Establishment Inspection Report	FEI:	**1815692**
Abbott Nutrition	EI Start:	9/16/2019
Sturgis, MI 49091-9302	EI End:	9/24/2019

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SUMMARY

This comprehensive surveillance inspection was conducted as part of the Infant Formula Program and Medical Foods Program-FY19 Schedule of Inspections/Sample Collections under DFPG#19-01, FACTS#1186396, eNSpect ID#127000. This is assignment was conducted pursuant to Compliance Programs 7321.006, Infant Formula Program-Import and Domestic, 7321.002 Medical Foods-Domestic and Import, and 7321.005 Domestic and Import NLEA. Additional guidance was obtained from 21 CFR Part 117-cGMPs, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods-Subparts A,B,D,&F. Abbott Nutrition is located at 901 N. Centerville Road Strugis, MI 49091. The firm manufactures exempt and non-exempt powder and liquid infant formula products, and medical food products.

The previous inspection was conducted on 09/10-09/13/2018 and 09/18/2018 and was classified NAI. No FDA 483, Inspectional Observations was issued.

During this inspection, we observed the firm's [redacted] drying process and filling/packaging for Similac Pro-Sensitive Batch No. [redacted] and the firm's Low-Acid Canned Foods (LACF) liquid 8oz. production of Pediasure Enteral with Fiber, Vanilla Batch No. [redacted] Inspectional coverage included GMPs,

complaints, recalls, training program, quality control procedures, environmental monitoring, product testing programs, calibrations, pest control, and record review.

At the conclusion of the inspection, 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 aggregate meets the required microbiological quality standards.

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

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

- On 09/16/2019, we observed a window screen located on floor of Dryer 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 **General Discussion with Management** for detailed response.

The following samples, requested as part of this inspection and FY19 SCOPE, were collected from the firm's distribution center by FDA Investigators:

-INV1117355 60 12 oz cans of Similac Total Comfort, batch code 0 for micro analysis.

-INV1117356 12 12 oz cans of Similac Total Comfort, batch code (b) (4) for nutrient analysis.

-INV1117357 12 14.1 oz. cans of Propinex 2, batch code for nutrient analysis.

-INV1033030 30 14.1 oz. cans of Propinex 2, batch code 0 for micro analysis.

(b) (3) (A) .

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

No refusals were encountered.

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:	susan.elgan@abbott.com
Dates of inspection:	9/16/2019-9/19/2019, 9/24/2019
Days in the facility:	5
Participants:	**Daniel B Arrecis, Investigator** **Dariusz Galezowski, Investigator**

Non-FDA Participants:

On 09/16/2019, I, Investigator Daniel B. Arrecis and Investigator Dariusz Galezowski presented our credentials and issued Form FDA 482, Notice of Inspection, to TJ Hathaway, Manufacturing, Operations Manager. Mr. Hathaway stated he was the most responsible person at the firm at the time of the inspection. We informed Mr. Hathaway that we would be conducting a comprehensive surveillance inspection of the firm. We issued Form FDA 482a Demand for Records and Form FDA 482b, Request for Information to Mr. Hathaway. Additionally, we presented our credentials to Keenan Gale, Food Safety & Compliance Manager, Susan M. Elgan, Site Quality Assurance Director, and [redacted] Quality Engineer. Ms. Elgan, Mr. Gale, and Mr. Hathaway accompanied us throughout the inspection.

On 09/18/2019, Investigator Theodore N. Sietsema and Investigator Danny Tuntevski issued Form FDA 482 to Mr. Cooper. Investigators Sietsema and Tuntevski visited the firm to collect infant formula and medical foods samples. FDA 484, Receipt for Samples, was given to Mr. Cooper at the conclusion of the inspection. Per company policy, Mr. Cooper did not sign the FDA 484.

This Establishment Inspection Report (EIR) was written by Investigator Daniel B. Arrecis, with contributions from Investigator Dariusz Galezowski.

HISTORY

Abbott Nutrition-Sturgis (AN Sturgis) is located at 901 N. Centerville Road Sturgis, MI 49091. The firm has been at this location since the 1960's. This location houses the liquid and powder manufacturing facilities, administrative and management offices, [redacted] laboratories, ambient and temperature controlled warehousing, and bulk receiving and storage. The firm manufactures exempt and non-exempt powder and liquid infant formula products, and medical food products. Abbott Nutrition Division (AN Division) headquarters is based Columbus, OH. World headquarters is located in Abbott Park, IL.

The firm employs approximately [redacted] employees, [redacted] are full-time. [redacted]. Office hours are 8:00am-5:00pm.

The firm uses an off-site warehouse, [redacted] This warehouse is used for some finished product and packaging storage.

Since the last inspection, the firm has made the following changes to manufacturing operations:
The firm [redacted] during the [redacted] on

8/22-9/6/2019.

The firm reported three formulation changes since the previous inspection. Two of these formulations have label changes. The firm's reformulations include: 1.) Similac Advance Infant Formula with Iron Powder (20cal), 2.) Similac ProAdvance Infant Formula with Iron (20cal), and 3.) Similac Sensitive Non-GMO with Iron Powder (19cal).
"Reporting Changes in Processing and Formulations for Infant Formulas (Compliance Program 7321.006-Attachment A)" were completed (**Attachments 7-9**). We received the formulation information documentation and labels (**Ex.1-3**) from the firm.
The information for "Infant Formula Nutrient Information Reporting Form (Compliance Program 7321.006-Attachement B)" for Similac Pro-Sensitive Non-GMO Powder (19cal) (**Attachment 10**) was completed on a separate form received from the firm (**Ex.4**).

The firm initiated a recall starting on 09/13/2019 for Calcilo XD Batch No. See **Recall Procedures** section regarding this recall.

(b) (3) (A)

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

Susan M. Elgan, Director, Site Quality Assurance
Abbott Nutrition
901 N. Centerville Road
Sturgis, MI 49091
(269)651-0394
susan.elgan@abbott.com

INTERSTATE (I.S.) COMMERCE
The firm receives raw materials from (b) (4). Suppliers include (b) (4) Ms. Elgan provided us with Bill of Lading No. 2922953396 documenting the shipment of pallets of amino acid premix from (b) (4) to the firm (**Ex.5**). The firm ships its domestic finished product into interstate commerce from the firm location and Abbott Nutrition Warehouse .

All product is . The firm also distributes "gratis" packs. The firm exports finished product infant formula .

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
Abbott Nutrition Sturgis (AN Sturgis) manufactures exempt and non-exempt liquid and powdered

infant formulas, and liquid and powdered medical foods, which are subject to the FD&C Act. These products include approximately infant formulas under Abbott brand names such as Similac, Alimentum, Elecare, and Calcilo XD, and also private label products. Additionally, the firm manufactures approximately medical foods under brand names such as Pediasure, Glutarex 2, and Hominex 2. Ms. Elgan provided us with an infant formula product list (**Ex.6**) and medical foods product list (**Ex.7**). Approximately of product manufactured at the firm is infant formula, with medical foods accounting for the remaining
Infant formulas and medical foods are packaged in cans (8oz, 12oz, 1lb, 19.8oz) and tubs (22.5oz, 23.2oz).
Vitamin and mineral premixes used in this facility come from
Mr. Keenan S. Gale, Manager-Food Safety and Compliance, provided us with labels for Similac Pro-Sensitive For Fussiness & Gas due to Lactose Sensitivity Infant Formula (**Ex.8**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
TJ Hathaway, Manufacturing Manager-Mr. Hathaway is responsible for manufacturing and material control operations, implementing manufacturing continuous improvement projects, and cleanliness and sanitation in manufacturing areas.
Susan M. Elgan Director, Site Quality Assurance-Ms. Elgan responsibilities include food safety, food quality, and regulatory compliance. Additionally, she is responsible for batch work order information accuracy, batch release, CAPA program, overall plant personnel practices, and management of laboratories conducting analytical and microbial testing on ingredients, in-process product, and finished product.
Keenan S. Gale Manager, Food Safety Compliance-Mr. Gale leads the development and implementation of SQF components. Mr. Gale also conducts the firm's internal audit.
Patrick A. Cooper, Site Director-Mr. Cooper is the most responsible person at the plant. He is responsible for food safety, quality, regulatory compliance, SQF implementation, crisis management, and employee communication.

During the inspection, we were accompanied by Mr. Hathaway, Ms. Elgan, and Mr. Gale, all of whom provided inspectional access, copies of records and reports, and information contained in this Establishment Inspection Report (EIR). The firm arranged for other individuals to either call in or accompany us during the inspection and provide information in this EIR, including:
(b) (6) , Quality Engineer
Coordinator
Front Line Leader-Dryer
Bob Stuart, Operations Manager-Packaging
Front Line Leader, Packaging
Front Line Leader for 8oz Production
Processing Front Line Leader
Microbiology Front Line Leader
Principal Engineer
Michael P. Collins, Engineering Manager
Validation/Previous Quality System Front Line Leader

(b) (6) Senior Front Leader of Product Packaging
Operator Tech
, Principal Process Engineer-Calibration Coordinator
Deanna L. Denton, Lab Manager
Megan Fry, Quality Systems Manager
Lesa L. Scott, Director Regional QA Operations
Dana A. Limpert, Director Food Safety
Wendy S. Fox, Program Manager, Microbiology

We were provided with a Sturgis Plant organizational chart (**Ex.9**)

FIRM'S TRAINING PROGRAM

The firm's AN-Sturgis Training department oversees the firm's training programs. Ms. Elgan stated the firm uses (b) (4) to track training. In addition, training is conducted (b) (4), (b) (4). Each job title has a job description with associated competencies and educational requirements. New hire employees receive (b) (4) (b) (4). Training topics include allergen control, food safety, GMPs, root cause analysis, laboratory methods, and cleaning/sanitation.

We reviewed the training records for the following individuals:

- (b) (6), Liquid Packaging Sterilizer Operator
- (b) (6), Packaging Tech
- (b) (6), Dryer Operator

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

MANUFACTURING/DESIGN OPERATIONS

Production

AN-Sturgis houses management and administrative offices, production areas, laboratories, and warehousing. The firm uses the following electronic tracking systems: for ingredients and inventory; and for finished product release. There are areas consisting . There are lines and line. During this inspection, we reviewed the process for Similac Pro-Sensitive for Fussiness & Gas Infant Formula with Iron (22.5oz tub), running on dryer and Line In addition, we reviewed the . Filling line was also observed to review can seamer operations.

Batch records document the ingredient and material use; wet processing, refrigerated storage, and drying parameters; packaging, in-process and finished product analytical and microbiological testing. Batch records are signed by operators in each individual section and reviewed.

Raw Material and Bulk Receiving

The firm identifies locations within the plant as "buildings," each with a specific number. Most raw

material is received in Building through any of the receiving docks. ingredients and packaging materials are received in Building and Finished Warehouse The firm has tanks for receiving ingredients such as railcars and tanker trucks. The firm conducts inbound trailer, tanker, and railcar inspections. Upon arrival, ingredients are staged in the receiving area of the warehouse and entered into the firm's . An internal lot number is generated, linking with the supplier lot number. A ticket is applied to each pallet. Ingredients are placed on hold and are categorized by a supplier category: approved, certified, or conditional. The category dictates the extent of testing to release an ingredient. Vitamin and mineral premixes receive full label claim testing, conducted by Product categories and acceptance criteria are found in the firm's SOP AN12-98-001 Material Receiving, Sampling, Testing, and Acceptance (**Ex.10**).

The warehouse has a (b) (4) cooler (set point: freezer (set point: and a (b) (4) room (b) (4) The room" is typically used for (b) (4) The units are monitored and calibrated (b) (4) by the firm. Standards are calibrated by The most recent calibrations occurred as follows: cooler-02/05/2019, freezer-05/03/2019, and " room-05/03/2019.

Labels are stored in a label cage on the floor.

Ingredient Weighing

With the exception of minerals, minor ingredients, such as vitamins are brought over from the warehouse to Building for weighing. There operators and weigh stations. The work order in identifies all of the ingredients and amounts for weighing. The weigh ticket is applied to both the weighed ingredient and the "parent" container. The remaining ingredient remains in the weigh room. Weight history is captured. Minerals are weighed in Building .
Major ingredients are controlled by flow meters and (b) (4) throughout the system, which are routinely calibrated. Weights, amounts, additions, and lot numbers are documented in the production batch records. Major dry ingredients are (b) (4) added.

Wet Processing

The process begins with loaded dry ingredients room, which are mixed with , and tanks. The ingredients approximately The , which includes in a tank for approximately . The tank are added directly tanks, where product blends for approximately and is checked

A the product tank , the product with a then . Product samples . After

(b) (4)

The firm has tanks in building and n building additions and tanks. Product is stored up to but can be extended, testing . Once product tank. products will . Additionally, products pr . For the product reviewed, Simlac Pro-Sensitive, the product has and). , the product), a , a and, to the dryer .
The firm provided a wet-processing process flow (**Ex.11**). Sample locations and criteria are determined by the firm's critical parameters in , which are notated in the batch records.

Finished Product Refrigerated Storage Silos (FP tanks)
The firm has refrigerated silos in building in building can and . The firm uses to store in-process infant formula or condensed skim milk (CSM). Temperatures are maintained no higher than F and are monitored and recorded. tanks. Product is stored up to but can be extended testing. FP tank temperatures in the batch records reviewed did not indicate any temperatures As justification for in-process and finished infant formula held at temperatures above F and not-to-exceed ^{0}F, Ms. Elgan provided us with an Abbott Technical Report, *Effect of Cold Storage Temperature on the Potential Growth of Microorganisms of Public Health Concern in Infant Formula* (**Ex.12**) and a supplement to this assessment dated June 25, 2019 (**Ex.13**).

Dryer and Abbott Design Dryer

The firm uses dryers for powdered infant formula and medical food production. (b) (4) dryer manufactured has and operates at . (b) (4) dryer was manufactured by Abbott and installed in . This dryer and operates are dryer . Dryer (b) (4) is used for specialty products and batch records showed Alimentum powdered infant formula run on this dryer. During this inspection, we focused primarily on dryer . The firm provided a schematic of dryer (**Ex.14**).

Dryer was installed in The dryer dryer were replaced in The dryer system consists Product is delivered, , to the dryer

(b) (4) introduce product . , Principal Process Engineer-Calibration Coordinator, provided dryer component calibration information. The introduces product at It is manufactured calibrated with the last calibration on 06/02/2019. are calibrated A was previously calibrated on 12/29/2019 and 12/13/2019. is calibrated , most recently on 02/24/2019. Dryer and are calibrated , most recently on 08/25/2019. vary by product, but range approximately . Calibration schedule and records for the , dryer were reviewed with no discrepancies noted. are located . The firm monitors and records production parameters using Alarms flash if any parameter is out of specification.

(b) (4) dryer (b) (4) , (b) (4) collected by the (b) (4) . The firm uses a (b) (4) system (b) (4) A (b) (4) along (b) (4) . The (b) (4) g. The firm monitors this as part of (b) (4) activity is regarded as a non-routine intervention and requires and procedures. (b) (4) .

The system employs . .

(b) (4) air enters the from outside into the . Air is ses through (b) (4) . Document ST-1600.08 identifies (b) (4) standard operating procedure and locations for the dryer and other processing systems (**Ex.15**). (b) (4) (b) (4)) conducts the firms (b) (4) certification, (b) (4) , and reporting (**Ex.16**). The report shows (b) (4) of the Dryer (b) (4) bank, which is tested (b) (4) and changed (b) (4) . The last change was September 2018. (b) (4) are changed (b) (4) schedule (**Ex.17**). No discrepancies were noted in these records.

(b) (4) dryer i(b) (4) tests and repairs are conducted(b) (4) . (b) (4), The firm provided us with the (b) (4) Procedure (**Ex.18**), dryer report summaries and work orders (**Ex.19**), and dryer(b) (4) summaries and work orders (**Ex.20**).

The following conditions and repairs are indicated in the reports: **Dryer #4**-1.) Small stress crack on upper right-hand of the main inspection door. No moisture detected. Crack repaired and finished ground. 2.) Small surface pit under the at west side of third floor-line. Pit repaired and finished ground. 3.) Weld stain from from the outside. Stain was removed. **Dryer**

(b) (4) -1.) One repair of the (b) (4) duct. A CIP (b) (4) (b) (4) was cracked about 1" long on the (b) (4) . 2.) On repair was made on the exhaust fan unit on (b) (4) floor. This was on a support brace on the (b) (4) side about 2" long. Crack was only on the outside structure and did not penetrate the wall of the (b) (4) (b) (4) One repair on the on the (b) (4) . This was on the (b) (4) body at the floor line. **Dryer** (b) (4) On the underside of (b) (4) directly under the (b) (4) the dryer, the support brackets were cracked through. (b) (4) braces were welded on both sides of support and stain removed. **Dryer #3**- 1.) One 3" long crack on upper left hand side of the (b) (4) from the inside of the dryer. Crack was repaired and finished ground. 2.) One crack repaired under the (b) (4) on the (b) (4) (b) (4) This had been repaired in the past but metal seemed good during the repair. 3.) One crack on the (b) (4) 2" long. Repair was made inside and out and finish ground. 4.) (b) (4) were cracked on the (b) (4) were repaired and stain removed from inside the dryer. **Dryer** (b) (4) One repair was made on the (b) (4) (b) (4) (b) (4) This the (b) (4) (b) (4) . Crack was less that one inch and was finished ground. **Dryer** (b) (4) no repairs no findings.

Filling and Packaging

After the drying system, the located in Building Building each capable is then packaged into finished product containers). We observed Similac ProSensitive Batch No. USE BY APR 2021 packaged into 22.5 oz plastic tubs on Filler Line and Packaging Line The filling/packaging area is a high-care zone, requiring a gowning changes, gloves, and sanitizer use. Employees were observed meeting high-care practices and gowning requirements.

Containers are depalletized in Building , , and conveyed to the . The filler is manufactured . The containers r to filling. Product is located . A Container weight is t . All containers pass t containers at). Additional testing includes: testing and . The containers are conveyed to the Building hallways for video jet coding of batch number, use by date, and product codes.

Containers are conveyed to Building labeling and secondary packaging. (b) (4) Building . The product proceeds to the labeler. Once applied, the label barcode is scanned. This bar code is generated with the work order. An operator (b) (4) the bar code to the label scanner and (b) (4) (b) (4) . Records of this process are included in the batch records. Samples are pulled (b) (4) . We observed containers obtained for sampling for Similac ProSensitive. The firm's microbiological testing includes for *Salmonella spp*, EB, *Cronobacter*, *S.*

Since 2017, the firm started collecting *Listeria* spp. samples. The firm had a series of 6 positive results in the 8oz. filler area over the dates of 04/30/2019-06/15/2019. We were provided with nonconformance (**Ex.25**), which includes root cause analysis and corrective actions. *Salmonella* spp. and EB are analyzed in-house, *Listeria* spp. is analyzed by (. The firm provided *Listeria* swab results taken at the affected location during this period (**Ex.26**).

Ingredient Water and Additives
Ingredient water is obtained ty water We reviewed bacterial testing from 01/01/2019 to 08/22/2019. No discrepancies were noted. In addition, we reviewed the firm's chemical testing results dated 08/15/2019. No discrepancies were noted.) conducts water testing analysis. All water samples are drawn from used in the manufacture of infant formula. The firm conducts radiological testing on water. The water for this testing is drawn from the See **General Discussion with Management**.
The firm uses the following
The firm provided documentation that these products meet 21 CFR 173.310.

Sanitation
The firm's SOP Document ID: ST-1000.24 Cleaning and Sanitation provides guidance for the plant's master sanitation plan (**Ex.27**). The SOP covers procedures, documentation, training, monitoring, and management oversight requirements for plant cleaning including, non-product contact, product contact, dry clean, and CIP.

Product contact surfaces are cleaned by CIP, COP, and cleaning. equipment is listed in the SOP with maximum production run and maximum interruption during production. CIP circuits are monitored , and visual cleanliness checks.

We reviewed change-over sanitation documented in the aforementioned batch records. We reviewed the Dryer 4 non-product cleaning records from April 2019-September 2019. On 09/16/2019, during the facility walk-through, we observed a window screen located on floor of Dryer with accumulated dust-like debris on the exterior of the screen. The cleaning of this area had not been completed . See **General Discussion with Management** for the firm's response to the cleaning and review of the screen.

The facility is divided into three hygiene zones: low care, medium care, and high care. The firm has a c and gowning is hygiene zone specific. An outside service provide uniform laundering services.

Pest Control
The firm employs) as the the firm's pest control service provider. monitors rodent traps and internal plant traps . We reviewed records from 01/29/2019 to 09/17/2019. utilizes indoor/outdoor rodent traps, light

stations, glue boards, and has a bird deterrent program in place. No discrepancies were noted. No pest activity was observed during this inspection.

Internal Audits
The firm conducts internal audits that cover GMPs and quality control procedures. The firm audits GMPs and quality systems Keenan Gale, Food Safety & Compliance Manager is the internal auditor. The firm's SOP, Document ID: ST-1000.46, provides guidance for audit locations, rotation and schedule, techniques, findings reporting, and the audit certificate. The firm's SOP Document ID: ST-1000.63, AN Sturgis Quality and Food Safety Manual (**Ex.28**) describes the the Compliance Manager as qualified by training and experience to conduct audits and is independent of the functions being audited. We reviewed the audit certificate for the plant GMP and Quality Systems Internal Audit (Closing Meeting date of 06/24/2019). No discrepancies were noted.

IT Programs/Automatic Equipment (Mechanical or Electronic)
Document ID: ST-1600.8 Validation and Change Control (**Ex.29**) describes the scope of policies and procedures for change control and validation. , Senior Infrastructure Analyst, provided information regarding equipment and systems. , Principal Process Engineer, stated that the manufacturer has written procedures to ensure all hardware is routinely inspected and checked and that the hardware that is capable of being calibrated is routinely calibrated. We observed various calibration points and associated documentation throughout the firm's manufacturing system. stated that the manufacturer checks and documents the accuracy of input and output of systems manufacturing infant formula. Document ID: ST-1600.8 describes software change control record-keeping and documentation guidelines. A quality engineer is assigned a particular change control. The firm has file security and record retention procedures for validation files. The firm uses for ingredient inventory and usage, and is used for finished product release. is used for maintenance.) is used to monitor and control manufacturing equipment, such as drying and filling. The laboratory inputs and stores analytical information into the system. The firm has a Master Validation Schedule which is part of AN Division plan.

LACF Operations
This inspection also covered the manufacturing of liquid RTE infant formulas and medical foods. On 09/18/2019, Investigator Galezowski observed the processing of Pediasure Enteral with Fiber, Vanilla. Batch No Product Code: 51806; Exp date: 1 JAN 2021. A FDA LACF Inspection Report (FDA 3511) and a) were completed and attached (**Attachment 11 & 12**).

Field Exam
During this inspection, Investigator Galezowski conducted a field exam for Pediasure Enteral with Fiber, Vanilla. Batch No. Product Code: 51806; Exp date: 1 JAN 2021. No discrepancies were noted.

The firm provided a facility map (**Ex.30**).

MANUFACTURING CODES

The firm utilizes a batch code system. The batch code observed: [redacted]
[redacted])

COMPLAINTS

Abbott Nutrition Division manages and stores records of complaints. Abbott Nutrition Sturgis is informed of any complaints requiring follow-up and investigation. We reviewed the firm's complaint log since the last inspection. We reviewed the following FDA and AN Sturgis complaints:

FACTS ID 157482/AN-280804, 280805, 280806, 280807, 28080810: Complainant (Pediatric Nurse Practitioner) stated that there were 5 babies [redacted] onths that consumed Similac Sensitive Infant Formula 12 oz. PWD 6CT (Batch codes [redacted] and one unidentified batch code.). PNP stated all babies were projectile vomiting.
Response: Batch record review, analytical, and microbiological tests reported as acceptable. Checks for [redacted], and physical condition reported normal. Abbott Medical Reporting conducted a two year review of the product, found no other medical complaint, and a sound safety profile.
FACTS ID 157121/AN-274846: Complainant's [redacted] consumed three different infant formula products: [redacted] 34 oz., Similac Sensitive-88163SH00 2.13lbs & 95139SH00 2.13lbs, and Similac Pro-Advance-no batch code identified 12 4-pack 2oz bottles. She had a seizure and was diagnosed with *Enterobacter sakazakii*. Infant had diagnosis on [redacted] and was in recovery with antibiotics on [redacted] gaining weight.
Response: The firm conducted a 2-year complaint review with no other similar complaints with the [redacted] of Similac Pro-Sensitive products. FDA collected samples on 05/28/2019. The firm reviewed batch records, EB environmental monitoring for food-contact areas, *Cronobacter* for non-food contact areas, with negative result for pathogens. The firm closed the quality review on 05/10/2019 and the medical review on 06/04/2019.
FACTS ID 158215/AN-295571: Complainant stated [redacted] experiencing GI upset after consuming Similac Sensitive - 02542SH00 Powdered Infant Formula 22.5 oz. Complainant stated that the product did not look or smell like infant formula, believed it may have been flour.
Response: The firm received returned samples from Walmart. The firm's spectrometry test confirmed the product was flour. The firm reviewed batch records, quality checks, line and dryer checks, and [redacted] and [redacted] checks, all acceptable. The firm stated that the addition of flour appears to have occurred after the product left Abbott Nutrition control. The firm found no trend for similar complaints and no medical concerns identified. The firm closed the quality review on 08/15/2019 and the medical review on 08/16/2019.

FACTS ID157425/AN-278985: Similac Pro-Sensitive - 01326SH00 and 01413SH00 22.5 oz. Complainant stated they observed live maggots in near empty container.
Response: The firm conducted batch, [redacted] maintenance, filling/packaging, and pest activity record review. The firm responded that there was no activity that would contribute to this complaint. The firm closed the quality review on 05/31/2019.
FACTS ID156876/AN-268755: Similac Total Comfort - 93772K800 7.6 oz. and Similac Total Comfort - no batch code 12 oz. Complainant stated that [redacted] consumed product and tested positive for *Salmonella*.
Response: The firm did not have any other reports of Salmonella for this lot. The firm reviewed batch records, finished product analytical and micro tests, both were negative. The firm conducted a 2-year review of the product, which indicated no serious reports of symptoms (diarrhea, pyrexia). The firm stated no reports in which *Salmonella* confirmed due to intake of product.
FACTS ID 156177/AN-293357: Complainant found what appeared to be red/white worms in Similac Pro-Advance - 904755SH00 12 oz.
Response: Firm conducted an investigation regarding their potentially affected lot and found no issues. The firm did not have any other related complaints documented concerning the investigated.
FACTS ID 155545/AN-228131: Complainant stated [redacted] experienced vomiting and fussiness. Similac Sensitive - [redacted]00 12oz. Mother and pediatrician stated objects in the bottle appeared to be worms.
Response: Firm conducted an investigation regarding their potentially affected Batch [redacted] and found no issues. The firm did not have any other related complaints documented concerning the investigated.
FACTS ID 158078/AN-293230: Complainant reported finding a rusty nail found inside Alimentum Infant Formula - 02460Z201 19.8 oz.
Response: Firm conducted an investigation regarding their potentially affected batch and found no issues. The firm did not have any other related complaints documented concerning the investigated.
FACTS ID 155525/AN-293359: An infant with high temperature and vomiting, diagnosed with *Salmonella*. Similac Sensitive-90457K800 12 oz.
Response: Firm conducted an investigation with retain product microbiological testing and found no issues. The firm did not have any other related complaints documented concerning the investigated.
FACTS ID 155442/AN-293355: [redacted] baby tested positive for Cronobacter. Product used was Similac Pro-Advance Optigro Batch no. [redacted]
Response: Firm conducted an investigation with retain product microbiological testing and found no issues. The firm also conducted microbiological testing on the consumer's opened product with negative results for Cronobacter. No other complaints were documented concerning the investigated lots.

We reviewed the following AN-Sturgis complaints for Calcilo XD Cal w/o VitD-79696K800 375g. This product was recalled on 09/13/2019
AN-290013: Sales representative reported that a customer opened a can of Calcilo and stated it smelled like "sawdust and paint". Reported product is Calcilo XD Cal w/o VitD-79696K800 375g.
Response: The firm's complaint summary stated that there is no trend for similar complaints registered against this batch.
AN-286369: Complainant stated that [redacted] after feeding on Calcilo, received from

(b) (4) experienced constipation, "rock hard stools", upset stomach, and halitosis. One batch of Calcilo XD, , was identified, the other was an unknown batch.
Response: For batch no. the firm's review stated that there is no trend for similar complaints registered against this batch. The unidentified batch was recorded for trending purposes.

We reviewed the following AN-Sturgis complaints:
AN-246395: using Similac Advance-91611SH00 23.2oz. passed away. Cause of death is unknown.
Response: The firm conducted a 2 year complaint review on this product. No other serious reports and no trends for specific signs/symptoms associated with this batch.
AN-228648:- male using Similac Sensitive-82428SH00 34 oz. tested positive for *Salmonella*. Product was sent to firm for examination
Response: The firm received 1 opened container and 1 closed container. Finished product testing was reviewed and was negative for *Salmonella*. The firm did not receive similar complaints from customers on this lot.
AN-278789: Complaint was related to a possible baby being effected by *Salmonella,* Similac Sensitive-86261K800 and 93798K800 12 oz.
Response: Firm conducted an investigation with retain product micro testing regarding their potentially affected lots and found no issues. No other related complaints were documented concerning the investigated lots manufactured by the firm.

RECALL PROCEDURES
The firm has a written recall procedure and conducts mock recalls. The program identifies responsible individuals and recall methods used to withdraw or recall product. The firm also conducts traceback and trace forward audits .
Prior to the start of this inspection, on 09/13/2019, the firm initiated a recall for the following product:
Calcilo XD
Date of Recall: 09/13/2019
Batch: 79696K8
Reason for Recall: Off-color and aroma
Date of manufacture: 07/17/2017
Expiry date: 08/01/2020
The firm has received complaints regarding this product from the United States, Canada, and Malaysia. The complaints pertained to aroma/color issues and medical. The firm conducted an investigation of a product retain and identified a can seam defect. The firm has not conducted any microbiological testing of the retain. The firm did conduct final product testing prior to release of the batch, management stated that no issues were noted. Management stated that they believe the U.S. product is 100% consumed, Malaysia-100% consumed, and Canada-85% consumed. We reviewed complaints 290013 and 286369 for product consumed in the U.S. See **Complaints** for details. Ms. Elgan stated that the firm has been in contact with and providing documents to FDA HAFE VI Recall Coordinator regarding this recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

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.

Specifically, on 09/16/2019, your firm was observed collecting 30 samples of Similac Pro Sensitive Batch No. during packaging on Packaging Line Your firm's document, Document ID: AN06-99-004, Global Microbiological Standards, Effective Date 26-Jun-2019, page 27 of 41, 5.5.6.1, notes sixty samples for Salmonella spp testing will be collected(b) (4) (b) (4) .

Reference: 21 CFR 106.55(c)

Supporting Evidence and Relevance:
21 CFR 106.55 (c) states that a manufacturer of powdered infant formula shall test representative samples of each production aggregate of powdered infant formula at the final production stage, before distribution, to ensure that each production aggregate meets the microbiological in the table of 21 CFR 106.55(e). This table lists 60 as the number of samples required for *Salmonella* spp. testing. 21 CFR 106.3 defines *Representative sample* as a sample that consists of a number of units that are drawn based on rational criteria such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled. The firm was observed collecting 30 samples of Similac Pro Sensitive Batch No. during packaging on Packaging Line . The firm's document, Document ID: AN06-99-004, Global Microbiological Standards (**Ex.21**), Effective Date 26-Jun-2019, page 27 of 41, 5.5.6.1, notes sixty samples for Salmonella spp testing will be collected from 30 containers, 25g from the top of each container, and 25g .

Discussion with Management:
Susan Elgan stated the firm will meet as a team and well reach out to FDA Compliance Department with 15 days of the closeout meeting.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

On 09/24/2019, a closeout meeting was held. Lesa L. Scott, Director Regional QA Operations, Dana A. Limpert, Director Food Safety, and Wendy S. Fox, Program Manager, Microbiology called in to the meeting. Attendees at the firm included: Keenan Gale, Food Safety & Compliance Manager, Susan M. Elgan, Site Quality Assurance Director, TJ Hathaway, Manufacturing Operations Manager, Patrick A. Cooper, Site Director, and AN-Nutrition Sturgis staff members. A 1-point Form FDA 483, Inspectional Observations, was issued to Patrick A. Cooper, Site Director. The following items were discussed with management:

- On 09/16/2019, we observed a window screen located on floor of Dryer building with accumulated dust-like debris collected on the exterior of the screen (**Ex.31-Photograph DSC02397**).

Management Response-The firm conducting a cleaning of the screen on 09/16/2019. During the inspection, we discussed with Ms. Elgan, Mr Hathaway, Mr. Gale, and , Principal Engineer, and Michael P. Collins, Engineering Manager details about the window screen and pressure in the building. Floor was described as having from floors and also . We discussed with possible concerns of contamination from the outside environment entering into dryer processing area. The purpose of the window is to help remove heat from the building. Additionally, the firm will begin an engineering study on 09/25/2019. The engineering study is described in pNCR (**Ex.32**).

- 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.

Management Response-The firm will change the water sample for radiological testing to be obtained from (b) (4), a point where the water is used in the manufacture of infant formula. The firm plans to initiate this change by 12/31/2019.

ADDITIONAL INFORMATION

Nonconformance Reports

During this inspection, we reviewed the firm's nonconformance reports. Since the last inspection, the firm had nonconformance reports. Nonconformance reports contain event details, root cause analysis, corrections, corrective actions, and effectiveness check plans. Nonconformance (**Ex.33**) pertained to *Cronobacter* spp. in finished product testing and nonconformance (**Ex.25**) pertained to *Listeria* spp. EM positive results.

Nonconformance Initiated 08/08/2019

On 08/05/2019, the firm's microbiology lab reported Batch Alimentum Advance Powder 12.1 oz. presumptive positive for *Cronobacter* spp. and subsequently confirmed positive on 08/13/2019. The firm bracketed production batches produced before and after the effected batch. Batch was placed on IM (in material review) status, a status reserved for product destruction. The firm identified the root cause due to a non-routine intervention. The firm identified corrective actions and listed implementation checks. In addition, the firm plans, as a planned correction, to destroy Batch . The implementation date for destruction is 10/15/2019. The firm provided a list

of license plates, which includes the number of cases, for this batch in IM status (**Ex.34**). Additionally, the firm provided EM/*Cronobacter* spp. results of the area of concern after the nonconformance was initiated (**Ex.35**). EM results show two fail results, but with two pass results on *Cronobacter* spp. testing follow up.

Nonconformance # Initiated 06/26/2019
Listeria testing conducted on 04/30/2019 in the 8oz. filler room yielded "suspect" results. The firm identified the root cause as an issue with with the filler can track area, allowing for spillage and seepage. The firm created a corrective action which involves equipment redesign and a cleaning job aid/work order to address a more detailed cleaning of the area. The firm plans to complete the redesign by 04/15/2020. The firm provided *Listeria* swab results taken during this period.

Infant Formula Submissions
The firm reported three formulation changes since the previous inspection. Two of these formulations have label changes. The firm's reformulations include:
1.) **ABBOTT Tracking** (b) (4) (No **IFTRACK** number)-- Similac Sensitive Non-GMO with Iron Powder (19cal)
2.) **IFTRACK** (b) (4) - Similac ProAdvance Infant Formula with Iron (20cal)
3.) **IFTRACK** (b) (4) - Similac Advance Infant Formula with Iron Powder (20cal)

The following **IFTRACK** #'s have not yet been produced by the firm: (b) (4) .

The following product submissions were withdrawn:
1.) IFTRACK (b) (4) refiled under IFTRACK (b) (4)
2.) IFTRACK 3 refiled under IFTRACK

Export formula:
1.) IFTRACK -export product-no information available

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

SAMPLES COLLECTED
The following samples, requested as part of this inspection and FY19 SCOPE, were collected from the firm's distribution center by FDA Investigators Theodore N. Sietsema and Danny Tuntevski:
-INV1117355 60 12 oz cans of Similac Total Comfort, batch code for micro analysis.
-INV1117356 12 12 oz cans of Similac Total Comfort, batch code for nutrient analysis.
-INV1117357 12 14.1 oz. cans of Propinex 2, batch code for nutrient analysis.
-INV1033030 30 14.1 oz. cans of Propinex 2, batch code for micro analysis.
FDA 484, Receipt for Samples, was given to Mr. Cooper at the conclusion of the inspection. Per company policy, Mr. Cooper did not sign the FDA 484.

VOLUNTARY CORRECTIONS
The firm initiated a recall starting on 09/13/2019 for Calcilo XD Batch No. . See **Recall Procedures** section regarding this recall.

EXHIBITS COLLECTED
1(DBA) Abbott Attachment A Simliac Advance, 1 page
2(DBA) Abbott Attachment A Similac ProAdvance, 2 pages
3(DBA) Abbott Attachment A Similac Sensitive, 3 pages
4(DBA) Abbott Attachment B Document, 1 page
5(DBA) Bill of Lading , 3 pages
6(DBA) AN-Sturgis Infant Formula Product List, 2 pages
7(DBA) AN-Sturgis Medical Foods Product List, 1 page
8(DBA) Abbott Similac Pro-Sensitive Label, 1 page
9(DBA) AN-Sturgis Organizational Chart, 1 page
10(DBA) AN-Sturgis Material Receiving SOP, 11 pages
11(DBA) Liquid Blend Process Flow, 1 page
12(DBA) Abbott Technical Report, 27 pages
13(DBA) Abbott Technical Report, 30 pages
14(DBA) Dryer Schematic, 2 pages
15(DBA) AN-Sturgis , 3 pages
16(DBA) Quality Air (b) (4) Report, 14 pages
17(DBA) AN-Sturgis (b) (4) , 2 pages
18(DBA) (b) (4) Procedure, 2 pages
19(DBA) Dryer Report, 10 pages
20(DBA) Dryer Report, 7 pages
21(DBA) Global Microbiological Standards, 41 pages
22(DBA) Abbott Microbiological Test Methods for Salmonella and Cronobacter, 20 pages
23(DBA) AN-Sturgis Environmental Monitoring SOP, 4 pages
24(DBA) AN-Sturgis EM for Qualified Building, Facilities, and Utilities, 35 pages
25(DBA) NCR , 14 pages
26(DBA) EM Listeria Results, 4 pages
27(DBA) Sanitation SOP, 15 pages
28(DBA) AN-Sturgis Quality and Food Safety Manual, 19 pages
29(DBA) Validation and Change Control, 12 pages
30(DBA) AN-Sturgis Facility Map, 2 pages
31(DBA) Photograph Drye Floor Window screen, 1 page
32(DBA) pNCR , 6 pages
33(DBA) NCR , 22 pages
34(DBA) Alimentum License Plates, 2 pages
35(DBA) EM for Finished Product Area, 1 page

ATTACHMENTS

1(DBA) Issued 483, 2 pages
2(DBA) FDA 482 Notice of Inspection issued to TJ Hathaway, Manufacturing Operations Manager, 3 pages
3(DBA) FDA 482, Notice of Inspection, issued to Patrick Cooper, Site Director, 3 pages
4(DBA) FDA 482a, Demand for Records, issued to TJ Hathaway, Manufacturing Operations Manager, 1 page
5(DBA) FDA 482b, Request for Information, issued to TJ Hathaway, Manufacturing Operations Manager, 1 page
6(DBA) FDA 484, Receipt for Samples, issued to Patrick A. Cooper, Site Director., 1 page
7(DBA) Attachment A-1 Similac Advance, 3 pages
8(DBA) Attachment A-2 Similac ProAdvance, 3 pages
9(DBA) Attachment A-3 Similac Sensitive, 3 pages
10(DBA) Attachment B Similac Pro Sensitive Non-GMO Powder, 4 pages
11(DBA) FDA 3511, 15 pages
12(DBA) [redacted], 14 pages

X Daniel B Arrecis
Investigator
Signed By: Daniel B. Arrecis -S
Date Signed: 10-07-2019 16:56:37

X Dariusz Galezowski
Investigator
Signed By: Dariusz Galezowski -S
Date Signed: 10-07-2019 17:01:47