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SUMMARY

Inspection	
Operation ID and Name	277194: Follow up for CC 184391

Summary Data	
This is a summary of findings report.	
Inspection Basis	Consumer Complaint

Summary

This was a directed inspection at Abbott Laboratories, doing business as (dba) Abbott Nutrition, in Sturgis, MI in order to follow-up on a consumer complaint. Abbott Laboratories dba Abbott Nutrition is under injunction (Case No. 1:22-cv-441) and will hereinafter be referred to as "Abbott Nutrition," "ANS," or "the firm." Abbott Nutrition is a manufacturer of powdered and liquid infant formula, toddler formulas, human milk fortifier, and medical food products, including exempt, powdered, and liquid infant formulas. eNSpect Operation ID #277194 was assigned to this inspection.

This inspection was conducted in accordance with Compliance Programs:

- 7321.006 Infant Formula Program – Import and Domestic,
- 7321.002 Medical Foods Program – Import and Domestic, and
- 7303.040U Preventive Controls and Sanitary Human Foods Operations.

The previous inspection was conducted by the Food and Drug Administration (FDA) on 10/02/23-10/18/23, was classified No Action Indicated (NAI), and did not result in the issuance of an FDA 483, Inspectional Observations. The following item was discussed with the firm at the conclusion of the inspection:

- For the items requiring correction and completion from (b) (4) Audit Report dated 01/09-20/2023, you did not ensure your Auditor reviewed the corrective actions and reported those corrections to FDA within twenty days.

The current inspection also did not result in issuing an FDA 483, Inspectional Observations. One discussion item was discussed with the firm at the conclusion of the inspection. Employees performing the (b) (4) testing at the third party-manufacturer did so reportedly wearing street clothes and without hair restraints as listed in Abbott's Dress Code and Personal Hygiene (ST1000.08). Also, the use of sanitizer (b) (4) for sanitizing gloved hands when contacting surfaces other than overcaps, was reportedly not employed by the third-party manufacturer.

ANS management took the observations under advisement.

Summary
The current inspection covered the following products: Similac Total Comfort (powder), Elecare Jr (powder), Similac Sensitive (powder), and Pediasure (liquid). There have been no recalls since the previous inspection. No refusals were encountered. No samples were collected during this inspection. FDA consumer complaints #183753 (Pediasure enteral formula), #184391(Similac Total Comfort), #and #184750 (Elecare Jr.) were covered during this inspection.

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
03040U	PCHF FOLLOW-UP INSPECTIONS
21002	MEDICAL FOODS - IMPORT AND DOMESTIC
21006	INFANT FORMULA SURVEY

Summary of Past Observations	
CFR Number:	**Citation Text:**
n/a	Deviation from the procedural requirements of a decree of injunction.
Corrective Actions:	The firm had (b) (4) perform their verification for the outstanding observations as outlined in the discussion item. The firm provided their response via email which includes the corrections made (which are also included in the EIR), and (b) (4) report with their verification of Abbott's corrections.
Correction Status:	(b) (4)

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 106.10(b)(1)	Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wear clean outer garments.	No Firm Response Submitted

Correction Statuses current at time report was signed.

Inspection Complaints	
Complaint Number(s)	183753; 184391; 184750

ADMINISTRATIVE DATA

Administrative Data	
Firm	Abbott Laboratories
Physical Address	
Address Line 1	901 N Centerville Rd
City / State / ZIP	Sturgis, MI 49091-9302
Phone	269-651-0600
Fax	269-651-0959
Mailing Address	
Address Line 1	901 N Centerville Rd
City / State / ZIP	Sturgis, MI 49091-9302
Email Address	jeffrey.rasmussen@abbott.com
Website	www.abbott.com
Inspection Date(s)	11/21/2023, 11/22/2023, 11/29/2023, 11/30/2023, 12/1/2023, 12/5/2023, 12/6/2023, 12/7/2023, 12/8/2023, 12/13/2023, 12/14/2023, 12/15/2023, 12/19/2023

FDA Inspection Participants
Participant Name and Title
David Amy, Investigator
Danny Tuntevski, Investigator

FDA Team Members Not Present for the Whole Inspection
Investigator Danny Tuntevski was present at the firm on the following days: 11/29/2023, 11/30/2023, 12/4/2023, 12/5/2023, 12/6/2023, 12/7/2023, 12/8/2023, 12/13/2023, 12/14/2023, 12/15/2023, and 12/19/2023.

Issued 482 Forms	
On the date(s) below, credentials were presented and a "Form FDA 482, Notice of Inspection" (attached) was issued to the person listed.	
Date Issued	**Issued To**
11/21/2023	Erik B. Thompson, Site Controller
11/29/2023	Jeffrey G. Rasmussen, Site Director

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Jeffrey G. Rasmussen, Site Director
Person's Name and Title	David W. Van Daele, Director of Quality Assurance
Person's Name and Title	Keenan S. Gale, Sturgis Consent Decree Quality Assurance Director

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Anne Durcan, Food Safety Manager
Person's Name and Title	Erik B. Thompson, Site Controller
Person's Name and Title	Penny Nichols, Food Safety and Compliance Manager

Additional FDA Forms Issued		
Other		
Issued to	Eriik B. Thompson, Site Controller	
Other Form Number		Copy of Consent Decree
Issued to	Jeffrey G. Thompson, Site Director	
Additional Information	The FDA 482, Notice of Inspections (**Att. 1 & 4**), that were issued were modified to include the following language, "Notice of inspection is hereby given under the Authority of Injunction No: 1:22-cv-441 against the firm and pursuant section 704**" as required in the Investigations Operations Manual (IOM). Portions of 5.2.2.3 - Follow-Up Inspections by Court Order were read to Mr. Thompson and Mr. Rasmussen as outlined in that section. Copies of the Consent Decree (**Att. 2 & 3**) were provided to Mr. Thompson and Rasmussen.	

FMD 145 Recipient	
Person's Name and Title	Jeffrey G. Rasmussen, Site Director
Email Address	jeffrey.rasmussen@abbott.com
Mailing Address	The same as the firm's mailing address.
Phone Number	847-849-9077

Industry Portal Representative	
Person's Name and Title	Jeffrey Rasmussen, Site Director
Email Address	jeffrey.rasmussen@abbott.com

HISTORY

Food Firm Registration Status	Current
Other Registrations	(b) (3) (A) [redacted] .
Hours of Operation	Production hours (b) (4) [redacted] . Office hours are week days from 8:00 AM-4:00 PM.
Additional Information	Per Field Management Directives (FMD) 145, all future correspondence

	to the firm should be sent to: Jeffrey G. Rasmussen, Site Director 901 N. Centerville Road Sturgis, MI 49091 Phone: 847-849-9077 Email: jeffrey.rasmussen@abbott.com Correspondence with Abbott Laboratories Nutrition Division Office should be sent to: Joseph Manning, Executive Vice President, Nutritional Products 100 Abbott Park Road, AP06C Abbott Park, IL 60064 Email: joe.manning@abbott.com Correspondence with Abbott Laboratories Corporate Office should be sent to: Robert B. Ford, CEO and Chairman of the Board 100 Abbott Park Road Abbott Park, IL 60064 Email: robert.ford@abbott.com This report was written by Investigators Tuntevski (DT) and Amy (DMA).

INTERSTATE (I.S.) COMMERCE

Firm engages in interstate commerce	Yes		
Incoming	Yes	**Outgoing**	Yes
Description of Interstate Commerce	No changes to the amount of raw materials and finish products that the firm distributes into and receives via interstate. As a major infant formula producer, infant formula and toddler products made at the Sturgis, MI location are distributed globally. ANS used (b) (4) for the rework of Similac Total Comfort batch (b) (4). Bill of lading (BOL) packets (**Ex.1-3**) depicting the travel of batch (b) (4) on 07/17/2023, 07/18/2023, and 07/19/2023 from the Sturgis facility to (b) (4) were provided by the firm.		

	A label of Similac Total Comfort powdered infant formula was also collected (**Ex. 4-6**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Jeffrey G. Rasmussen, Site Director
Roles and Authorities	Mr. Rasmussen oversees and leads operations at the Sturgis, MI site. He has been in his current role at the site since approximately August 2022. Prior to this position, he was the Site Director at the Tipp City, OH location. Mr. Rasmussen reports directly to Mr. Oliver McBrearty, Divisional Vice President Nutrition Manufacturing, and has (b) (4) direct reports. Mr. Rasmussen identified himself as the most responsible individual on site.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, FMD 145 Recipient, Accompanied During the Inspection
Email Address	jeffrey.rasmussen@abbott.com
Mailing Address	The same as the firm's mailing address.
Phone Number	847-849-9077
Person #2	
Person's Name and Title	David W. Van Daele, Director of Quality Assurance
Roles and Authorities	Mr. Van Daele was present for a large part of the inspection. He directs and coordinates the quality assurance activities and functions for the Sturgis, MI site. During the inspection he was observed directing QA staff to gather information and documentation. He previously was the Director of Quality at the Columbus, OH site for approximately two years. He reports directly to Mr. Christian Lee, Director of Quality Assurance Operations North America. Mr. Van Daele has (b) (4) direct reports.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #3	
Person's Name and Title	Keenan S. Gale, Sturgis Consent Decree Quality Assurance Director
Roles and Authorities	This is a new role for Mr. Gale as detailed in the October 2023 EIR. Mr. Gale was present for most of the inspection, where he facilitated information requests. He has held various positions in the quality department over the course of his career at the Sturgis facility. Mr. Gale reports to Fiona Mullins, Divisional Vice President of Quality, and has (b) (4) direct reports in this new position.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection

Person #4	
Person's Name and Title	Anne Durcan, Food Safety Manager
Roles and Authorities	Ms. Durcan was present during most of the inspection where she assisted in providing information on production batches. She has been in this new role since mid September 2023. Ms. Durcan transferred from the Abbott Nutrition's Ireland manufacturing facility where she was employed for 16 years prior. She reports to David M. Van Daele, Quality Assurance Director, and has (b) (4) direct reports.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #5	
Person's Name and Title	Erik B. Thompson, Site Controller
Roles and Authorities	Mr. Thompson, Site Controller, was only present for the issuance of the initial FDA 482, Notice of Inspection, on 11/21/2023. Has has been in this current position since 2018 and have been with Abbott since 2007.
The following are applicable to this person	FDA Credentials Displayed to This Person
Person #6	
Person's Name and Title	Penny Nichols, Food Safety and Compliance Manager
Roles and Authorities	Ms. Nichols was present during the first week of the inspection. She manages and maintains the effectiveness of the quality system at the firm. Ms. Nichols has (b)(6),(b)(7) direct report and she reports directly to Mr. Gale.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection

MANUFACTURING/DESIGN OPERATIONS

Other Areas Covered
pNCR #892633
DT & DMA The large investigation into the bubble leak test failure with the sanitary can seam ends on Filling Line (b) (4), which occurred on 04/04/2023, is captured in potential non-conformances (pNCR) pNCR #892633 (**Ex. 7**). Initially the event was captured in quality assessment (QA) QA #886311 (**Ex. 8**). PNCR #892633 was initiated on 05/01/2023 as an elevation of seriousness around the event. PNCRs are used when a product was going to be impacted by an event(s). NCRs are used when a product recall is needed. The pNCR contains a statement in the executive summary that states, “defect of thin sealing

Other Areas Covered

compound was causing filled cans to leak powder in production." We verified with the ANS management team that this did not occur. The statement is taken from PMAP Q-044 (**Ex. 52**), where large seam defects do usually result in a leaky can. (b) (4) ANS management promised a revision to pNCR #892633 to clarify the leaking can statement; however, an updated version was not available prior to the closeout of the inspection. Mr. Van Daele informed us that QA #886311 contains the accurate details of the incident as it occurred.

On 04/04/2023, during the filling of Similac Sensitive Early Shield, batch (b) (4), sealed containers of powdered infant formula undergoing routine testing on the production floor, failed two consecutive bubble leak tests. Per ANS policy (**Ex. 9**) the Filling Line was stopped for an investigation.

Composite cans (b) (4) travel (b) (4) Filling Line (b) (4) with the ultra-seal end of the can, which is the foil peeled off by the consumer, at the bottom. Once cans are (b) (4) of the can, is crimped onto the package as it travels over a (b) (4). The sanitary ends contain (b) (4) that fills the void between the double seams applied by the (b) (4). ANS operators perform various tests to check the application of the sanitary can seam ends and the overall sealing of the cans. These (b) (4) tests are recorded in each batch record.

At 06:00 am on 04/04/2023, cans tested for bubble leaks failed for the second consecutive time and the Filling Line was stopped (**Ex. 8 Att. 1**). The bubble leak test is performed on the production floor by ANS Operators. Operators (b) (4) from the production line. Cans (b) (4), (b) (4). At that point, the line pulling the vacuum is inspected for any signs of little bubbles being pulled from the can (**Ex. 8 Att. 1**). If the can was properly sealed and the test administered correctly, there would not be signs of bubbles on the vacuum line.

Employees on the manufacturing floor determined the issue to be the sanitary can seam ends. There was a noticeably thinner amount of the paste compound present in (b) (4) can seam end. This was captured in "Photos of Thin Compound on (b) (4) (b) (4), lot (b) (4) (**Ex. 7 Att. 1**). At 2:34 PM of the same day, ANS management made the decision to restart Filling Line (b) with a new lot of sanitary can seam ends. They also increased the frequency of bubble leak testing to be performed every (b) (4). No other bubble leak test failures were reported. Lot (b) (4) of sanitary can seam ends were isolated (**Ex. 8 Att. 2**) to prevent further use.

The lot numbers used at the Abbott Sturgis location are specific to this location. Lot numbers are assigned according to the receipt date of the material. It is possible for the same lot of a vendor commodity to have different Abbott lot numbers due to being received on different days. Mr. Van Daele stated that this approach allowed the firm to have an additional layer of granularity to the inventory of their materials.

Other Areas Covered

Management provided a trace of lot (b) (4) report from the firm's inventory system, showing the status of the reject batch of sanitary can seam end (**Ex. 10**). ANS performed a commodity search for batches that were filled with lot (b) (4) of the sanitary can seam ends with the Abbott commodity number (b) (4). These (b) (4) batches were placed on hold and are known as the (b) (4) ".

Abbott's investigation into the bubble failures began with attempting to recreate the failure. According to Mr. Van Daele, the firm could not recreate the issue with the same lot, (b) (4) of the sanitary can seam ends. Abbott Sturgis reached out to Abbott's Supplier Control group at Division office about the initial observation of the minor thinning of the sealing compound. This group mentioned that they were investigating a potential issue at Abbott's Casa Grande, AZ facility with sanitary can seam ends. The Casa Grande facility was transitioning to new size of sanitary ends (b) (4) and encountering issues when sealing cans. One of the theories being investigated around this issue was that the sanitary can seam ends packaged (b) (4) were not performing as well as sanitary can seam ends in (b) (4).

Sanitary can seam ends are supplied (b) (4) A (b) (4) lot is produced (b) (4) of machines. The sanitary can seam ends are packaged (b) (4) with (b) (4) machine. The (b) (4) that the (b) (4) packages sanitary can seam ends in (b) (4). The differentiation of the (b) (4) is only (b) (4) (b) (4) of (b) (4) and not by ANS.

Deviation #887123

DT

All remaining lots of sanitary can seam ends in ANS inventory contained comingled (b) (4). The thin compound appeared to be only found (b) (4) of sanitary can seam ends received from (b) (4); However, all lots of these seam ends contain (b) (4) and (b) (4). (b) (4) does not assign separate lot numbers to sanitary can seam ends made on different lanes. ANS also does not assign a different lot number to the different (b) (4) of the sanitary can seam ends as they are considered the same lot by the supplier.

On 04/07/2023, ANS management initiated Deviation #887123 (**Ex. 11**) in order to resume production on Filling Line (b) (4) The solution developed by Abbott Management was for pallets of sanitary can seam ends to be brought to the staging area. There they would be cut open and staff (b) (4) sort out the (b) (4). The (b) (4) of sanitary can seam ends would continue to Filling Line (b) (4) to be used in production. The (b) (4) of sanitary can seam ends are placed onto a nearby pallet to be wrapped and removed from the facility. They are moved to a trailer outside of the facility, where they are currently held. Deviation #887123 also called for the bubble leak tests to be conducted (b) (4) for a total of (b) (4) cans. Mr. Van Daele explained that the decision to not use the sanitary can seam ends

Other Areas Covered

packaged in the (b) (4) wasn't based on concrete evidence that they were defective, but out of abundance of caution. The goal of the deviation was to allow production to continue without having to place additional lots of powdered infant formula on hold. The deviation allowed ANS to continue to package powdered infant formulas on Filling Line (b) while the sanitary can seam ends issue could be further investigated.

Abbott management stated that the primary barrier on the cans was the double seam. The seaming compound is additional layer of protection for shipping per the firm (**Ex. 9**). The firm also provided a chart showing the effects of altitude on a can seam (**Ex. 12**). A lack of sufficient seaming compound between the two seams could cause a "micro leak". With a micro leak, the firm expects that nitrogen in the can would escape the saturated powder and head space. The escape of the nitrogen would cause the oxidation of the powder and the degradation of nutrients. These are categorized as (b) (4) leaks because of the double seam. If the double seam were not to be applied correctly and a "gross" leak were to occur, the loss of nitrogen would be accelerated, and the chance of microbial contamination would be greater according to Mr. Gale.

The lot of sanitary can seam ends that caused the failed bubble leak, was not used after the test failure on 04/04/2023. Deviation #887123 was in place until 10/06/2023 and was successfully performed except for a single instance.

PNCR #900164

DT

PNCR #900164 (**Ex. 13**) captures that single instance in the 6+ months that Deviation #887123 was in place that it failed. On 05/03/2023 (b) (4) during the packaging of Similac Total Comfort batch (b) (4) , it was discovered that sanitary can seam ends, commodity number (b) (4) from Lot (b) (4) in (b) (4) were loaded into the Line (b) (4) equipment and used in production by an operator. According to Mr. Kane Wu, Operations Manager who works on the filling lines, another operator in the area noticed that sanitary can seam ends from (b) (4) were in the area and being loaded into the (b) (4) This operator stopped the loading of sanitary can seam ends and the line. Mr. Wu stated that the one operator failed to sort that pallet of sanitary can seam ends. This pallet of sanitary can seam ends was then moved from the room to the staging area where (b) (4) were sorted. Sanitary can seam ends loaded into (b) (4) were removed and discarded. Then the pallet returned with only sanitary can seam ends with (b) (4) . These were then loaded into the machine and the line was restarted.

Based on the speed of Filling Line (b) (4) the incident was believed to have occurred for approximately (b) (4) cases were placed into quarantine as outlined on Attachment 1 (b) (4) addition report for commodity (b) (4) Ends in Batch (b) (4) **Ex. 13**) (b) (4) cases were left of the batch after (b) (4) cases were picked by (b) (4) as part of their intensified microbial testing over the batch. The (b) (4) cases were ultimately destroyed on 06/07/2023 per Action Plan QR #900191 (**Ex. 14**). Attachment 2 Divisional Plant Destruct Form (**Ex.14 Att. 2**) captures the destruction performed by

Other Areas Covered

(b) (4).

The investigation into the matter was short. It was quickly determined that the operator failed to follow the procedure outlined in the deviation. In the deviation, there are instructions that read: "(b) (4) that the ends have been sorted accordingly." The form, Attachment 1- Deviation 887123 (**Ex. 11 Att. 1**), has a space for the batch number, columns for the commodity number, pallet ID number, lot number, as well as a signature from the operator. According to pNCR #900164, "This employee performance event is being documented per the Abbott Employee Relations process."

Sonoco Investigation

DT & DMA

Abbott Nutrition's supplier control team visited (b) (4) from (b) (4) to investigate the machines that produce the sanitary can seam ends. The investigation is documented as Quality Record (QR) #892642 (**Ex. 15**). It was determined that the (b) (4), which manufacturers the sanitary can seam ends packaged (b) (4) (b) (4), was applying the sealing compound differently. The sanitary can seam ends are (b) (4) (b) (4) the sealing compound. The (b) (4) . The (b) (4) is also (b) (4) enough (b) (4) provided by (b) (4) within QR #892642 (**Ex. 15**). The investigation identified the thickness of the sealing compound overlapping as the root cause of the issue. The sealing compound, which is (b)(6),(b)(7)(C), begins to taper near where it meets the start of the application.

(b) (4) technicians reported that the reason the sealing compound was applied in this matter was due to a (b) (4) was retightened to specifications and (b) (4) the sanitary can seem end travels to receive a complete application of the seaming compound was increased (b) (4). As part of the long-term correction, (b) (4) maintenance teams were to refocus on (b) (4) and verify that they were fitting correctly. They stated that cam adjustments are rarely made (b) (4) properly fit. (b) (4) performs preventative maintenance on the machine and (b) (4) every (b) (4).

Lots of sanitary can seam ends manufactured after the adjustment was made can be used without Deviation #887123.

(b) (4)

(DT & DMA)

Abbott's Division office approves all third-party manufacturers (TPM) for contact work. Ms.

Other Areas Covered

Kellie Healy, TPM Quality Assurance Director and Mr. Nick Urh, Supervisor of Quality Assurance, were conferenced in from Abbott's Divisional office to explain how Abbott uses TPMs.

TPMs are inspected on a frequency based on potential risk to product shown in AN11-02-018, AN Supplier Quality Compliance Audits (**Ex. 16**). Part of the approval process is assessing each individual TPM's capabilities. (b) (4) is a facility that would primarily repack/relabel items and has never done any primary packaging for ANS. As a (b) (4) would be inspected (b) (4). (b) (4) was last (b) (4) by Ms. Amie Boyd, Manager of Compliance Quality Assurance (Lead), and (b) (4) (**Ex. 58**). No major findings were observed. ANS provided us with a copy of Ms. Boyd's Food Safety Preventive Controls Alliance (FSPCA) Preventative Control for Human Food certification (**Ex. 17**) as proof of the auditor's qualifications.

ANS management stated that using a TPM to perform the rework associated with the batches that used the sanitary can seam ends, commodity number (b) (4) from Lot (b) (4), was based on many factors. These include the amount of labor involved to complete the activity, space onsite at the Sturgis facility to perform this work, and the length of time to accomplish the task. Based on these considerations, Abbott Nutrition made the decision to keep the Sturgis facility operating in a normal fashion and send the finished products packaged with the sanitary can seam ends, commodity number (b) (4) from Lot (b) (4) to a TPM that they had already been approved.

To assess the effect of using sanitary can seam ends from (b) (4) on the (b) (4), Abbott's divisional team developed a test. The test would need to be performed (b) (4) of the affected batches and conducted in a manner that doesn't destroy the packaging. The non-destructive vacuum leak test was developed to evaluate the (b) (4) and allow them to be released for use.

Engineering Study
(DT & DMA)

The intent of the study is to verify the effectiveness of the vacuum testing prior to sending the cans to (b) (4). ANS sent (b) (4) cases from (b) (4) different batches, (b) (4) and #(b) (4) to Abbott Nutrition Packaging Lab RP3-LL 3300 Stelzer Rd, in Columbus OH on 07/05/23 to be used in the development of the test.

Ms. Phyllis Ragan, from Abbott's Divisional office, conducted the study (**Ex. 18**). The engineering study concluded that the (b) (4) is able to effectively (b) (4) (b) (4) can sizes. The study was completed (b) (4) only. The test (b) (4) developed by the supplier (b) (4). No recipe change is required when (b) (4) is required.

Other Areas Covered

(b) (4)
(DT & DMA)

Abbott Nutrition provided the vacuum leak testing equipment to (b) (4) for performing vacuum leak testing (b) (4) % of the batch. Because (b) (4) had not done rework testing in the past, Mr. David Van Daele, Quality Assurance Director at the Abbott Sturgis facility, worked with (b) (4) Quality Manager and Operations department in developing the procedure for handling reworked cans (**Ex. 7**). Ms. Carrie Young, Quality Specialist that worked directly with TPMs in the past for Abbott, was recruited to directly work on the project.

Procedures for handling the cans of finish product and overcaps are different than those in place in the secondary packaging area at the Sturgis facility. Mr. Van Daele explained that the workers at (b) (4) conducting the vacuum leak testing are performing (b) (4) Line Operators on Filling Line (b) perform many tasks (i.e., adding labels, pulling samples, interacting with monitoring equipment) and thus must sanitize their gloves prior to accessing the (b) (4) (b) (4). On 12/19/2023 ANS provided a copy of (b) (4) new hire/GMP manual (**Ex. 19**) and an attestation from (b) (4) regarding the sanitizing of their gloves (**Ex. 20**).

The (b) (4) vacuum leak testing procedure developed called for (b) (4) operation. (b) (4) (b) (4) shuttle pallets of infant formula cans to be tested from the (b) (4) to the (b) (4) There they would unwrap the cans and remove any can that had visible damage. (b) (4) , would then perform the vacuum leak test. They would (b) (4) . The sanitary can seam end is not removed. (b) (4) . A reading on the instrument would indicate a passing or failure of the seam. Employees performing the (b) (4) vacuum leak testing did so reportedly wearing street clothes and without hair restraints (**Discussion Item**) as listed in Abbott's Dress Code and Personal Hygiene, ST1000.08 (**Ex. 51**).

Cans that would successfully pass the test would be place on a new tray, inked coding would be applied to the tray, and the tray rewrapped as a case. (b) (4) did not perform any other alteration of the packaging. Cans that failed the (b) (4) vacuum leak test were separate out for destruction. These cans never returned to Abbott's Sturgis facility. Testing done on the cans from the (b) (4) lots of was done over the (b) (4) . Ms. Young's primary responsibility was to provide (b) (4) oversight of the progress. She also performed (b) (4) reconciliation of the batches that (b) (4) was testing.

The cans of infant formula that passed (b) (4) vacuum leak test all traveled back to Abbott's Sturgis facility to complete the reconciliation process. Once the testing records were reviewed, ANS released those lots into commerce. The following chart (**Ex. 21**) was provided by Abbott Nutrition explaining the status of each of the (b) (4) lots.

Other Areas Covered

Each lot in the (b) (4) has their own individual action plan. These action plans contain specific instructions for that batch. Generating action plans are the first step in authorizing rework instructions. The existence of an action plan does not automatically mean that any rework has been completed. Once rework is completed, the action plans are updated accordingly. ANS provided action plans for (b) (4).

Table Answer_255_1

On 12/15/2023, we were informed that further distribution of the above batches was halted based on a marketing decision. (b) (4) Mr. Gale, stated that AN still plans on continuing processing the (b) (4) to evaluate the seam defect issue, even if they do not plan on releasing the product to market.

ANS management, including Jeff Rasmussen, David Van Daele, and Keenan Gale review batches prior to them being released. Mr. Jordan Ness, Site Compliance Coordinator, reviews the consolidated environmental monitoring data and sanitation records and includes this information in his written review of the batch. As part of our review of the incident, we also reviewed the Clean-in-place (CIP) and sanitation records for the above batches.

(b) (4)

(DMA)

After review of production records, the investigative team was unable to find when batches (b) (4) were dried and filled. Firm management explained these batches were batch (b) (4) but were given separate batch numbers due to a labeling issue captured in QR #884825 (**Ex. 22**). During an outgoing packaging quality check of Similac Sensitive Early Shield, on the Filling Line (b) (4), cans were found to have misaligned labels. After inspecting all cans on the line, it was found that almost every can had a misaligned label. Cans wrapped since the last acceptable check was isolated and reinspected. Lot code (b) (4) was given to cans that were inspected and the labels were adequate. Lot code (b) (4) was assigned to cans whose labels were removed and reapplied.

Complaints associated with (b) (4)

There were four complaints associated with the (b) (4) in total. The following table captures some of the complaint information.

Table Answer_255_2

Packaging Integrity Complaints for products filled on Filling Line 1

Complaints related to Packaging Integrity issues for products filled on Filling Line (b) (4) were queried

Other Areas Covered

out by ANS per our request (**Ex. 23**). Many of the listings in this report are duplicates due to the use of multiple keywords. For example, a complaint about a product appearance (dent) and resulting in a fuss baby would get entered twice. The following table captures the complaints that were reviewed because they were found most relevant to the packaging integrity issue on Filling Line 1.

Table Answer_256_1

QR #795230 (**Ex. 24**) was collected and reviewed during the inspection to evaluate the severity of packaging issues at ANS. QR #795230 involved issues with blistering of the foil liner and not sanitary can seam ends.

Tables and Figures

Table: Answer_255_1

Batch Number	Product	Quality Records	Exhibits	Status
(b) (4)	SIM TOTAL COMFORT	QR 906060	(**Ex .7,33**)	Distributed to market
(b) (4)	SIM TOTAL COMFORT	QR 906062	(**Ex. 7,34**)	Distributed to market
(b) (4)	SIM TOTAL COMFORT	QR 906065	(**Ex. 7,35**)	Distributed to market
(b) (4)	SIM TOTAL COMFORT	QR 906069	(**Ex. 7,36**)	Distributed to market
(b) (4)	SIM SENSITIVE	QR 906071	(**Ex. 7,37**)	Sturgis
(b) (4)	SIM SENSITIVE	QR 906073	(**Ex. 7,38**)	Sturgis
(b) (4)	SIM SENSITIVE	QR 906074	(**Ex. 7,39**)	(b) (4)
(b) (4)	SIM SENSITIVE	QR 906077	(**Ex. 7,40**)	(b) (4)
(b) (4)	SIM SENSITIVE	QR 906079	(**Ex. 7,41**)	(b) (4)
(b) (4)	SIM SENSITIVE	QR 906078	(**Ex. 7,42**)	(b) (4)
(b) (4)	SIM SENSITIVE	QR 906849	(**Ex. 7,43**)	Sturgis
(b) (4)	SIM SENSITIVE	QR 906850	(**Ex. 7,44**)	Sturgis

Table: Answer_255_2

Plant Report	Product	Batch Number	Description	Exhibit
675332	Total Comfort	(b) (4)	Black object – plastic? Possible burnt object	(**Ex. 54**)
676443	Total Comfort	(b) (4)	Product not fully dissolving and foamy	(**Ex. 55**)

Tables and Figures

673136	Total Comfort	(b) (4)	Cans looked like they had sat awhile. Not expired	(**Ex. 56**)
675090	Total Comfort	(b) (4)	(b)(6),(b)(7)(C) old infant death	(**Ex. 57**)

Table: Answer_256_1

Plant Report	Product	Batch Number	Description	Exhibit
678528	Sim Sensitive	(b) (4)	Product contained small lumps	(**Ex. 46**)
663174	Sim Sensitive	(b) (4)	Formula turned hard. Daughter sick	(**Ex. 47**)
660096	Sim Sensitive	(b) (4)	Rust on the bottom of the can	(**Ex. 48**)
659427	Total Comfort	(b) (4)	Dry clumps	(**Ex. 49**)
629292	Sim Sensitive	Multiple	Missing inner seal on 5 cans	(**Ex. 50**)

MANUFACTURING CODES

No changes were made to the manufacturing codes used by the firm. Please see previous reports for a breakdown of those codes.

COMPLAINTS

Complaint Description(s)	
Complaint Number	184391
Consumer complaint #184391 was received on 11/16/2023 by FDA's Cincinnati office via the Centers for Disease Control (CDC). This complaint was the death of a (b)(6),(b)(7)(C) infant due to *Cronobacter* sepsis on 11/05/2023 and the impetus for this inspection. The infant had consumed two (2) 4-packs of liquid Similac Total Care 360 (lot # unknown) provided by the hospital, before consuming powdered Similac Total Comfort batch (b) (4). The complaint follow-up investigation focused on the Similac Total Comfort batch (b) (4) as it was made at Abbott Nutrition's Sturgis, MI facility.	

Consumer Complaints Related to Food Safety	
Complaint #1	
Complaint Number	CC #184391
Complaint Description	(DT & DMA) Consumer complaint #184391 was received on 11/16/2023 by FDA's Cincinnati office via the Centers for Disease Control (CDC). This complaint was the death of a (b)(6),(b)(7)(C) old infant due to *Cronobacter* sepsis on 11/05/2023 and the impetus for this inspection.

Consumer Complaints Related to Food Safety	
	The infant was (b)(6),(b)(7)(C) s old at time of illness onset,10/31/2023, and was admitted to the hospital on 11/1/2023. The infant had consumed two (2) 4-packs of liquid Similac Total Care 360 (lot # unknown) provided by the hospital, before the parents purchased two cans of powdered Similac Total Comfort batch (b)(6),(b)(7)(C). The complaint follow-up investigation focused on the Similac Total Comfort batch (b)(6),(b)(7)(C) as it was made at Abbott Nutrition's Sturgis, MI facility. Please see CC #184391 for further details and the Office of Human and Animal Food East 5 (HAF E5) activities for additional investigations. The firm's record of CC #184391 is documented in PR #675090 (**Ex. 45**). The record, initiated on 11/08/2023, details, "Abbott Nutrition Product Department (ANPD) representative was leaving a pediatrician's office that he calls on when the pediatrician mentioned one of his patients was admitted to the hospital with *Cronobacter sakazakii* and passed away. ANPD sales rep states that the pediatrician stated the infant who passed away was using Similac Total Comfort. ANPD sales rep states the hospital is doing testing on the formula, but the sales rep does not call on the hospital, so he is unable to gather information from the infant's admission or batch information on the formula used." The complaint report states the complaint was received on 11/07/23. The firm conducted a batch record review and found no trends and a division physician determined there were no health hazards associated with this product. The implicated batch, Similac Total Comfort batch lot (b) (4) (internal to ANS (b) (4)), was manufactured (b) (4) on Dryer (b) (4) in Building (b) (4) and was packaged into 12.6 ounce/357-gram composite cans on Filling Line (b) (4) . A review of the batch record (**Ex. 25**) indicated there were two pNCRs of note. an over action level (OAL) swab in the facility, pNCR #884505 (**Ex. 26**), and a can seam integrity issue with another batch, (b) (4) made in the same campaign, pNCR #892633 (**Ex. 7**). **pNCR #884505** PNCR #884505 was opened to track the trend of OAL swab found in the (b)(6),(b)(7)(C) in Building (b)(6),(. The OAL swab was taken from the (b)(6),(b)(7)(C) Building (b)(6),(b) which is not directly connected to the product stream. (b) (4) from

Consumer Complaints Related to Food Safety	
	(b) (4), per Aaron P. Ledlow, Electrical Engineering Manager. ANS provided flow charts for Building (b) (4) (**Ex. 27**) and Building (b) (4) (**Ex. 28**), (b) (4) liquid processing lines, showing that (b) (4) (b) (4) are not connected to the product stream. The OAL swab is not indicative of a positive swab, only that the number of colony-forming units were over the internally established limit of the firm, per Mr. David Van Daele. A sister swab taken at the same location and time was tested for *Enterobacter* and was found to be negative (**Ex. 29**). This information was included in the batch record per ANS policy, which is to include all swabs taken in the facility during the production time frame and include them in the environmental monitoring records for the batch.
Complaint #2	
Complaint Number	CC #183753
Complaint Description	DT Consumer complaint #183753 was received on 10/05/2023 by FDA's Minneapolis District office. The complainant found dark matter in 6 different cans of PediaSure Enteral Formula 1.0 Cal with Fiber batch #(b) (4) This a liquid product that the complainant was opening and transferring into a bag to be used with a feeding tube for the complainant's (b)(6),(b)(7)(C) The product was not fed to the child and no illness resulted. PR #668673 (**Exhibit 30**) was opened by ANS in response to receiving the complaint. The report investigated the complaint and others similar to it. A determination into what the black parts are was not made. I also concluded the black objects in the pictures submitted by the complainant lacked any characteristics that would identify them as an insect. Liquid product passes through a (b) (4) At the filler for the 8 oz liquid line, liquid product would then (b) (4) prior to being dispensed into cans that have been pre-rinsed. The Pediasure product and production records for June of 2023 were reviewed during the last annual inspection.
Complaint #3	
Complaint Number	CC #184750
Complaint Description	DT Consumer complaint #184750 was received on 12/06/2023 by FDA's

Consumer Complaints Related to Food Safety	
	Dallas District office. The complainant stated that her child experienced colic, diarrhea, and a rash on abdomen as the result of consuming EleCare Jr. The formula was consumed from 11/23/2023 to 12/02/2023 when the child was taken to an urgent care. After that visit, the complainant switched formula from EleCare Jr back to EleCare. 48-hours after switching, the symptoms had dissipated according to the complainant. The complainant stated that the child had a milk and protein sensitivity. During 11/23/2023 – 12/02/2023, two 14.1 OZ cans of EleCare Jr batch (b) (4) and 7 OZ of a third can of 14.1 OZ were consumed. The EleCare family of products are exempt formulas exclusively made at ANS's Strugis, MI facility. These formulas are dried exclusively on Dryer(b) (4) and packaged on Filling Line(b) (4) ANS had opened PR #679844 (**Exhibit 31**) in response to receiving the complaint. PR #679844 contained the statement, "A complaint review conducted for EleCare Jr batch (b) (4) showed no similar serious complaints or a trend for any specific sign or symptom. A one-year historical complaint review conducted for conducted for [sic] all EleCare Jr brand products showed the rate of reports of any type of serious allergic was less than 0.01 reports per (b)(6),(b)(7)(C) distributed." The allergen testing performed on EleCare Jr batch (b) (4) for in-process and finish product samples were reviewed and found negative. Products can be dried or filled over the course of multiple days in what is referred to as a campaign. This will consist of several batch numbers and may consist of different products. What type of clean is required between different products is managed by the changeover matrix. This chart was developed at the divisional level and dictates the appropriate course of action between products, for example, (b) (4) dried product or a (b) (4) The changeover matrix for the Dryer(b) (4) Dryblending, and Filling Line(b) (4) for EleCare Jr batch (b) (4) were reviewed and found to be performed accordingly. ANS management was asked about the ingredient formulations of EleCare, the product that the complainant's child formerly was consuming; EleCare Jr, the new product suspected of causing the adverse reactions; and EleCare CADR (Central America and Dominican Republic) the product filled on Filling Line(b) (4) prior the suspect batch. Management developed a chart (**Exhibit 32**) showing the percentages of ingredients in all three of the above products. There are no significant

Consumer Complaints Related to Food Safety	
	formulation changes concerning allergens or protein concentrations between the three above products.

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wear clean outer garments.
Observation Details	Specifically, This is a repeat observation from the previous inspection(s) conducted on 12/16/2022 (written observation), 03/18/2022 (written observation). The rework instructions specific to each batch below and provided to your third-party manufacturer performing the (b) (4) vacuum leak testing on powder infant formula Similac Total Comfort batches (b) (4), (b) (4) and Similac Sensitive batches (b) (4) did not include instructions on employees' use of clean outer garments, hair restraints, or the use of sanitizer on gloves, which are different from those used at the Abbott Nutrition facility in Sturgis, MI. The rework instructions for their third-party manufacturer relate to the sanitary handling of overcaps. Supporting evidence. The action plans provided to your third-party manufacturer listed as Quality Records (QR) for each batch: Similac Total Comfort batches (b) (4) (QR 906060), (b) (4) (QR 906062) (b) (4) (QR 906065), (b) (4) (QR 906069), and Similac Sensitive batches (b) (4) (QR 906071) and (b) (4) (QR 906073) do not contain instructions on personal hygiene during rework for the above batches of product. Furthermore, Abbott's Dress Code and Personal Hygiene (ST1000.08) procedure states that clean captive clothing and hair coverings are needed to enter the secondary packaging area of Filling Line (b) (4) where the above batches were originally manufactured. Filling Line (b) (4) is considered a Medium Care Area. Abbott Nutrition potential Non-Conformance Record (pNCR) 876377 contains the policy that was updated in February 2023, which prescribes when Labeler Operators should sanitize their gloves with (b) (4) sanitizer. Application of (b) (4) sanitizer is required immediately prior to handling overcaps.

Observations Not Listed on FDA Form 483	
	Employees performing the (b)(6),(b)(7)(C) vacuum leak testing at the third party-manufacturer did so reportedly wearing street clothes and without hair restraints as listed in Abbott's Dress Code and Personal Hygiene (ST1000.08). Also, the use of sanitizer (b) (4) for sanitizing gloved hands when contacting surfaces other than overcaps, was reportedly not employed by the third-party manufacturer.
Citation Reference	21 CFR 106.10(b)(1)
Correction Status	No Firm Response Submitted

REFUSALS

Inspection Refusals
No refusal

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Jeffrey G. Rasmussen, Site Director; Mr. Keenan S. Gale, Sturgis Consent Decree Quality Assurance Director; Mr. David W. Van Daele, Director of Quality Assurance; and Ms. Chelsea A. Hansman, Quality Administrative Assistant, were present at the firm during the closeout meeting and general discussion with management portion of the evaluation. A single item was discussed with the firm:

> Employees performing the (b) (4) vacuum leak testing at the third party-manufacturer did so reportedly wearing street clothes and without hair restraints as listed in Abbott's Dress Code and Personal Hygiene, ST1000.08 (**Ex. 51**). Also, the use of sanitizer (b) (4) for sanitizing gloved hands when contacting surfaces other than overcaps, was reportedly not employed by the third-party manufacturer.

We explained that while we recognized that the employees (b) (4) were performing different tasks that the Operators working in the packaging departments at the Sturgis facility, the attention to personal hygiene was different between the two operations. Mr. Rasmussen stated that they would take our observation under consideration.

ADDITIONAL INFORMATION

(DT)

Cans of powdered infant formula provided by pediatricians and doctor offices are known as gratis cans. They are typically 7 oz but can be any size and normally filled from their own production batch. While ANS could fill both regular sized cans and gratis cans from (b)(6),(b)(7)(C) batch, management stated this is not a common practice.

On 11/29/2023, we discussed the accuracy of the Consolidated Data for Production and Testing spreadsheet that Abbott has been providing FDA since the consent decree. The gap between batch #(b) (4) of Total Comfort completing fill on Filling Line (b) (4) on 04/01/2023 and then clean-in-place (CIP) activities not reportedly occurring until 04/03/2023 was noted. ANS management reviewed the matter and confirmed that the batch did finish filling on 04/01/2023. CIP also was performed and finished on that same day. 04/02/2023 was a Sunday and the line was not in use. On Monday, 04/03/2023, the signoff to restart were done and that date was used in the spreadsheet. Management stated that the spreadsheet would be updated to state this.

(b) (4)

(b) (4) was not involved with the bubble leak issue. Mr. Keenan Gale explained that their expertise is in Good Manufacturing Practices (GMPs), sanitation, and microbiological procedures. (b) (4) did not pull any samples for (b) (4) after they were reworked.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

This was a directed inspection with specific instructions to review the products associated with consumer complaints #184391. Corrections to the inspection that occurred during 10/02/2023-10/18/2023 were not reviewed.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	BOL from 7-17-23	3

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
2	BOL 7-18-23	3
3	BOL 7-19-23	3
4	Copy of label	1
5	Copy of label	1
6	copy of label	1
7	pNCR #892633	126
8	QR #886311	41
9	PMM-1680	35
10	(b) (4) report for lot T18395	2
11	Dev. #887123	4
12	Altitude Pressure Table	1
13	pNCR #900164	27
14	QR #900191	16
15	QR #892642	11
16	AN Supplier Quality Compliance	24
17	Certification	1
18	Eng. Study	7
19	(b) (4) GMP training	66
20	(b) (4) Attestation	1
21	Table	1
22	QR #884825	7
23	Compliant log	7
24	pNCR #795230	115
25	Batch record	1032
26	QR #884505	9
27	Flow diagram	1
28	Flow diagram	1
29	EB results	1
30	PR #668673	58
31	PR #679844	18
32	Nutritional Chart	6
33	QR #906060	167
34	QR #906062	61
35	QR #906065	94
36	QR #906069	75
37	QR #906071	75
38	QR #906073	77

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
39	QR #906074	31
40	QR #906077	33
41	QR #906079	33
42	QR #906078	31
43	QR #906849	28
44	QR #906850	28
45	PR #675090	130
46	PR #678528	12
47	PR #663174	13
48	PR #660096	26
49	PR #659427	12
50	PR #629292	60
51	ST 1000.08	32
52	PMAP Q-044	2
53	List of complaints	1
54	PR #675332	12
55	PR #676443	15
56	PR #673136	13
57	PR #675090	52
58	(b) (4) audit report	4

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FDA 482, Notice of Inspection	3
2	Consent Decree	33
3	Amendment to Consent Decree	2
4	FDA 482, Notice of Inspection	3

SIGNATURE

Danny Tuntevski
Investigator
Signed By: Danny Tuntevski -S
Date Signed: 01-29-2024 15:50:26

David M Amy
Investigator
Signed By: David M. Amy III -S
Date Signed: 01-29-2024 14:57:26