plant locations. (b) (4) audit is conducted (b) (4) and includes quality systems, sub-quality systems and processes required for infant formula manufacturing, testing and distribution. pNCR #774238 containing results of the (b) (4) cGMP audit (b) (4) was reviewed. Additionally, the (b) (4) audit report dated 12/21/2020 was reviewed. No discrepancies were noted.

MANUFACTURING CODES

The firm utilizes a batch code system. An example batch code, (b) (4), breaks down as follows:

(b) (4)

Location codes for the code vary on the production line: (b) (4)

Example additional coding used by the firm:

(b) (4)

COMPLAINTS

The firm's document "Complaint Management and Investigations" describes the complaint procedures, roles, and responsibilities. (b) (4) is the electronic divisional complaints system used for registering, documenting, and maintaining complaint information and investigations. Consumer Relations collects and

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documents information received from complainants. Division Quality Assurance-Complaint Handling Unit (DQA-CHU) evaluates the complaints, requests investigations, and identifies trends. The firm categorizes complaints, which can include quality issues, extraneous matter, product shortage, Adverse Events (AE) and Serious Adverse Events (SAE). An AE can be any medical occurrence not necessarily caused by the product. An AE can trigger a medical assessment, which are evaluated by the firm's Medical Safety & Surveillance Department (MS&S). An SAE can include death, life threatening, hospitalization, and disability.

Complaints are reviewed for trends. If trends are identified, investigations are initiated, and CAPA projects can be started. Products manufactured at a single plant or multiple plants can be included in trends. Data analyzed can include product/brand family, type of complaint, and specific batch. Investigations can also be initiated if the complaint meet the definition of "high impact" complaints, which includes potential product-related SAE or AE.

During this inspection, complaints relating to infant death, *Salmonella spp.* and *Cronobacter (Enterobacter) sakazakii* since 09/01/2019 to present were covered.

- *Cronobacter (Enterobacter) sakazakii* (1 complaint) 455195: (b) (4) 0-Infant born on (b) (4) used Similac Pro-Sensitive 7.6oz Expiration date 08/01/2020. Infant was diagnosed with *E. sakazakii* and remained in hospital for 10 days. Investigation consisted of evaluating (b) (4) batches, record review, finished product micro testing review, and (b) (4) complaint review. Complaint was reviewed by AN-Medical Team. Batch record review (BRR) including filling records were acceptable, no other complaint reports, and micro testing was negative for *C. sakazakii*. The firm closed the complaint.
- Infant Death (1 complaint) 528006: (b) (6) infant death. Investigation was conducted on 3 lots numbers of Similac Alimentum 7oz. BRR for all three lots were found acceptable. No sign, symptom, or SAE noted with lots. No medical concerns were identified with products. (b) (4) product report indicated no cause of death related to product list number. No complaints on batch. Notes included that death could have been possible (b) (4). Complaint closed by firm.
- *Salmonella* (15 complaints reviewed):
Similac Alimentum-481688 on 11/18/2020, 535823 on 08/25/2021, 350599 on 03/20/2020, 323782 on 11/19/2020
Similac ProAdvance-485768 on 12/08/2020, 538048 on 09/07/2021, 537138 on 09/01/2021
Similac Spit-Up-504933 on 03/15/2021 and 475944
Similac Total Comfort-330995 on 12/30/2019 and 353148 on 04/01/2020
Similac Advance-472005 on 10/05/2020, 359208 on 04/28/2020
Similac Pro Sensitive-369168 on 6/11/2020
Elecare for Infants-531299 on 08/02/2021

These complaints involved infants testing positive for *Salmonella*. Investigations were opened on each complaint. BRR results for all complaints came back acceptable. Finished product microbiological and analytical testing results came back acceptable and negative for *Salmonella*. (b) (4) trend analysis either showed no complaint trend on batch or no *Salmonella* complaints due to intake of product. A finished product sample for 472005 Similac Advance was obtained by the firm. The firm performed a visual exam and sent the sample to the packaging lab for examination. No microbiological analysis was conducted on the sample. Ms. Elgan stated that the testing is based on (b) (4) review and requires VP approval for microbiological testing. The SOP, "Procedure for Handling Complaints" also indicates that "any chemical or microbial testing of an unopened customer sample requires the approval of the AN Vice President Quality or delegate."

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FDA Complaints

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

FACTS ID 169448/PR#532905: On 08/10/2021, a complaint was received reporting a foreign object, described as black, hard, and approximately 1cm in diameter inside a 12.1oz. can of Similac Alimentum powder infant formula (15416Z260). The firm opened an investigation and found no adverse findings or medical concerns. The firm reviewed testing for can and tailings foreign objects and scorched particles. None were found. No non-routine interventions were conducted. Except for a possible duplicate complaint, there were no other similar complaints. Complaint is closed

FACTS ID 167840/PR#511174: On 04/12/2021, a complaint was received regarding a labeling change that included an ingredient change (corn maltodextrin and sugar) in 2-23.2 oz. plastic tubs of Similac A2 Organic Infant Formula powder infant formula (14155SH00). The complainant bought containers with a white label and one with a gray label. The complainant was concerned the product with the gray label contained sugar and corn syrup. The complainant was concerned that there was no way to tell the products apart. The firm investigated and determined that the product is not manufactured with corn syrup, but with corn maltodextrin. At the time of manufacture, there were no reformulation labels at the firm, as the reformulation occurred after the products in question were manufactured.

FACTS ID 166665/PR#495197: On 01/25/2021, a complaint was received reporting that a (b) (4) old began projectile vomiting after consuming a 2.13lb can of Similac ProAdvance infant formula powder (23430SH00). The firm conducted an investigation that included acceptable BRR review and finished product analytical/microbiological testing. FDA received a sample of the product on 02/08/2021. Lab results indicated <100 B. cereus, <3.0 MPN, and no staphylococcal enterotoxin detected. The firm determined no medical concerns were identified with the product. No complaint trend on batch. No medical concern was identified with the product.

FACTS ID 162735/PR#369480: On 06/12/2020, a complaint was received reporting a foreign object, described as a long dime-sized black chunk inside a 12oz. can of Similac Sensitive powder infant formula (15325K800). Upon receiving a sample and the foreign object, the firm conducted an investigation. The firm confirmed the object to be (b) (4). The investigation reported acceptable results for BRR, analytical/microbiological testing, no complaint trend on the batch, and supported no further action. No root cause was determined, no CAPA was initiated.

FACTS ID 164402/PR#466240: On 09/08/2020, a complaint was received reporting a foreign object, described as a large clump of dried powder formula in a 12.1oz. can of Similac Alimentum powdered infant formula (11774Z2260). The firm investigation reported acceptable results for BRR and analytical/microbiological testing.

FACTS ID 163496/PR#456045: On 07/27/2020, a complaint was received reporting a foreign object, described as a dark, wet clump resembling phlegm/mucus in a 12.1oz can of Similac Alimentum powdered infant formula (08280Z260). A product sample was received and examined by the firm. The firm evaluated the clump by sifting and (b) (4). It was determined that the product may have been exposed to excessive moisture. The firm found acceptable results with the BRR, analytical/microbiological testing, and viscosity/color/bulk density testing. No complaint trend on the batch.

FACTS ID 158942/PR#530709: On 09/26/2019, a complaint was received indicating an infant became ill after consuming Similac ProAdvance powdered infant formula packaged in a 23.2oz. plastic tub. Infant was hospitalized with colon/intestine infection. The firm's investigation indicated that Dryer (b) (4) had a SPC microbial event. The batch and the previous batch both tested acceptable and were released. The firm's review of the BRR and environmental results for the dryer, filler, and packaging were all acceptable. No

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complaint trend was identified.

FACTS ID 170111/PR#539602: On 09/16/2021, a complaint was received reporting a foreign object, described as a clump of plastic or glue in a 2.13lb plastic tub of Similac ProSensitive. The complainant stated that infant threw up the entire bottle of formula. The firm opened an investigation including a BRR. The investigation was still open at the closeout of the inspection. During the review of the complaint, no BRR concerns were identified. The firm found no complaint trend on the product batch.

RECALL PROCEDURES

The firm has a written recall plan and conducts annual mock recalls. The firm's document, "AN Product Action Procedure" (**Exhibit 26**) establishes roles, responsibilities, and the following procedures: product action procedures; communication to customers, healthcare providers, and the public; effectiveness plan; and product disposition.

The last mock recall was conducted on 10/07/2020. It was classified as effective, which included final contact with regulatory agencies, final reconciliation of product, and product disposition.

During the last inspection, the firm was involved in a product recall for Calcilo XD Lot 79696K80. The firm provided documentation that the recall has been terminated. Review of OSAR (EVENT ID 83807) also indicated the recall was terminated on 04/30/2020.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

Specifically, on 09/20/2021 and 09/21/2021, in Building (b) (4) Dryer (b) (4), standing water was observed in the following locations: under and adjacent to the (b) (4) air handling unit, outside the (b) (4) door associated with the Dry Blending Room and in the clean-out-of-place (COP) area. On 09/23/2021, in the same room, standing water was observed on the floor below the (b) (4).

On 09/23/2021, a forklift was observed moving ingredient pallets from the liquid processing mineral storage location to the Building (b) (4) Dryer (b) (4) location. The forklift was numbered (b) (4) and displayed a sign reading "Liquid Processing Room Only". Additionally, wooden pallets with ingredients for the liquid processing operation were stored in the same area. Finally, a box fan with a sign reading "Liquid Line" was observed blowing in the direction of the (b) (4) cabinet in Building (b) (4) Dryer (b) (4). This fan was observed with extensive debris and dust-like build up.

(b) (4)

Supporting Evidence and Relevance:

On 09/20/2021, during the walk-through of Building (b) (4) Dryer (b) (4), we observed standing water under and adjacent to the (b) (4) air handling unit. At the time of this observation, the area was not blocked off to prevent access by personnel. Standing water was also observed outside the (b) (4) door associated with the

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On 09/23/2021, during a walk-through of Building (b) (4) Dryer (b) (4) standing water was observed on the floor below the (b) (4) (Exhibit 32-Photographs RIMG0014 & RIMG0015). The firm's document "ST-1000.24 SOP Cleaning and Sanitation" (Exhibit 19), describes in Appendix 1 Standards Applicable to All Areas, Including Utility Areas (page 9 of 15), "Floors are clean and in good repair....No dust, debris or stagnate water".

On 09/23/2021, a box fan with a sign reading "Liquid Line" was observed blowing in the direction of the (b) (4) cabinet in Building (b) (4) Dryer (b) (4). Extensive debris and dust-like build-up was observed (**Exhibit 34-Photographs RIMG0011 & RIMG0012**).

The facility map “Site Layout 2nd Floor” (**Exhibit 35- second page**) shows that Building (b) (4) is an (b) (4), (b) (4) between any storage areas and (b) (4) Dryer (b) (4) or the associated (b) (4). The firm’s document “Zone Definitions” (**Exhibit 21**) provides definitions for each zone. The firm identifies Building (b) (4) zone. The (b) (4) (b) (4) is defined as “(b) (4) prior to (b) (4) treatment, (b) (4) (b) (4) r (b) (4).” The document further notes that (b) (4) is located (b) (4) Areas, then a (b) (4) (b) (4) should be visible.” No visible areas of separation were observed.

During the inspection, we discussed with management the concerns of standing water in Building (b) (4) Dryer room, including how long the water was standing before it was noticed and concerns with personnel and

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equipment traffic in this area. Further discussion included the standing water observed located by the (b) (4) and the observed insulation installed on the pipes behind the (b) (4) air handling unit.

During the closeout meeting, Lesa Scott, Director of Quality Assurance-Operations North America, stated that the firm will work so the firm does not have standing water and will also review the firm's other sites. She stated the firm will respond within 15 days. **(DBA)**

Observation Correction Status: Not Corrected

OBSERVATION 2

You did not install a (b) (4) capable of (b) (4) when (b) (4) is used at a product filling machine.

Specifically, on Filler Lines (b) (4), the finished product is (b) (4). On Filler Line (b) (4) (b) (4) is used at the following locations: filler (b) (4), seamer (b) (4), and seamer. On Filler Line (b) (4) (b) (4) is used at the following locations: (b) (4) ls and seamer/(b) (4).

(b) (4)

Supporting Evidence and Relevance:

On powder filling lines (b) (4) the finished powder is (b) (4) at the filling machine, as the open cans are conveyed to the seamer (b) (4) and at the seamer prior to seaming. On the (b) (4) lines, a (b) (4) is utilized **(Exhibit 36)**.

Discussion with Management:

We discussed with management that the (b) (4) (b) (4) required. Mr. Gale stated that the other powder filling lines (b) (4) use (b) (4) (b) (4) and that lines (b) (4) are the oldest. He further explained that the firm has already implemented a plan to change the current (b) (4) to meet the required size. **(EPM)**

Observation Correction Status: Not Corrected

OBSERVATION 3

Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

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Specifically, on 09/20/2021, in the Mineral Weigh Room, the Processing Operator did not sanitize nor change his gloves after touching non-food contact surfaces; immediately afterwards, he touched food contact surfaces including the inside of the potassium chloride ingredient bag and a clear plastic bag used to store weighed ingredient.

In addition, the Operator's exposed wrists, between the glove and smock cuff, were observed entering the inside of the potassium chloride ingredient bag when scooping ingredients.

Reference: 21 CFR 106.10(b)(2)

Supporting Evidence and Relevance:

The deficiencies noted were observed by FDA investigators during the walk-through of the Mineral Weigh Room during the weighing of (b) (4) Potassium Chloride Lot (b) (4). This ingredient was used in Lot SP (b) (4). Management stated that this lot is Alimentum Advance base powder.

The Mineral Room Senior Process Operator Tech (b) (4) (referred to as Processing Operator in the FDA 483) was observed wearing gloves while performing mineral weighing operations. The firm's document, "Dress Code and Personal Hygiene" (**Exhibit 37**), describes procedures/requirements for handwashing, sanitizers, and using sanitary gloves. This document also refers to the firm's document, "ANPPR13-001 Global Gowning Standard" (**Exhibit 38**), which describes glove procedures including when to wear, how to wear (over clean, dried, sanitized hands) and that the gloves must be long enough to cover hand areas up to the wrists. Touching non-food contact surfaces and then immediately touching food contact surfaces without changing or sanitizing gloves can present a food safety hazard.

Additionally, review of NCR #732675, dated 06/22/2020, indicated that a finished product batch of Similac for Spit-Up NonGMO Powder tested positive for *Cronobacter* (**Exhibit 18**). One of the probable causes documented was "poor GMP habits-operators touching hoist, then proceeding to open (b) (4) without sanitized gloved hand." This event underscores the importance of handwashing, glove sanitizing, glove changing and GMP practices.

On 09/22/2021, the firm provided Sanitary Glove group retraining, which included the Senior Process Operator Tech (b) (4) (referred to as Processing Operator in the FDA 483) observed in the Mineral Room (**Exhibit 39**). Management also stated that a one-on-one session was provided to the employee.

Discussion with Management:

We discussed with management the concerns involving touching non-food contact surfaces and then touching food contact surfaces without changing or sanitizing gloves, and how this may present a contamination or cross-contact hazard. Management stated they take the concern seriously and will respond within 15 days. (DBA)

Observation Correction Status: Not Corrected

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OBSERVATION 4

An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

Specifically, your firm does not calibrate the following system components:

- The flow sensor for the (b) (4) system located on the product line between the (b) (4) pasteurizer and (b) (4) Dryer (b) (4)
- The pressure sensor for Tank (b) (4)
- The pressure sensors for Tanks (b) (4)
- The flow meters for the bulk oil silos into Tank (b) (4)

Reference: 21 CFR 106.30(d)

Supporting Evidence and Relevance:

For the manufacture of infant formulas, the above systems are critical to ensure that ingredient and/or (b) (4) additions are accurate per the product formulation and therefore, nutrient levels required in the finished product are achieved. In addition, the final weights of tanks (b) (4) are considered crucial as they (b) (4) documented in the batch record. As such, pressure sensors and flow meters associated with these systems must be routinely calibrated to ensure their accuracy.

Review of batch records indicated that the flow rate for the (b) (4) system is identified as (b) (4) and must be verified (b) (4) ch; calibration of the flow sensor is critical to ensure its accuracy and that the specified flow rate is achieved.

Discussion with Management:

We discussed with management that the plant has a calibration program in place and that these critical systems must be included. Routine calibration ensures that these sensors and instruments are accurate and functioning as designed.

Mr. Gale and Ms. Elgan stated that corrections will be implemented. (EPM)

Observation Correction Status: Not Corrected

OBSERVATION 5

You did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control.

Specifically, review of Master Work Order 01-0X290-MWO (Alimentum Dryer) for the product Alimentum Advance (packaging dates 04/21/2021, 04/25/2021, 06/18/2021, 07/14/2021 and 07/17/2021) did not document the indicating thermometer temperature for the (b) (4) Temperature is identified as a critical control point (CCP).

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Reference: 21 CFR 106.30(e)(5)

Supporting Evidence and Relevance:

During review of the above batch records, it was determined that the temperature for the indicating thermometer (TID) for the (b) (4) pasteurizer was not (b) (4) documented yet process temperature is identified as a CCP per the firm's Master Work Order. Currently, the temperature is only captured per the temperature recording device (TRD); a (b) (4) r chart is used.

The TID is the "official" thermometer to confirm that process temperature is achieved; as such, the TID is not adjusted between calibrations. The TID is comparted to the TRD to ensure that the TRD does not read higher than the TID. If so, adjustments to the TRD are made as it is not the "official" thermometer. Currently, the firm is performing a (b) (4) and the TID and TRD are comparted yet temperature readings are not manually documented.

Discussion with Management:

We discussed with management that temperature readings of the TID and TRD must be (b) (4) documented at a minimum (b) (4) to verify that the process temperature is achieved per the Master Work Order and that the TRD does not read higher than the TID; if necessary, adjustments are made. This also ensures that the Operator is actively monitoring the system.

In addition, we discussed with management that the flow rate also be (b) (4) documented at a minimum (b) (4) y to ensure that flow parameters are achieved; currently, the flow rate is captured solely via the (b) (4) chart.

Mr. Gale and Ms. Elgan stated that corrections will be implemented. (EPM)

Observation Correction Status: Not Corrected

Mr. Hathaway was provided with the following email to respond to the observations listed in this report: orahafeast6firmresponses@fda.hhs.gov.

ADDITIONAL OBSERVATIONS

Observations not listed on form FDA 483

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REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

On 09/24/2021, a closeout meeting was held with management. Ms. Elgan provided a list of attendees (**Exhibit 40**). A 4-point Form FDA, Inspectional Observations was issued to TJ Hathaway, Site Director. A 483 Amendment 1 was also issued. See **Objectionable Conditions and Management's Response**. During the meeting, the following items were discussed with management:

- For the temperature-controlled storage areas, ingredient bulk tanks and finished product tanks, temperatures are electronically monitored; alarms are in place, but they not challenged to ensure they are functioning properly. We discussed with management that these alarms should be routinely challenged to verify their accuracy and a record maintained. We further explained the importance of challenging the alarms for the finished product tanks since they have identified alarm set-points (b) (4) and that product must be maintained (b) (4)

In addition, for the finished product tanks, the temperature sensor is calibrated at (b) (4) -points (b) (4) we discussed with management that the sensor also be calibrated at a (b) (4) closer to the alarm set-points (b) (4). (EPM)

- (b) (4) is equipped with a backflow prevention unit (b) (4) which is inspected (b) (4) in-house. The inspection dated 6/4/21 indicated that the relief valve did not open and therefore, the (b) (4) not pass the inspection. The (b) (4) during this time. On 9/22/21, during record review, we discussed with Mr. Eric Bower, Energy Center Manager that the relief valve had failed inspection; he stated that he would explore this issue further. The (b) (4) was repaired by (b) (4) on 9/23/21.

We questioned Mr. Bower as to why (b) (4) was not repaired sooner and that repairs were only implemented after we pointed out the deficiency; in response, Mr. Bower stated that (b) (4) was very busy this summer. We further explained that the (b) (4) device was not functioning properly; therefore, the potential existed to contaminate (b) (4). Mr. Bower stated that the design of the (b) (4) would (b) (4) and this (b) (4).

We discussed with management that if (b) (4) does not pass inspection, immediate corrections should be implemented or (b) (4) off-line until it is repaired. (EPM)

- In the South cooler, the overhead fan was blowing directly on a (b) (4) of stage two metabolic powder, which was stored on the top storage rack. We discussed with management that ingredients or in-process product should not be stored adjacent to the fans to minimize the potential for microbial, chemical or physical contamination. During this inspection, the (b) (4)

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was moved and slots (b) (4) and (b) (4) were disabled for use (b) (4) (Exhibit 41—firm taken photographs). (EPM)

- Review of both the Line (b) (4) Room Wet Wash and the Line (b) (4) Filler Wet Wash records dated 07/17-07/18/2021 indicated that a Pre-Clean EMP was required for both. The entry for the EMP was not signed off by the operator. Two areas of the “Review after Clean” were signed. This included a signature for the Packaging Review, which indicates that “work order has been reviewed for compliance and completeness,” and a signature for Quality Systems Review, which indicates “this completed work order has been reviewed and found to be acceptable.” We discussed the importance of accurate sanitation monitoring and record-keeping. Management responded that the firm will investigate by 09/24/2021. (DBA)
- During the walk-through, a screen in the ceiling directly above the (b) (4) Dryer (b) (4) in Building (b) (4) was observed with trapped dust-like debris. Management identified this as an exhaust fan pushing air out of the tower. Management stated that the fan screen is on an (b) (4) sanitation frequency. Mr. Hathaway stated that the firm will determine an appropriate sanitation frequency by conducting a study. This would start within 15 days. (DBA)
- In the Cool Room/Flavor Room, (b) (4) drums of (b) (4) Sanitizer Lot (b) (4) (b) (4) were stored next to (b) (4) premises, vitamin D₃, E, & K₁ in (b) (4). The practice of segregating chemicals from food ingredients was discussed. The sanitizer drums were moved from the Cool Room/Flavor Room to the (b) (4) Room, where no food items are stored (Exhibit 42—Firm taken photograph). (DBA)

ADDITIONAL INFORMATION

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 sampling assignment, were collected from the firm by FDA Investigators Danny Tuntevski and Micmarie Ramos:

1033049-60 cans Similac Pro-Advance 34oz. Lot 32669SH0 1358 228 USE BY 1SEP2023 SIMESPWD for microbial analysis

1033050-12 cans Similac Pro-Advance 34oz. Lot 32669SH0 1358 228 USE BY 1SEP2023 SIMESPWD for nutrient analysis

1033051-60 cans of ProViMin 5.3oz. Lot 31393K0 1050 USE/BY 1 MAY2022 196 PROVIM for microbial analysis

1033052-12 cans of ProViMin 5.3oz. Lot 31393K0 1050 USE/BY 1 MAY2022 196 PROVIM for nutrient analysis

The firm provided interstate documentation (Exhibits 2 & 43) and certificates of analysis for both Lot

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32669SH0 (**Exhibit 44**) and Lot 31393K800 (**Exhibit 45**).

Form FDA 484, Receipt for Samples, was issued to Mr. Hathaway at the conclusion of the inspection. Per company policy, he did not sign the form.

VOLUNTARY CORRECTIONS

The following correction to the observation from the previous FDA inspection dated 09/16-09/19/2021 was noted:

Observation 1-You did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards.

Correction Verified: The firm provided pNCR #699517 (**Exhibit 46**), indicating Action Plan #703976 (page 9 of 18). This plan includes the corrective action of increasing the number of collected containers from (b) (4) to (b) (4). Also documented, are changes to affected documents, including "Global Microbiological Standards", and associated Manufacturing Operations and Quality Assurance personnel training. The firm provided the document "Global Microbiological Standards", Effective-by date: 27-Apr-2020 (**Exhibit 47**). Page 28 of 45 of this document indicates (b) (4) samples for *Salmonella* testing will be collected (b) (4). This change is in agreement with the 21 CFR 106.55(e) sample table. Additionally, during this inspection, at the packaging stage of Similac Alimentum Lot (b) (4), stickers were applied to cans indicating the sample number. Stickers were observed on cans (b) (4) and on a sticker sheet for remaining sample numbers continuing (b) (4).

The following corrections to the discussion items from the previous FDA inspection dated 09/16-09/19/2021 were noted:

Discussion Item 1-On 09/16/2019, we observed a window screen located (b) (4) of (b) (4) Dryer (b) (4) building with accumulated dust-like debris collected on the exterior of the screen.

Correction Verified: The firm provided pNCR #696498 (**Exhibit 48**), containing an Engineering Study, specialty microbiological testing results and evaluation of HVAC conditions. Based on the Engineering Study, the firm sealed the window louver with a stainless plate. Photographs taken by the firm are included in the pNCR.

Discussion Item 2-On 09/18/2019, we observed that the firm does not obtain water samples for radiological testing from a point in the system in which water is in the same condition as when used in infant formula manufacturing.

Correction Verified: The firm provided pNCR #699517 (**Exhibit 46**), indicating Action Plan #703994 (page 13 of 18) and Action Plan #703694 (page 15 of 18). This plan includes the corrective action of testing of ingredient water at both (b) (4) in the Energy Center. Records reviewed for radiological testing on 11/05/2019 indicated no discrepancies. These test records are cited by the firm as evidence of the implementation of the location change.

EXHIBITS COLLECTED

1(DBA) AN Nutrition Sites, 2 pages
2(DBA) Packing List and Bill of Lading (b) (4) for Similac ProAdvance, 3 pages

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3(DBA) 3. Infant Formula Product List, 2 pages
4(DBA) Medical Food Product List, 1 page
5(DBA) Products with Dry Blend Ingredients, 2 pages
6(DBA) Label Similac Alimentum, 1 page
7(DBA) New Infant Formula Labels, 38 pages
8(DBA) New Medical Foods Labels, 23 pages
9(DBA) Organizational Chart, 1 page
10(DBA) Process Flow-Powder (b) (4) System, 1 page
11(DBA) FP Tank Hold Time Monitoring, 1 page
12(DBA) Interoffice Memorandum, 61 pages
13(DBA) (b) (4) y Dryer (b) (4) Inspection Report, 3 pages
14(DBA) (b) (4) Dryer (b) (4) Inspection Report, 4 pages
15(DBA) Dryer (b) (4) Inspection Procedure, 2 pages
16(DBA) Dryer (b) (4) Inspection Procedure, 2 pages
17(DBA) NCR 697464, 18 pages
18(DBA) NCR 732675, 40 pages
19(DBA) SOP-Cleaning and Sanitation, 15 pages
20(DBA) Sanitation Chemical List, 1 page
21(DBA) Zone Definitions, 2 pages
22(DBA) Animal Food Tag, 1 page
23(DBA) Water Flow for Ingredient and Rinse Water, 2 pages
24(DBA) Firm Issued Attachment B document, 1 page
25(DBA) AN Stability Testing Letter, 29 pages
26(DBA) SOP-Product Action Procedure, 13 pages
27(DBA) Photographs RIM00003 RIM00004, 2 pages
28(DBA) Photograph RIM00007, 1 page
29(DBA) Report for Insulation-(b) (4) 7-28, 1 page
30(DBA) Report for Insulation Repair-Work Order History, 2 pages
31(DBA) Firm Photograph-Installation of Insulation, 1 page
32(DBA) Photographs RIM00014 RIM00015, 2 pages
33(DBA) 33. Photograph RIM00016, 1 page
34(DBA) 34. RIM00011 RIM00012, 2 pages
35(DBA) Facility Map, 2 pages
36(DBA) (b) (4) Lines (b) (4), 1 page
37(DBA) SOP-Dress Code and Person Hygiene, 19 pages
38(DBA) Global Gowning Standard, 19 pages
39(DBA) Sanitary Glove Training and Training Attendee List, 8 pages
40(DBA) Attendee List, 1 page
41(DBA) Firm Photos Location Change Metabolic Base, 4 pages
42(DBA) Firm Photographs-(b) (4) Relocation, 3 pages
43(DBA) Packing List and Bill of Lading-00700740087067475, 2 pages
44(DBA) CoA Similac ProAdvance (b) (4), 3 pages
45(DBA) CoA ProVimin 31393K800, 4 pages
46(DBA) pNCR 699517, 18 pages

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47(DBA) Global Microbiological Standards, 45 pages
48(DBA) pNCR 696498, 39 pages

ATTACHMENTS

1(DBA) FDA 482, Notice of Inspection, issued to TJ Hathaway, Site Director, 3 pages
2(DBA) Issued 483, 4 pages
3(DBA) Amendment 1, 4 pages
4(DBA) FDA 484, Receipt for Samples, issued to TJ Hathaway, Site Director, 2 pages
5(DBA) Plant Report, 22 pages
6(DBA) Attachment A Major Changes, 25 pages
7(DBA) Attachment A Minor Changes - Before First Processing, 28 pages

X Daniel B Arrecis
Investigator
Signed By: Daniel B. Arrecis -S
Date Signed: 10-15-2021 13:09:41

X Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer -S
Date Signed: 10-15-2021 13:33:42
