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SUMMARY

Inspection	
Operation ID and Subject	293389: FY 25 Domestic and Foreign IFMF Inspections Schedule.

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This comprehensive inspection of an infant formula manufacturer was conducted in accordance with the FY'25 Schedule of Inspections/Sample Collections for Infant Formula (7321.006) and Medical Foods (7321.002) Programs, DCI # 25-01, FACTS #12388746, eNSpect OP ID #293389; the Infant Formula Program – Inspection, Sample Collection, and Examination Compliance Program Guidance Manual. The inspection included coverage of 21 CFR 117, subpart G – Supply Chain Program.

The previous inspection was conducted from 04/22/24 – 04/26/24 and was classified as NAI with one discussion for the following: The (b) (4) filter for air used at the "(b) (4)" can (b) (4), and the (b) (4) (b) (4) filter for the (b) (4) system, were equipped with (b) (4) micron filters. The firm immediately corrected this discussion item by replacing both filters with (b) (4) micron.

BlendHouse Portland manufactures a single infant formula product for the firm's parent company ByHeart (New York, NY). The product is packaged in metal cans and single serving size stick packs. The infant formula is distributed under the brand name "ByHeart". BlendHouse Portland began blending and filling operations for ByHeart in July 2023. BlendHouse Portland's operations consist of receiving base powder from its sister facility located in Allerton, IA, (b) (4) the base powder with lactoferrin, and filling cans and stick packs. The cans and stick packs are sent to the firm's co-packer, (b) (4) for final packaging. The finished product is sent from (b) (4) to (b) (4) for distribution to stores, and customers who order from the websites www.byheart.com: (b) (4)

BlendHouse Portland has not received any base powder from the Reading, PA facility since 12/01/23.

The first production date of stick pack manufacturing was (b) (4)

At the time of the inspection, the firm was manufacturing (filling) stick packs.

The inspection included a review of the following: stick pack manufacturing operations; food safety plan; complaints/complaints procedure; sanitation; environmental monitoring; deviations; interventions; water events; supply chain program; product release and distribution; finished product microbiological and nutrient testing; expiration dating; stability testing; retained samples; out of date retail product; stick pack process qualification; transportation and storage of components and finished product; internal audits; equipment calibration; food contact air and (b) (4); pest control; quality growth factors; and major food allergens. The inspection also included a comprehensive review of seven batch production records of the stick pack product.

The inspection also included a follow up to the following consumer complaints received by FDA #187867; #188454; and #189239.

No Form FDA-483 Inspectional Observations was issued at the close of the inspection. There was one discussion item regarding the firm's calibration procedure and identification of critical devices so Quality Assurance can conduct a risk assessment of potentially impacted product in the event critical devices are found to be out of calibration.

Summary
Sample #INV1223862, collected on 03/18/25, consisted of 25 environmental swabs collected in the (b) (4) room and (b) (4) room. Sample analyzed for *Cronobacter*. Sample #INV1223863, collected on 03/18/25, consisted of 25 environmental swabs collected in the (b) (4) room and (b) (4) room. Sample analyzed for *Salmonella*. Sample #INV1290948, collected on 03/19/25, consisted of 75 environmental swabs collected in the (b) (4) room, (b) (4) room entrance hallway, (b) (4) room, secondary gowning area, and gowning and handwash area. Sample analyzed for *Cronobacter* species. Sample #INV1290949, collected on 03/19/25, consisted of 75 environmental swabs collected in the (b) (4) room, (b) (4) room entrance hallway, (b) (4) room, secondary gowning area, and gowning and handwash area. Sample analyzed for *Salmonella* species. Sample #1290950, collected on 03/20/25, consisted of eight, 17-gram stick packs of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months*. Sample analyzed for HPAIV. Sample #1291577, collected on 3/20/2025, consisted of 60 cases (each containing approximately 200, 17-gram stick packs), of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months*. Sample analyzed for Cronobacter and Salmonella. Sample #1291578, collected on 03/20/25, consisted of 300, 17-gram stick packs of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months.* Sample analyzed for Nutrients. All samples were classified as lab class 1. Attachment A – *Reporting Changes in Processing for Infant Formula* and Attachment B - *Infant Formula Nutrient Information Reporting Form* were collected. (b) (3) (A) FDA guidance material was provided to firm management. There were no refusals, and a reconciliation exam was not conducted. This establishment inspection was written by Gerard D. DiFiore.

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
03040	FOOD CGMP INSPECTIONS
03040U	FOCUSED PCHF INSPECTIONS
21006	INFANT FORMULA SURVEY

Summary of Past Observations	
CFR Number:	**Citation Text:**
21 CFR 106.30(g)	You did not install a filter capable of retaining particles 0.5 micrometer or smaller when (b) (4) gas is used at a product (b) (4) machine.
Correction Status:	Corrected & Verified

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 106.100(f)(2)	You did not maintain a certification of accuracy of a known reference standard that was used and a	No Firm Response Submitted

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
	history of recertification.	

Correction Statuses current at time report was signed.

Consumer Complaints Review

All complaints are initially received by ByHeart corporate. ByHeart corporate is responsible for the management, investigation, record maintenance and retention of complaints. ByHeart has a written procedure titled “Complaint Management Policy” (QUAL-2503-POL) that describes ByHeart’s procedure for receipt, handling, and investigation of complaints and was reviewed by me without comment.

Complaints are initiated through ByHeart Customer Experience Group and are reviewed by ByHeart’s Pharmacovigilance Group (PVG). The Director of Pharmacovigilance works closely with the Parent Experience Team and is responsible for reviewing all health complaint records and performing an assessment of complaints and conducting periodic reviews of complaints and for making the final determination of the complaint. The Chief Medical Officer (CMO) at ByHeart (or a designee) is responsible for reviewing all health-related complaints to determine if FDA-Reportability criteria are met, and if there is a potential for hazard to health, or if there a potential for serious adverse health consequences.

Complaints are categorized as either health related complaints or quality complaints. Health related complaints are complaints in which there is any sign, symptom, disease, or illness. Health related complaints include serious health related complaints that include the following: hospitalization; prolongation of hospitalization; death; life threatening; disability; or anything that would require significant medical intervention.

The Parent Experience Team is responsible for immediately notifying ByHeart Quality Management and Pharmacovigilance of any sensitive complaints. Sensitive complaints include those complaints where a potential hazard to health exists and is determined to possibly be related to a company product.

The CMO at ByHeart (or a designee) is responsible for reviewing all health-related complaints to determine if FDA-Reportability criteria are met, and if there is a potential for hazard to health, or if there a potential for serious adverse health consequences.

Quality complaints are complaints related to the physical characteristics of the product or package.

ByHeart manufacturers (BlendHouse Portland, BlendHouse Allerton and BlendHouse Reading) are responsible for support in the complaint investigation, trends, corrective actions, reports and the retention of all hard copy and electronic records associated with the complaint. Complaints can also be sent to the firm’s contract manufacturer responsible for putting the lid and collar on the on the finished product ((b) (4) to conduct their own complaint investigation. The quality Management at the manufacturing sites are responsible for reviewing complaint information for accuracy, facilitating complaint investigations, including reviewing batch production records, implementing corrective and preventive actions and for conducting trending of complaints. All investigations of health-related complaints include review of the batch production records, test results and any deviations associated with the batch.

The firm has established a threshold for the number of health-related and quality complaints that may trigger further investigation. The threshold for health-related complaints is (b) (4) the threshold for quality related complaints is (b) (4) the threshold for foreign body complaints is (b) (4) and the threshold for severe, unusual, or sensitive complaints is (b) (4) If the PVG identifies (b) (4) complaint records with a relatedness assessment of related or possibly related to a particular batch, then the PVG will notify Quality that the threshold has been met and the batch may require further investigation.

Consumer Complaints Review

From 04/26/24-03/14/25, ByHeart received 3,247 complaints, of which 2,167 were categorized as health-related complaints. Of the 2,167 health-related complaints received by received by ByHeart, 69 were forwarded to BlendHouse Portland for review and investigation. Of the 69 health-related complaints received by BlendHouse Portland, 10 were further categorized as sensitive complaints. The firm did not receive more than one sensitive complaint for any batch.

During the inspection, I conducted a review of the 10 sensitive complaints received by BlendHouse Portland since the previous inspection (see below).

Complaint 24-003 (batch (b) (4)
Nature of Complaint: The Complainant reported her daughter was diagnosed with Salmonella.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm also reviewed pest monitoring records for the date range that the batch was being processed and no pest sightings were reported. No employees were absent from work or were sent home due to gastrointestinal illness. The firm's investigation conclusion reported there was no evidence that the batch of infant formula was contaminated with Salmonella and that all process controls were effective at managing any risks.

Complaint 24-011 (batch (b) (4)
Nature of Complaint: The Complainant reported infant was diagnosed with "a salmonella infection that has entered the blood stream.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records for both the base powder and canned product. The firm's investigation conclusion reported there was no evidence that the batch of infant formula was contaminated with Salmonella and that all process controls were effective at managing any risks.

Complaint 24-035 (batch (b) (4)
Nature of Complaint: The Complainant reported their infant had a bad diaper rash and diarrhea and was later diagnosed with a *Campylobacter* infection of the stool.
Firm's Complaint Investigation and Conclusion: The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm's investigation conclusion reported there were no immediate actions to be taken by the firm as a result so the investigation as no causes of any microbiological risk were identified.

Complaint 24-047 (batch (b) (4)
Nature of Complaint: The complainant reported infant's stool tested positive for Salmonella.
Firm's Complaint Investigation and Conclusion: The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported there was no evidence that the batch of infant formula was contaminated with Salmonella and that all process controls were effective at managing any risks.

Complaint 24-059 (batch (b) (4)

Consumer Complaints Review

Nature of Complaint: The complainant reported infant's stool tested positive for Salmonella.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported there was no evidence that the batch of infant formula was contaminated with Salmonella and that all process controls were effective at managing any risks.

Complaint 24-061 (batch (b) (4)
Nature of Complaint: The Complainant reported their infant developed Salmonella poisoning.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified.
Note: The complainant reported the infant consumed two batches of BlendHouse's infant formula. The firm opened a separate complaint investigation for this complaint. The second complaint investigation was given complaint number 24-063 (See below).

Complaint 24-063 (batch (b) (4)
Nature of Complaint: The Complainant reported their infant developed Salmonella poisoning.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified.

Complaint 24-066 (batch (b) (4)
Nature of Complaint: The Complainant reported their infant developed mucous in stool, diarrhea, and blood. The cultures subsequently confirmed Salmonella in the stool.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified.

Consumer Complaints Review

Complaint 24-080 (batch (b) (4)
Nature of Complaint: The Complainant reported an infant experience diarrhea for two weeks tested positive for E. coli.
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing for Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion revealed that there was no evidence that the batch of infant formula was contaminated with E. coli. and that all process controls were effective at managing any risks.

Complaint 24-0084 (batch (b) (4)
Nature of Complaint: The Complainant reported an infant with diarrhea, high fever, and blood and mucous in stool was diagnosed with Salmonella (firm reported the method of diagnosis was unspecified).
Firm's Complaint Investigation and Conclusion: The firm followed its written procedure for conducting complaint investigations (QUAL-2503-POL). The investigation included a complete review of the batch records, including production records, interventions, sanitation, in-process and finished product microbiological testing and environmental monitoring records. Additionally, the firm reviewed the certificates of analysis for the lots of lactoferrin used in the batch that included testing Salmonella. The firm also reviewed the ARC for the lots of base powder used the manufacture the batch. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified. The firm's investigation conclusion reported no that there was no evidence of Salmonella contamination with the batch and that all process controls were effective at managing risk and that no immediate actions would be taken as a result of the investigation as no causes of any microbiological risk were identified.

Consumer Complaints

Complaint ID	Complaint Coverage
187867	A follow up to this complaint revealed the firm received the same complaint and the complaint was assigned complaint tracking code #24-040. The complainant provided a photograph of the foreign material. The firm requested a return of the foreign material. The firm provided the complainant with a return shipping label; however, the complainant did not return the foreign material to the firm. The complainant did provide the firm with photographs of the foreign material. The firm has controls in place to prevent the introduction of foreign material into the infant formula. The firm audits its suppliers and cans are inspected at the time of receipt for evidence of damage, adulteration, and evidence of pests. After depalletizing, the cans go through an (b) (4) during which the cans are (b) (4) and (b) (4) The cans then pass through an (b) (4) System that is intended to identify, and reject, cans with foreign material. The (b) (4) System is checked (b) (4) with test cans. There is a (b) (4) below the bulk bag unloader and a (b) (4) located (b) (4) that are intended to stop any foreign material from getting into the cans. The (b) (4) are inspected (b) (4) (b) (4) Additionally, there is an (b) (4) after the cans are sealed. The firms investigation conclusion stated that the foreign material did not visually match any material that is used in the process and equipment to the foreign material in the photograph provided by the complainant, and the firm did not contribute the foreign material being found in the can (see EX. 1 for firms Complaint Investigation Report).

Consumer Complaints	
Complaint ID	**Complaint Coverage**
188454	See Memo dated 04/07/2025 for complaint coverage.
189239	A follow up to this complaint revealed the firm received the same complaint and the complaint was assigned complaint tracking code #24-059. The firms investigation included a review of the following: batch records; manufacturing records; CCP monitoring records; results of in process tests; finished product microbiological tests; finished product microbiological indicator results; finished product nutritional results; investigations; interventions; and sanitation records (including zone (b) (4) nvironmental monitoring of (b) (4) food contact locations). The firms investigat summary reported that there was "no evidence of Salmonella contamination with the batch and that all process controls were effective a managing any risk". This was the only illness-related complaint received by the firm for this batch (see EX. 2 for firms Complaint Investigation Report).

Inspection Samples	
Sample Number(s)	1223862; 1223863; 1290948; 1290949; 1290950; 1291577; 1291578

ADMINISTRATIVE DATA

Administrative Data	
Firm	BlendHouse Portland LLC
Physical Address	
Address Line 1	19217 Ne San Rafael St
City / State / ZIP	Portland, OR 97230-7445
Phone	1-503-288-6502
Mailing Address	
Address Line 1	19217 Ne San Rafael St
City / State / ZIP	Portland, OR 97230-7445
Website	www.byheart.com
Inspection Date(s)	3/17/2025, 3/18/2025, 3/19/2025, 3/20/2025, 3/21/2025, 3/24/2025, 3/25/2025, 3/26/2025, 3/27/2025

FDA Inspection Participants
Participant Name and Title
Desiree Iya, Compliance Officer
Jeffrey Leclair, Investigator
Delanie Browning, Investigator
Gerard Difiore, Investigator

FDA Team Members Not Present for the Whole Inspection
Investigators Desiree Iya and Delanie Browning were present on 03/18/25, 03/19/25, 03/20/25 to conduct environmental monitoring and collection of product samples. CSO Jeffrey LeClair was present on 03/18/25 and 03/19/25 to conduct environmental monitoring. CSO Gerard DiFiore was present on 03/18/25, 03/20/25, 03/21/25, 03/24/25, 03/25/25, 03/26/25 and 03/27/25.

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**
3/18/2025	Svyatoslav O. Kleschev, Quality Operations Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	William Thomas, Senior Director - Manufacturing

Guidance Documents Given to the Firm

The following guidance documents were provided to William Thomas, Senior Director Manufacturing:

- FORM-002828 (Rev02) OHFI Incoming Firm Correspondence Letter Template with the attached document titled "FDA Firm Resources."
- FDA 3/8/23 "Call to Action Letter" directed to manufacturers, packers, distributors, exporters, importers, and retailers involved in the manufacturing and distribution of powdered infant formula.
- OII Vendor Sample Reimbursement Payment Process Letter.

HISTORY

Food Firm Registration Status	(b) (3) (A)
Hours of Operation	The firm operates (b) (4)
New or Current Firm Legal Name	BlendHouse Portland LLC
Legal Status	LLC
State of Incorporation	DE
Year of Incorporation	2022
Additional Information	BlendHouse Portland was registered as a foreign LLC with the Oregon Secretary of State on 6/28/23. BlendHouse Portland is owned and operated by ByHeart 131 Varick St. 11th Floor New York, NY 10013. Gross annual sales for ByHeart for the year 2024 were approximately $(b) (4) USD. ByHeart has approximately (b) (4) employees across all facilities.

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	(b) (4) percent of components and ingredients used to manufacture the infant formula are received from outside the State of Oregon, and (b) (4) % of finished product is shipped outside the state of Oregon. Lactoferrin is supplied by (b) (4) Base powder is supplied by BlendHouse Allerton, IA and is shipped directly to

	(b) (4) where the product is held for BlendHouse Portland. Base powder is shipped from (b) (4) to BlendHouse Portland for processing, where the based powder is (b) (4) with lactoferrin and canned. After blending and packaging, the infant formula is shipped on day trucks from BlendHouse Portland to (b) (4) under hold status. After the product is released by BlendHouse Portland, it is shipped from (b) (4) to (b) (4) for further packaging. Collars and lids are placed on the canned product and the product is case packed and palletized. Individual stick packs are placed in pouches (14 stick packs per pouch) then case packed and palletized. Pallets of the infant formula are shipped from (b) (4), to (b) (4) for distribution to select (b) (4) stores and customers who order from the firm's website www.byheart.com and (b) (4) ByHeart's top customers are (b) (4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	The firm continues to operate as a manufacturer of a powdered infant formula labeled in part, "ByHeart Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 Months". The firm's operations consist of receiving infant formula base power from BlendHouse Allerton, IA and (b) (4) the base powder with lactoferrin, and filling cans or stick packs. The stick packs are packaged into labeled pouches/bags. A proof of the stick pack pouch; an enlarged view of the ingredients and nutrients per 100 calories listed on the stick pack pouch; and a section of the foil stock used for packing the infant formula powder into stick packs were collected during the inspection (**See EX. 3**). In addition, the firm provided a copy of the marketing material(s) used to market its infant formula product (**See EX. 4**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	William Thomas, Senior Director - Manufacturing
Roles and Authorities	Mr. Thomas is ultimately responsible for all sites owned and operated by ByHeart including the BlendHouse Portland, OR; BlendHouse Reading, PA; BlendHouse Allerton, IA. He is responsible for overseeing manufacturing operations at each location. The Plant Directors for each location report to him and he reports to the Vice President of Supply Chain.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #2	
Person's Name and Title	Kathleen "Katie" Whitesell, Vice President - Quality
Roles and Authorities	Ms. Whitesell is responsible for overseeing the QA and QC William owned/operated by ByHeart. The Site Quality Directors and Sanitation

	Managers report to her. She reports to the Chief Quality Officer. She has worked for the firm since June 2023.
The following are applicable to this person	Interviewed
Person #3	
Person's Name and Title	Lori Boyd, Director of Quality
Roles and Authorities	Ms. Boyd is responsibilities include overseeing food safety and product quality, releasing and holding of product and the firm's environmental monitoring program. The Regulatory Compliance Manager, Release Services Manager, Environmental Monitoring Coordinator, and Lab Technicians Report to her. She reports to the Vice President of Quality. She has worked for the firm in the current position since June 2023.
The following are applicable to this person	Interviewed, Accompanied During the Inspection

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

The firm continues to operate from a (b) (4) square foot facility. Production areas are designated as (b) (4) hygiene and (b) (4) hygiene areas (**see EX. 5 for "Hygiene Area and Traffic Pattern Program" (QUAL-4530-SOP) including hygienic area map; personnel traffic pattern map; and depiction of flow of equipment and materials**).

The manufacturing rooms have no overhead water pipes or drains. The only water pipes in the (b) (4) (b) (4) area are located in the gowning area and are located against a wall. There are no floor drains located in (b) (4) (b) (4) areas. The only floor drains are located in the employee rest rooms and behind the "(b) (4) Room" which is a low traffic area that has a "dead end" (leads to nowhere) and is gated.

The firm's operations consist of (b) (4) base powder with lactoferrin and filling cans or stick packs with the finished infant formula powder. Since the previous inspection, the firm has completed the installation of the (b) (4) line.

The following is a description of the blending and filling operations, and the in-process controls, tests and examinations that are conducted during blending, stick pack filling, and case packing.

Material Handlers stage base powder and lactoferrin in the (b) (4) (b) (4) adjacent to (b) (4) Room (b) (4) The (b) (4) (b) (4) is under (b) (4) relative to the warehouse and (b) (4) Room (b) (4) s under (b) (4) relative to the (b) (4) (b) (4) The outer container (cardboard box) of the lactoferrin removed, and the plastic bags are sanitized with (b) (4) The base powder is brought to the (b) (4) (b) (4) with a (b) (4) The outer shroud (plastic or cardboard) is removed, and the bulk container of base powder is wiped down and sanitized with (b) (4) . The (b) (4) is positioned in place so only the (b) (4) break the plane between the (b) (4) (b) (4) and the (b) (4) room, while the (b) (4) stay in the (b) (4) (b) (4) The bulk container of base powder is then placed on a (b) (4) plastic pallet. The bulk container (referred to as a tote at this point) is positioned (b) (4) and (b) (4) of the bulk bag unloader. The (b) (4) on the bottom of the bag is opened and sanitized with (b) (4) and (b) (4) through a (b) (4) (b) (4) into a receiving hopper (b) (4) of the blender. The powder is (b) (4) through a (b) (4) transport system equipped with a (b) (4) into a (b) (4) before being deposited into the blender. The bag of lactoferrin and the (b) (4) on the blender are sanitized with (b) (4) and the lactoferrin is (b) (4) deposited (b) (4) of the base powder through the (b) (4) . The base powder and lactoferrin are blended at (b) (4) RPM for (b) (4) (b) (4) The firm conducted a validation of the blending time and speed (**See previous establishment inspection report section titled "Blending Validation**"). The blender is a (b) (4) blender with (b) (4) on (b) (4) with a (b) (4)

Process Flow, Operations, and Product Coverage

liter capacity. The firm uses the (b) (4) principal for documenting/recording the lot numbers of components (base powder and lactoferrin) used. The HMI for the blender is set to only allow the blender to proceed (b) (4) The input data in the program is based on the (b) (4) as (b) (4) the blender (b) (4) has a blending job number which is a (b) (4) job number issued by the (b) (4) system. The system generates a separate job number for packaging. The firm processes (b) (4) (b) (4) from which can consist of (b) (4) blends (production units). (b) (4) has a (b) (4) blend number (b) (4) starting at (b) (4) The blended material is deposited into (b) (4) hopper and is (b) (4) through a (b) (4) system to a (b) (4) located at the (b) (4) line (b) (4) line. The powder is deposited into a (b) (4) hopper located (b) (4) of the (b) (4) machine (b) (4) enters the hopper (b) (4) of the (b) (4) and is dispersed throughout the hopper through (b) (4). Labeled stick pack film enters the back of the (b) (4) and passes over a series of (b) (4) and is sliced into (b) (4) pieces (for (b) (4) stick packs). The film wraps around a series (b) (4) inside) that are connected to the (b) (4) hopper. The (b) (4) is (b) (4) sealed to form a (b) (4) seal then crimped at the bottom to form a pouch with an opening (b) (4) to form a (b) (4) around the (b) (4) tube. The powder is fed (b) (4) of the (b) (4) is the (b) (4) is then cut and crimped (b) (4) to form a sealed stick pack in its final form. The stick packs fall though a (b) (4) into a (b) (4) that (b) (4) The stick packs are conveyed from the (b) (4) room through a (b) (4) opening into the (b) (4) room and then to the (b) (4) care (b) (4) (b) (4) room. The stick packs pass through an (b) (4) Stick packs rejected by the (b) (4) machine are placed in a plastic bag labeled (b) (4) Detector Rejection Log" and Quality conducts an investigation consisting of (b) (4) the powder of the rejected stick pack through a (b) (4). After exiting the (b) (4) the stick packs are conveyed to a hopper where the stick packs are continuously deposited into a box lined with a food grade plastic bag and filled by weight to (b) (4) stick packs (b) (4) stick packs). The cases are labeled with a bar code, sealed, palletized, and shrink wrapped for shipping.

In-process controls, tests, and examinations

(b) (4) QA will print out a Lot Code Check Sheet with the lot code for the batch of product being manufactured. (b) (4) during manufacturing a Production Operator will monitor (b) (4) from (b) (4) to verify that the product code being ink jetted onto the stick pack matches the product code on the Lot Code Check Sheet.

(b) (4) during (b) (4) operators pull (b) (4) from (b) (4) on the (b) (4) machine to verify the weight. Underweight stick packs are collected in a box the firm weighs the weight of the rejected stick packs for reconciliation of the batch.

(b) (4) during (b) (4) operators pull (b) (4) from (b) (4) and conducts a leak test.

The (b) (4) is challenged (b) (4). The firm passes (b) (4) from (b) (4) with (b) (4) and then a (b) (4) test (b) (4) to the stick pack.

Quality collects stick packs after the (b) (4) for finished product micro and nutrient testing, quality indicators, retained samples, and for stability testing. The firm has a spreadsheet that describes the frequency and quantity of stick packs to be collected so that the product that is tested is representative of the batch. A total of (b) (4) sticks (b) (4) cases) are collected for testing finished product micro, nutrients, quality indicators, and retained samples, and (b) (4) sticks are collected for stability testing. Additionally, quality pulls samples for weight check (b) (4) sticks (b) (4) sticks (b) (4) and (b) (4) of a product run for reconstitution and organoleptic testing. Additionally, the firm test (b) (4) of the stick packs (b) (4) after packaging.

Other Areas Covered

Food Safety Plan

The firm has a written Food Safety Plan (QUAL-4532-HACCP) that is overseen by a PCQI. Since the

Other Areas Covered

previous inspection the Food Safety Plan has been revised and hazard analysis was conducted for the stick manufacturing process and packaging. The Food Safety Plan includes a written hazard analysis; written preventive controls; written supply chain program; and a cross reference to the firm's product recall plan. The Food Safety Plan was reviewed without comment (**See EX. 6 for firm's written Food Safety Plan**).

Sanitation

The firm has a written procedure titled, "Master Sanitation Procedure" (SAN-4700-SOP) that describes the firm's sanitation program. The firm maintains a master sanitation schedule that describes the frequency of cleaning of equipment, tools, containers, structures, and grounds.

The firm has written SSOPs and work instructions that describe the procedures for each task listed in the master sanitation schedule that includes the frequency of cleaning, chemicals used for cleaning, and sanitation procedures.

(b) (4) sanitation is conducted by production personnel and is documented on the respective forms (i.e. (b) (4) sanitation forms).

(b) (4) sanitation covers external areas of equipment, surfaces, platforms, walls, and floors. The firm conducts (b) (4) sanitation of the whole facility which is describe in the (b) (4) Sanitation Schedule" (SAN-4700.01-FM). (b) (4) sanitation is described in the "(b) (4) Sanitation Schedule – General Warehouse" (SAN-4700.02-FM).

Sanitation breaks are conducted after (b) (4) of production. The sanitation breaks are (b) (4) and covers all of the rooms and equipment including packing equipment in (b) (4) care areas. Sanitation breaks are documented on the following forms: "Bulk Bag Unloader and Blender Cleaning Record" (SAN 4712.01-FM); "Sanitary Break Pre-Op inspection Stick Pak" (PROD-4317.11-FM); (b) (4) and (b) (4) Room Cleaning Record" (SAN-4713.01-FM).

The firm maintains a list of approved chemicals "Approved Chemical List" (SAN-4710.02-FM). The only food contact sanitizer used by the firm is (b) (4) which is a (b) (4) sanitizer (**see EX. 7 for sanitizer technical data sheet**).

After a sanitation break, the firm conducts a Post Sanitation Break Pre-Op inspection that includes a detailed visual inspection of each piece of equipment using a (b) (4) Closed powder transfer piping is visually inspected using a (b) (4) . A production employee is present during the Post Sanitation Break Pre-Op inspection and is responsible for conducting (b) (4) recleaning of equipment that does not pass the inspection. The Sanitation Manager is responsible for reviewing all sanitation related records the day after sanitation is conducted.

After signing off on sanitation the firm conducts allergen swabbing for (b) (4) using (b) (4) Test followed by pathogen indicator swabbing. The firm also swabs for pathogens using (b) (4) (b) (4) for Listeria; (b) (4) for Salmonella and Cronobacter; and (b) (4) for Enterobacteracea and APC. After swabbing, the area swabbed is sanitized with (b) (4) and wiped with a clean room cloth. The firm collects nearly (b) (4) swabs (b) (4) of the (b) (4) room, (b) (4) room, and (b) (4) room (**see section titled, "Environmental Monitoring" for a description of the firm's environmental monitoring program**).

During the inspection I observed the firm conducting a post sanitation break pre-op inspection including allergen and environmental sampling.

Tools and utensils for cleaning and sanitizing are confined to each room and are color coded for the area of usage (White – Food Contact; Blue – Exterior parts of equipment; Red – Nonfood contact). (b) (4) used for cleaning are tagged with a "Zone ID" which shows the zone the (b) (4) can be used. Small equipment pieces are stored in dedicated buckets.

Other Areas Covered

Environmental Monitoring

The firm has a written procedure for conducting environmental monitoring titled, "Environmental Monitoring Program" (QUAL-4510-SOP) that describes the environmental monitoring program at BlendHouse Portland (**EX. 8**).

The firm monitors the environment for Salmonella, Cronobacter spp., Listeria spp., Enterobacteriaceae (EB), APC, Yeast and Mold. The firm also monitors water quality, though water is not used in the production of product nor during cleaning of the equipment or facility.

The work instruction titled, "Environmental Surface Sampling" (QUAL-4510.07-WI) describes the instructions for collection and testing of (b) (4) and swab samples from environmental surfaces for detection and analysis of microbial pathogens (**EX. 9**). The work instruction covers both routine environmental sampling and vector swabbing in the event of a presumptive positive for Salmonella spp., Cronobacter sakazakii, Listeria spp., or out of spec swab for aerobic plate count (APC) or enterobacteriaceae (EB). (b) (4) is used for both Salmonella spp., and Cronobacter sakazakii; (b) (4) is used for both EB and APC; (b) (4) is used for the collection of Listeria spp. Swabs are collected using (b) (4) Swabs and are sent to IEH Laboratories, Seattle Washington.

See section in this report titled, "Tables and Figures" (Table Answer_67_1) for the tests, methods and specifications for microbiological surface sampling.
Table Answer_67_1

The firm maintains an environmental master site list of areas and locations to be swabbed and the type of analysis to be conducted on the swabs (**EX. 10**). All areas are to be swabbed (b) (4) For routine environmental monitoring, most swabs (unspecified) are collected from zones (b) (4) and fewer swabs are collected from zones (b) (4) The firm collects (b) (4) swabs from zones (b) (4) for Salmonella spp., Cronobacter sakazakii, Listeria spp. and EB; and the firm collects (b) (4) swabs from zone (b) (4) or Salmonella spp., Cronobacter sakazakii, Listeria spp. A minimum of (b) (4) swabs are collected for Salmon a; (b) (4) swabs are collected for Cronobacter spp.; and (b) (4) swabs are collected for Listeria spp.

The firm conducts zone (b) (4) wabbing of equipment in (b) (4) Room (b) (4) and (b) (4) Room and (b) (4) Room durin sanitation breaks (**See section titled, "Sa ation" for information on sanitation breaks**). The firm has a visual aide for zone (b) (4) swabbing of the (b) (4) Room (b) (4) **see EX. 19 in the previous EIR for zone (b) (4) wabbing in (b) (4) room nd EX. 11 in this current re t for (b) (4) room zone (b) (4) wabbing sual aid**).

No product is released until the results of all environmental monitoring, including zone (b) (4) nvironmental monitoring, is complete. In the event of a zon (b) (4) positive collected during a sanitary break, the product is moved from a hold status a quarantine status u l a disposition decision can be made.

Since the previous inspection, the firm collected the following swabs for Salmonella spp., Listeria spp., and Cronobacter.

Salmonella spp.:
(b) (4)

The firm had two presumptive positive swabs and zero confirmed positive swabs for Salmonella.

Listeria spp.:
(b) (4)

Other Areas Covered

(b) (4)

The firm had no presumptive positive swabs for Listeria spp.

Cronobacter sakazakii

(b) (4)

The firm had four presumptive positive swabs for Cronobacter of which two were confirmed positive swabs for Cronobacter (**see below for firm's follow-up investigation of the presumptive positives**).

Positive Environmental Samples

The SOP "Environmental Monitoring Positive Response Action Plan" (QUAL-4510.06-WI) describes the Actions to be taken by the firm in the event of a presumptive positive or positive finding (**EX. 12**). The SOP states, "Quality personnel will perform (b) (4) swabs following the vector sampling technique in QUAL-4510.07.WI – Environmental Surface Sampling to identify potential spread of the pathogen." (b) (4) swabs are initially collected which is followed by cleaning and sanitizing the area and then conducting vector swabbing for (b) (4) with a minimum of (b) (4) environmental swabs taken (b) (4). If a presumptive positive is received from a vector swab, management is notified for assessment of the cleaning effectiveness, root cause analysis, potential expansion of cleaning, the need for additional swabs or longer monitoring period. Environmental Monitoring Program (QUAL-4510-SOP) states "Confirmed pathogens must be identified using (b) (4)" (**EX. 8**).

Positive Swab 1 (see EX. 13 for firm's Environmental Positive Investigation Form for EMP 24-002)

On (b) (4) swabs (Cronobacter, salmonella, listeria) were collected as investigational swabs triggered by an unplanned zone (b) (4) water event. The water event was the results of a contractor using a wet saw to cut a hole through a wal o the exterior of the facility to facilitate installation of an (b) (4) system for the dust collector. The wet saw caused water to accumulate on the floor at the south wall of the warehouse. The dust collector was not in use and was not connected to the product stream. On (b) (4) the swab collected on (b) (4) was presumptive positive for Cronobacter and on (b) (4) the swab was confirmed positive for *Cronobacter turicensis*. Additional (b) (4) swabs were collected on (b) (4) (b) (4) for Cronobacter, salmonella and listeria were all negative. Upon learning of the presumptive positive for Cronobacter on (b) (4), investigational vector swabbing was conducted over (b) (4) swabs collected (b) (4) for Cronobacter, salmonella and listeria and all swabs were negative. The positive swab location was added to the firms (b) (4) environmental sampling program and swabs collected in the area (b) (4) for Cronobacter, salmonella and listeria were negative.

Finished Product Risk Assessment: The work conducted by the contractor occurred on the (b) (4) of a (b) (4) sanitary break. The affected area is a low-traffic area. The dust collector where the positive sample was collected was not (and is still not) in use and will be cleaned and sanitized prior to connection to product stream. All finished production lots undergo microbiological testing for pathogens including Cronobacter, salmonella, listeria. S. aureus, E. coli./coliforms, B. cereus, and APC. There have been no product positives for any pathogens and no APC testing have exceeded specifications of (b) (4) CFU/g. The firm's root cause investigation revealed the probable cause of Cronobacter being introduced into the plant was from the water used by the contractor to cut a hole through the wall to facilitate installation an (b) (4) for the dust collector. It is unknown if the water was the source of contamination or if the water acted as a carrier allowing Cronobacter to enter the facility from the outside.

Firm's Disposition Recommendation: No product was affected by the positive related to the water event. The disposition of the product will follow standard positive release procedures.

Other Areas Covered

CAPA 1: Implement process of a plant level project risk assessment as well as a process of documenting sign off notification of work being done.

During the walk through of the facility inspection I inspected the area where the positive environmental sample for Cronobacter was collected without comment. I also verified that the CAPA's described in the Environmental Positive Investigation Form were implemented.

Positive Swab 2 (see EX. 14 for firm's Environmental Positive Investigation Form for EMP 24-004)
On (b) (4), a swab collected as part of routine (b) (4) environmental sampling in a (b) (4) care area (zone (b) (4) located on the floor between two dock doors was presumptive positive for Cronobacter on 11/12/24. The presumptive positive swab collected on (b) (4) was confirmed positive by (b) (4) as *C. dublinensis* (b) (4) (b) (4). The last swab collected in this area prior to the positive environmental sample that was collected on (b) (4) as part of (b) (4) routine environmental monitoring and the swab was negative. The firm implemented its "Environmental Positive Response Action Plan" and collected (b) (4) swabs and (b) (4) swabs on (b) (4) swabs on (b) (4) and (b) (4) swabs on (b) (4) (all swabs tested for Cronobacter, Salmonella and Listeria) and all swabs were found to be negative.

The firm conducted a root cause investigation by reviewing cleaning records for the area; water events in the area (there were none); traffic in the area. Two root causes were identified which could have led to Cronobacter entering the facility.

Possible Root Cause 1: Lack of sanitation controls during trailer unloading: Trailers are not governed by plant GMP's which poses a risk of Cronobacter entry into the facility. Trailers are inspected prior to unloading and no deviations were noted during trailer inspections.

Possible Root Cause 2: Surface pitting (very minor) on concrete floor resulting in uneven and porous texture that is challenging for effective cleaning (the area that tested positive for Cronobacter was a 12"x12" area that included a portion of the floor with pitting).

Finished Product Risk Assessment: All finished production lots undergo microbiological testing for pathogens including Cronobacter, salmonella, listeria. S. aureus, E. coli./coliforms, B. cereus, and APC. There have been no product positives for any pathogens and no APC testing have exceeded specifications of (b) (4) CFU/g.

Firm's Disposition Recommendation: No product was affected by the positive related to the water event. The disposition of the product will follow standard positive release procedures.

CAPA 1: Add (b) (4) stored in area to EMP swabbing plan.
CAPA 2: Create a procedure for sanitizing (b) (4) stored in the area that is used for loading and unloading trailers (sanitize (b) (4)
CAPA 3: Repair cracks/crevices located in dock area where positive sample was collected.
CAPA 4: Add scale stored in area to master sanitation schedule.
CAPA 5: Create SSOP for cleaning floor scale stored in the area.
CAPA 6: Create dedicated cleaning paths for warehouse to ensure cleaning from lower risk to higher risk.
CAPA 7: Determine specification range for mop used for cleaning.
CAPA 8: Determine if mop head is appropriate tool for cleaning area.

During the walk-through inspection of the facility, the areas of the facility where the firm had positive environmental sample for Cronobacter were visually inspected without comment. I verified that the CAPA's described in the Environmental Positive Investigation Forms for EMP 24-002 and EMP24-004 were implemented.

Deviations

Other Areas Covered

The firm has a written procedure for handling deviations titled, "Event Reporting and Investigation Procedure" (QUAL-4509.05-WI) that provides instructions for event initiation, investigation, and for process and product related events that could potentially impact the safety, purity, quality or nutritive (SIPQN) value of a component, in-process material, or product **(EX. 15).**

The Director of Quality is immediately notified of any deviations during manufacturing and is responsible for making a decision to stop production and make immediate decision to place the material on hold and/or segregate the material pending an investigation, and for making a final disposition decision.

The firm assigns an event reporting and investigation number to each event and documents events and event investigations in the Event Reporting and Investigation Form ("ERIF"). The completed ERIF is printed on colored paper and placed in the batch record so that it can be reviewed as part of the final batch record review before release of the batch.

Events are logged in an "Event Reporting Tracking Log". The Event Reporting and Investigation Procedure has a list of defect codes for coding events by event types and the Director of Quality (or designee) is responsible for tracking and trending events based on the defect codes (**see EX. 15, page 6 for list of defect codes**).

Events are categorized as atypical, minor, major, critical. Minor events are events or conditions that are not likely to adversely affect the SIPQN of a product, function of a system, adequacy of a process, or adequacy of documenting, but is a departure from accepted procedures, practices, regulations, and guidelines that cannot be verified with other documentation or visual verification.

Major events are events or conditions which will likely adversely affect the SIPQN of a product, function of a system, adequacy of a process, or adequacy of documenting, if allowed to continue.

Critical Events are events or conditions which will likely adversely affect the SIPQN of a product, function of a system, adequacy of a process, or adequacy of documenting, if allowed to continue. Critical events may include a breakdown of control(s) at a critical point, pre-requisite program or other process step and are judged likely to cause a significant public health risk whereby food safety or compliance is compromised, and product may be considered to be adulterated or misbranded.

The firm provided a list of all deviations since the previous inspection (**EX. 16**). The events are listed by event criticality/category (Major, Minor or Critical), and the list includes a brief description of each event. Since the previous inspection there were a total of 137 events, of which 76 were categorized as major, 61 were categorized as minor and none were categorized as critical**.**

The following is a description of the major deviations that were selected for review:
Event Number: E24-089
Date of Event: 12/23/24
Description of Event: Lactoferrin results for composite were 22.7 mg/100kcal (acceptance range (b) (4)).
See EX. 17.

Event Number: E24-076
Date of Event: 10/21/24
Description of Event: Routine testing of infant formula canned lots showed some results for folic acid did not meet the canned finished powder release specifications.
See EX. 18.

Interventions

The firm has a written procedure for handling interventions titled "Interventions into Product Contact Zones" (PROD-4310-SOP) that contains procedures to follow when interventions into product contact zones to minimize the risk of contamination of product.

Other Areas Covered

The written defines product contact zones and non-product contact zones and the procedure

The firm documents the amount of time (start and end time) from when the system is opened until it is closed. Equipment that is removed as part of an intervention is cleaned and sanitized and (b) (4) swabbing of the equipment is conducted prior to the equipment being reinstalled.

The firm documents interventions in the document titled "Verification of Product Contact Zone Intervention Form" (PROD-4310.01-FM). The form is attached to the Master Batch Record of the product that was manufactured at the time of the intervention and the form is reviewed as part of the batch record release procedure.

During the inspection I requested all intervention(s) that were conducted by the firm since the previous sanitation break. During this time the firm had one intervention (documented as "PI-25-017-BHP"). The record was reviewed without comment or observation.

Water Events

The firm has a written procedure for handling of water events titled, "Facility Water Leak Control and Cleaning" (MAIN-4414-SOP) that describes the procedures to control, repair, clean and conduct environmental swabbing in the event of leaks (**EX. 19**).
In the event of an internal leak, the firm will quarantine the affected area and conduct (b) (4) swabbing. The firm conducts a minimum of (b) (4) swabs (b) (4) of the following pathogens: Listeria, Salmonella, Cronobacter. After collecting (b) (4) swabs, the firm will clean and sanitize the area and collect at least (b) (4) additional swabs for (b) (4) to ensure no pathogens of concerns (Listeria, Cronobacter, Salmonella) are present in the area.

In the event of an external leak, the firm will cordon off the area with "caution tape" and conduct (b) (4) (b) (4) swabbing. The firm will collect a minimum of (b) (4) swabs (b) (4) of the following pathogens: Listeria, Salmonella, Cronobacter. After collecting (b) (4) swabs, the firm will clean and sanitize the area, and QA will collect at least (b) (4) swabs for (b) (4) to ensure no pathogens of concerns (Listeria, Cronobacter, Salmonella) are present in the area.

After receiving the results of swabbing QA will conduct a risk assessment and make a disposition of potentially impacted product or materials.

Since the previous inspection, there were two water events in (b) (4) (b) (4) area and are described as follows:

Event Number: L-24-005
Location: (b) (4) (b) (4) hallway and mezzanine above (b) (4) (b) (4) hallway.
The firm followed the written procedure as previously described above and (b) (4) and (b) (4) swabs were collected and were found to be negative. The root investigation revealed water entered the (b) (4) (b) (4) hallway and mezzanine above the (b) (4) (b) (4) hallway from an air conditioning condensate drain line located on the mezzanine. This water event occurred during a sanitation break and the firm's risk assessment determine no product was impacted by the event.
See EX. 20.

Event Number: L-24-006
Location: (b) (4) room hallway and mezzanine.
The firm followed the written procedure as previously described above and (b) (4) and (b) (4) swabs were collected and were found to be negative. The firm's investigation revealed water from an air conditioning unit located on the roof entered the facility through a duct. Further investigation revealed a P-trap on the AC unit was installed incorrectly causing water flow into through ducting located in an interior wall.
Risk Assessment: The firm's risk assessment determine the risk to product was low.
See EX. 21

Other Areas Covered

Supply Chain Program/Receiving/Review & Release of Ingredients & Components

Supplier approval and ordering of all ingredients and components is conducted by ByHeart corporate. According to the firm, a purchase order cannot be generated in the firm's (b) (4) system unless a supplier had been approved by QC. ByHeart maintains a list of approved suppliers for ingredients and components (**EX. 22**).

The firm's hazard analysis did not identify any potential physical, chemical, or biological hazards associated with the ingredients and components it receives for manufacturing infant formula (**see EX. 6 for Food Safety Plan including hazard analysis**).

The firm continues to receive lactoferrin from (b) (4) and bulk infant formula powder from BlendHouse in Allerton IA. Management reported that, since the previous FDA inspection, BlendHouse Portland has not received any bulk infant formula powder from the firm's Reading PA facility.

The firm has a written procedure titled "Ingredients and Packaging Material Receipt and Handling" (WHSE-4201-SOP) that outlines the requirements for receipt, identification, and storage of ingredients and packaging materials (**EX. 23**). The firm also has a written procedure titled, "ByHeart Infant Formula Supply Chain Release" (QUAL-2510-SOP) for receiving ingredients and components that includes receiving ingredients and components only from approved suppliers.

BlendHouse Portland has written specifications for the ingredients and components it receives. For the ingredient lactoferrin, a pre-shipment sample is sent by (b) (4) to a third-party lab for microbiological testing on a (b) (4) basis. For the bulk infant formula powder, the firm receives an authorize release certificate from the supplier.

At the time of receiving a Material Handler inspects the condition of the delivery vehicle which is documented on the "Inbound/Outbound Load Inspection Checklist" (**EX. 24**). The Material Handler will also inspect the ingredient and verifies that the ingredient/components being received are consistent with the purchase order and is from an approved supplier, which is documented on the "Material Inspection Checklist" (**EX. 25**). An ingredient and packaging Status Form is applied to each pallet (if individual packages are received a Status Form is applied to each package). Status Forms are color coded which denotes the status of the component (Yellow – Pending; Blue – QA Sampled; Green – QA Released; Orange – QC Hold; Black – Rejected).

At the time of receipt, all ingredients and components are entered into the firm's (b) (4) system (b) (4) and a randomized lot code is generated for the ingredient/component. The default status when the ingredient/component is initially entered into the (b) (4) system is "QC Pending", which prevents the ingredients and components from being used in production. After QC conducts an inspection of the product and reviews the certificate of analysis the component status is updated in (b) (4) from "QC Pending" to (e.g. "QA Released", "QC Hold", "Rejected" etc.) and a color coded Status Form is affixed to the product container. If an ingredient or component is rejected, the product is status is changed in (b) (4) to "Rejected", a black Status Form is affixed to the product container, the product is moved to the QA cage, and orange tape is wrapped around the product.

Finished Product Release and Distribution

The firm has a written procedure titled "Batch Record Review" (QUAL-4531-SOP) that outlines the procedure and steps for batch documentation review for each lot (production aggregate) of product by BlendHouse Portland (**EX. 26**). The firm has a written procedure titled "ByHeart Infant Formula Supply Chain Release (QUAL-2510-SOP) that describes, in part, the requirements for the release of finished product at all ByHeart Facilities and third-party contractors (**EX. 27**). The firm has a written procedure titled "Finished Product Release (QUAL-2510-03-WI) that describes the process for releasing the finished product to fulfillment centers for commercial distribution (**EX. 28**).

Other Areas Covered

A Production Supervisor or Production Manager is responsible for conducting the initial review of manufacturing documents. A Batch Auditor is responsible for performing the initial quality review of all batch record. A Quality Operations Manager and/or the Director of Quality is responsible for conducting the final review and release of product batches from the third-party warehouse to the firm's contract manufacturer for final packaging. BlendHouse corporate is responsible for the final review and release of the finished product to the customer distribution centers.

A review of the batch production record (referred to by the firm as the "Master Batch Record") for each production aggregate is conducted and includes the following: Certificates of Analysis (COA's) for all components used to manufacture the batch including lactoferrin, base bulk powder, cans, can ends, etc.; results of all environmental monitoring for the (b) (4) during, and three weeks prior to, the date of manufacture; cleaning and sanitation and pre-operation inspections; review of all events, deviations, and interventions into product contact zones; CCP compliance; in-process lab results; COA's for microbiology and nutrients and heavy metals; investigation reports. Once the Batch Auditor has completed the review of the batch the folder is transferred to the Quality Operations Manager and/or the Director of Quality who conducts the final review of the Master Batch Record (**see EX. 31, pgs. 4-7 for a complete list of items reviewed by Quality before releasing the production aggregate for packaging**). For released product, a BlendHouse Portland will issue an "Authorized Release Certificate" (ARC) and COA's for microbiology and nutrients and release the product in the firm's (b) (4) system. If the batch is rejected an Authorized Destruction Notice (AND) is issued and the product is quarantined. Once the ARC is issued, the product is eligible for shipment to the firm's contract manufacturer (b) (4) for the addition of a cap, collar and scoop for cans, and for packaging of the stick packs into pouches. The product is first shipped to BlendHouse (b) (4) third-party warehouses (b) (4) under a hold status. (b) (4) (b) (4) has access to BlendHouse Portland's (b) (4) system and (b) (4) cannot ship product without a bill of lading issued from BlendHouse Portland's Supply Chain. ByHeart Corporate Quality is responsible for the determining the disposition of the finished product (released or rejected) from the contract manufacturer (b) (4) to the distribution centers. For released product, an ARC is generated to authorize the release of the finished product from contract manufacturer (b) (4) to the distribution centers. Rejected product is quarantined and an Authorized Rejection Notice (ARN) is issued, and a certificate or documentation of destruction is required for all rejected finished product.

The firm does not release any finished product until results of zone (b) (4) wabbing collected during a sanitary break have been completed. Environmental Monitoring Program (QUAL-4510-SOP) states (b) (4)

(**EX. 8**).

Finished Product Microbiological and Nutrient Testing

The firm has a written procedure titled "ByHeart Canned Infant Formula Powder Microbiological Sampling Plan" (QUAL-4512.06) that outlines the microbiological testing sampling plan for infant formula powder manufactured at BlendHouse Portland.

The previous establishment inspection report (EIR) describes the quantity of cans that are pulled during production for finished product microbiological testing of canned product (see previous EIR).

The firm has a sampling plan for collecting representative samples that describes the quantity and frequency of stick pack samples to be collected for finished product testing for microbiological testing, nutrient testing, quality indicators, and stability testing (**EX. 29**). The firm collects a total of (b) (4) 17 gram stick packs for microbiological testing and (b) (4) 17 gram stick packs for nutrient testing.

The following is a description of the microbiological testing conducted (b) (4) aggregate of stick packs: *Cronobacter* spp.; *Salmonella* spp.; Listeria spp.; Coagulase positive *Staphylococcus aureus; E. Coli*/Coliform; *E. coli* – Enrichment; *Bacillus cereus;* and aerobic plate count.

Stick packs are tested for nutrients per 21 CFR 107.100, including added nutrients (lactoferrin, arachidonic

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acid, docosahexaenoic acid and galactooligosaccharides).

The firm has finished product release specifications and release criteria for that describes the sample sizes, sample frequency and analytical testing methods for both microbiological and nutrient testing of the finished product that was collected for canned product (**EX. 30**).

A review of the finished product microbiological and nutrient testing for seven production aggregates of stick pack product that were covered
during the inspection was conducted without comment or observation (see section titled, "**Batch Record Review**" results of the review).

According to firm management, the firm has never had in-process material or finished product test positive for *Salmonella* spp. *Cronobacter* spp.

The firm's Environmental Monitoring Program (QUAL-4510-SOP) states, "(b) (4) (b) (4) (**EX. 8**).

Ms. Whitesell, explained that, if a product tested positive for a pathogen the firm would: notify the U.S. FDA even if the product did not leave the firm's control; conduct a comprehensive root cause analysis; and all product within a sanitation break would be destroyed. If any root cause analysis is dispositive, the firm would engage FDA ahead of any disposition decision. If any product is positive for Salmonella, Cronobacter or Listeria, (b) (4) would be conducted and the results of which will be shared with the U.S. FDA.

Batch Record Review

The inspection included a comprehensive review of seven master batch records (each master batch record representing a production aggregate) of the product Organic Milk-Based Infant Formula Stick Pack (206-VA). According to Lori Boyd, the first production date of stick pack manufacturing was (b) (4). At the time of the inspection the firm had manufactured (b) (4) production aggregates of the stick pack infant formula product. The first (b) (4) production aggregates of stick packs were part or the R&D production qualification protocol for the system development. The seven master batch records selected for review were of the seven most recent production aggregates manufactured.

The firm follows a written master manufacturing order that covers each point, step, or stage in the manufacturing process (b) (4); filling; packaging). The firm also has standard operating procedures that contain instructions for each point, step or stage in the manufacturing process for operators to follow. Batch production records are issued to operators at each, point, step, or stage of manufacturing to record in-process controls and production parameters. Manufacturing and packaging operations are documented in the (b) (4) Batch Record (PROP-4312.01-MI); (b) (4) Log (PROD-4312.02-FM); (b) (4) Room BR-Warehouse (PROD-4312.03-MI); (b) (4) Room BR-Production Stick Pack (PROD-4312.16-MI); (b) (4) Room (b) (4) Warehouse (PROD-4312.15-MI); Final Packaging BR-Production Stick Pack (PROD-4312.17-MI); Cardboard Shipper Use Tracking log (PROD-4312.18-MI); (b) (4) Liner Tracking Log (PROD-4312.48-MI).

The review included a review of all deviations and deviation investigations. As previously noted, deviations are reviewed by Quality before releasing the batch to (b) (4) for final packaging. See the section in this report titled "**Finished Product Release and Distribution**" for a description of the firm's procedure for releasing product for final packaging, and for releasing the packaged product for distribution to consumers. Also see section titled "**Deviations**" that describes the firm's procedures for handling of deviations. At the time of the inspection none of the (b) (4) batches of product manufactured by BlendHouse Portland since (b) (4) had been released by ByHeart Corporate for distribution to consumers.

During the inspection a review of the complete batch production records for the following production

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aggregates were reviewed without comment or observation:
(b) (4)

A complete master batch record for production aggregate (b) (4) was collected (**EX. 31**).

Expiration Dating, Stability Testing, Retained Samples, Out of Date Retail Product

Expiration Date

The base powder is received by BlendHouse Reading with a date of production and a best by date. Canned infant formula has a shelf life of (b) (4) from the date of packaging and stick pack products have a shelf life of (b) (4) from the date of packaging.

Stability Testing

For infant formula packaged in cans, the firm collects (b) (4) cases (b) (4) production (b) (4) (b) (4) for stability testing at time (b) (4) The firm has ongoing stability testing of nutrients in the (b) (4) of canned product produced at BlendHouse Portland (lot 232071P2). The product was tested at time (b) (4) (**see EX. 32 for results of stability testing**).

The first batch of stick pack products were manufactured on (b) (4) therefore, at the time of the inspection, the firm did not have ongoing stability testing of the first product packaged in stick packs.

Retained Samples

For infant formula packaged in cans, the firm collects (b) (4) trays from (b) (4) as a retained sample. Retained samples are held for (b) (4) past the expiration date and are stored under ambient conditions.

For infant formula packaged in stick packs, the firm has a sample pull spreadsheet that describes the frequency and quantity of stick packs to be pulled from the production line for the purpose of testing the products for microbiological contaminants, nutrients, stability, quality indicators and retained product samples (**EX. 29**).

Out of Date Retail Product

Firm management explained that out-of-date product still on the retail market, expiration dates are periodically checked by the product retailers, and any expired product would be destroyed, and the retailer reimbursed for the cost of expired product that is destroyed.

Stick Pack Process Qualification

The firm conducted a process qualification to confirm that the manufacturing process for the (b) (4) (b) (4) used to dispense powdered infant formula into stick packs, and the (b) (4) (b) (4) equipment and process consistently produce products that meet their pre-defined quality standards. The process qualification was conducted using the (b) (4) production aggregates of stick pack products manufactured (b) (4) The report concluded that the process qualification process "*demonstrated that the capability of the packaging system to consistently meet predefined quality criteria and operational requirements*" and that "*the packaging process is repeatable, and capable of consistently delivering products that adhere to the highest quality standards*" (**see EX. 33 for Process Qualification Report**).

Transportation and Storage

The firm has a written procedure titled, "Requirements for Storage and Transport" (QUAL 2505.01-SOP) that establishes specifications for the storage and transportation conditions of ByHeart ingredients, packaging, infant formula powder in bulk and canned product to protect the product from physical,

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chemical, and biological hazards, including temperature and humidity excursions (**EX. 34**).

Base powder from BlendHouse Allerton, IA is shipped in totes in refrigerated trucks to (b) (4) facilities located at (b) (4)

(b) (4) ' facility is not climate controlled, however, the temperature (but not humidity) at the facility is monitored, and BlendHouse Portland receives (b) (4) updates from (b) (4) on the temperature monitoring. The base powder is transported in non-refrigerated dry trucks from (b) (4) (b) (4) to BlendHouse Portland.

The canned infant formula and infant formula in stick packs are shipped on non-refrigerated dry trucks from BlendHouse Portland to (b) (4) after product (b) (4) for production completed on (b) (4)

Cans and stick packs are normally shipped from (b) (4) tc (b) (4) on refrigerated trucks. If the product is shipped in non-refrigerated dry trucks, temperature data loggers are shipped with the product and Director of Quality at BlendHouse Portland reviews the temperature collected from the temperature data loggers for temperature excursions.

There are no components received by BlendHouse Portland that require time and temperature controls to prevent microbial growth and toxin formation and the components and finished product are considered shelf stable.

The product data sheet for the product (b) (4) , provided by the manufacturer (b) (4) list the following storage conditions "Store in a cool, (b) (4) below (b) (4)° C (b) (4)°F) (b) (4) %" (**EX. 35**).

The storage requirements for the bulk intermediate infant formula powder is (b) (4) °F and (b) (4) % (b) (4) Bulk intermediate infant formula can be held under these conditions for up to (b) (4)

The storage requirements for the finished product in Cans/Stick Packs is (b) (4) °F and (b) (4) % (b) (4) for (b) (4) (b) (4)

Since the previous inspection, BlendHouse Portland conducted a Temperature Monitoring Study of its facility. Temperature monitoring devices with data loggers were placed throughout the warehouse in (b) (4) risk (adjacent to (b) (4) , risk and (b) (4) risk areas (**see EX. 36 for map with temperature monitoring device locations**). The study was conducted over (b) (4) time periods (b) (4) At the time of the inspection, the firm had not completed the study. Based on the data collected from the study, there was no period where the temperature was between (b) (4) °F for (b) (4) (b) (4) (see **EX. 37 for aggregate temperatures of all monitoring devices**).

During the summer months the firm holds the component lactoferrin in the (b) (4) room*. In addition, during the summer months the firm keeps only (b) (4) worth of bulk intermediate infant formula powder on hand and keeps the rest of the product at the firm's third-party logistics warehouse. While the third-party logistics warehouse is not air conditioned, the facility is larger than the BlendHouse Portland facility and has lower ambient temperatures in the summer months compared to BlendHouse Portland.

*The (b) (4) room is an enclosed room located in the warehouse that is temperature controlled via an air conditioner. The (b) (4) room was initially designed/built for the purpose of (b) (4) but has never been used by the firm for (b) (4) and the (b) (4) room is maintained as a dry environment.

Internal Audits

The firm has a written procedure for conducting audits titled, "Audits" (QUAL-4504-SOP) that outlines the plant auditing program to be completed in accordance with 21CFR 117 and 21CFR 106 (**EX. 38**). The firm also has a written work instruction titled, "Plant (b) (4) Auditing Program" (QUAL-4504.01-WI) that covers the areas of the plant to be audited (b) (4) that was reviewed without comment. The firm maintains a (b) (4) Register of Area GMP Audits that covers each area of the plant to be audits on a

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(b) (4) basis and is used by the firm for documenting the completion of the (b) (4) audits (**EX. 39**). Audit areas includ (b) (4) The written SOP, work instruction and (b) (4) Register of Area GMP Audits were reviewed without comment.

The audit program covers all procedures and processes subject to audits and audits are conducted (b) (4) against 21 CFR 106 & 107.

The Regulatory Compliance Manager is responsible for overseeing quality compliance, including internal audits. The Quality Control Auditor is responsible for internal auditing.

Auditors have knowledge and experience in the quality process and process controls methods related to the scope of the audit and have no direct responsibilities for matters that are the subject of the audit and no interest in the outcome of the audit.

Audits include direct observation and record review of the area being audited.

The major and critical observations, that are observed during internal audits, are discussed with management during (b) (4) quality review meetings.

Calibrations

The firm has a written procedure for the calibration of equipment titled "Calibration Procedure" (MAIN-4400-SOP) that establishes the requirements for calibration of instruments and equipment and associated standards that affect, may affect or are used to determine product quality and to ensure compliance with the calibration procedures (**EX. 40**).

According to the Calibration Procedure, the Maintenance Supervisor, or designee, is responsible for overseeing the calibration program; maintaining a list of equipment requiring calibration; generating CAPA's; and establishing a calibration schedule. A discussion was held with firm management regarding identification of critical equipment for the purpose of notifying QA so investigations and risk assessment of affected product can be conducted when critical equipment is found to be out of calibration/out of tolerance (**See sections titled, "ADDITIONAL OBSERVATIONS" and GENERAL DISCUSSION WITH MANAGEMENT for the discussion with firm regarding identification of critical equipment**).

The following routine equipment calibrations were reviewed and were found to be within tolerance::

- (b) (4) equipment (b) (4) used for the cans and (b) (4) equipment used for stick backs (calibration date 01/28/25)
- (b) (4) (calibration date 03/07/25)
- (b) (4) Rods (calibration date 01/23/25)
- Stick Pack (b) (4) (03/07/25)
- Can (b) (4) (04/22/24)

The following equipment calibrations were reviewed during the inspection and found to be out of tolerance at the time of the calibration:

- On 03/15/24, the firm opened an investigation after an operator observed the blend (b) (4) displayed on the HMI for the blender was not consistent with the amount of base powder deposited into the blender (**see EX. 41. for Event Report Investigation Report for event Number 24-017**). The (b) (4) on the blender were calibrated on 04/15/24 and were found to be out of tolerance (**EX. 41, pg 8**). The firm's investigation revealed that the hardware on

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the blender mounting brackets were loose. The firm tightened the hardware on the mounting brackets. The firm implemented a (b) (4) preventive maintenance to inspect and tighten the mounting hardware on the blender mounting brackets. From the time the issue was observed on 03/15/24, to the time the blender was calibrated on 04/15/24, a total of (b) (4) batches (production aggregates) were manufactured using the blender. The firm conducted a risk assessment of the (b) (4) batches and determined that no product was adversely affected by the blender being out of tolerance.

Food Contact Air/Gases

The firm has a written procedure titled, "(b) (4) Air Quality Sampling" (QUAL-4510-WI) that describes the procedure for sampling of (b) (4) air and gases that directly or indirectly contact food product for microbiological and physical contamination (**EX. 42**).

The filter for the (b) (4) gas on the (b) (4) line is (b) (4) microns. The filter on the (b) (4) (b) (4) can (b) (4) and (b) (4) can (b) (4) is (b) (4) microns. (b) (4) air that supplies air to the (b) (4) used for cleaning during sanitary breaks is (b) (4) microns.

The firm tests (b) (4) air for microbiological contaminants (APC, Yeast and Mold) (b) (4). The samples are collected (b) (4) and are sent to a third-party laboratory. The most recent test results for (b) (4) air used on the (b) (4) machine, (b) (4) tank, (b) (4) tank, can (b) (4) and can (b) (4) that was conducted on 12/17/24 were reviewed by me without comment or observation.

The firm also collects a sample of (b) (4) gas (b) (4) and tests for contaminants (b) (4) (b) (4) and for purity (percent (b) (4)

Pest Control

The firm has a written procedure titled, "Pest Management" (SAN-4711-SOP) that describes the firm's pest management program to protect the facility from ingress of pests and to minimize the risk of pest infestation in and around the facility that. The procedure was reviewed without comment.

The firm uses a third-party pest management firm to conduct inspections of the facility and to service pest stations. The interior of the facility has rodent stations (traps), insect light traps (ILT's) to control flying insects, sticky traps for crawling insects and pheromone traps to control for beetles. The exterior of the facility has rodent baits stations. The pest management company inspects the plant (b) (4) Interior rodent stations are serviced (b) (4) and exterior rodent stations are serviced (b) (4).

The Food Safety Manager meets with the Pest Control Operator (from the pest management company) to review observations and records after (b) (4) services are conducted. The Pest Control Operator provides (b) (4) trending reports for the analysis of pest activity throughout the plant.

During the inspection the (b) (4) pest inspection reports from (b) (4) were reviewed without comment. During this time no rodent activity was reported on the interior of the facility and minimal to no activity was reported in the ILT's and the insect sticky traps.

Quality Growth Factors

The clinical study showing the firm's infant formula, *ByHeart Whole Nutrition Infant Formula with Iron,* meets the requirements for quality growth factors set for in 21 CFR 106.96 was included with the firm's submission for its infant formula and is retained on file at the firm's corporate headquarters.

Plant Report

Submission Reference #BH9: ByHeart
On 10/11/24, ByHeart submitted a formulation change, whereby the firm proposed adding lactoferrin at the (b) (4) phase (as opposed to the process of adding lactoferrin in the (b) (4) phase). The submission included changes to the quantitative formulation, and changes to the nutrient label declarations

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for vitamin D, inositol, and manganese. According to the Senior Director of Manufacturing, William Thomas, the formulation changes described in the submission have not been implemented but probably will be implemented in the next few months. **See Attachment 2 for Plant Report**.

Tables and Figures

Table: Answer_67_1

Test	Method	Specification
Aerobic Plate Count	Aerobic Plate Count (b) (4) (AOAC -(b) (4) (b) (4)	(b) (4) CFU(b) (4)
Salmonella spp.	Salmonella spp. Detection (swab) (b) (4)	Absent
Listeria spp.	Listeria spp. (b) (4) (AOAC-RI #(b) (4))	Absent
Cronobacter spp. detection (swab): (b) (4)	Cronobacter spp. Detection (swab) (b) (4)	Absent

MANUFACTURING CODES

The firm has a written procedure for product coding and traceability titled, "Product Coding and Traceability" (QUAL-4519-SOP). **See EX. 43 for SOP**.

All products made at BlendHouse Portland are labeled with a unique identifying code that allows the firm to traceback the product code of a finished product to the ingredients and packaging components that were used to manufacture the batch of finished product.

Product Codes/Lot Codes and Use By dates for Cans and Stick Packs
The product code and use by date for cans is laser jet coded onto the can bottoms, and the product code and use by date for stick packs is ink jetted onto the roll stock as it passes through the (b) (4) machine.

Each product code/lot code is comprised of (b) (4) parts: The (b) (4)

The Use By Date is comprised of (b) (4)

Canned products have an expiration date that is (b) (4) from the date of packaging and stick pack products have an expiration date that is (b) (4) from the date of packaging.

RECALL PROCEDURES

The firm has a written recall plan titled "Product Recall Plan" (QUAL-4526-SOP) that describes the procedure for conducting product recalls **(EX. 44)**.

The recall plan includes procedures for conducting mock recalls. Mock recalls can be based on the premise that an ingredient supplier provided a material with a defect that was used in production, or it can based on a finished product that was inadvertently released with a defect. The recall plans include instructions for notification of FDA per 107.240(a). BlendHouse Portland has never had to conduct a product recalls.

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	You did not maintain a certification of accuracy of a known reference standard that was used and a history of recertification.
Observation Details	The firm's written procedure "Calibration Procedure" (MAIN-4400-SOP) states calibration is the responsibility of the Maintenance Supervisor, and that, Quality Assurance "*is responsible for reviewing calibration forms, frequencies, and tolerances for all calibrated GMP critical devices*", but the firm does not maintain a list of devices that are considered critical.
Citation Reference	21 CFR 106.100(f)(2)
Correction Status	No Firm Response Submitted

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

On 03/25/25, a discussion was held with Lori Boyd regarding the firm's written procedure titled, "Calibration Procedure" (MAIN-4400-SOP) which states that calibration is the responsibility of the Maintenance Supervisor, and that, Quality Assurance "*is responsible for reviewing calibration forms, frequencies, and tolerances for all calibrated GMP critical devices*" (**see EX. 40**). I asked Ms. Boyd if the firm maintains a list of critical devices. She explained that the firm does not maintain a list of critical devices. I also explained to Ms. Boyd that the written procedure titled "Investigation and Root Cause Analysis" (QUAL-2532-SOP), *"outlines the guidance and process for conducting effectiveness investigations, identifying root causes, assessing impact and risk, and producing high-quality investigations reports for deviations*" and that the SOP states, in part, that the procedure applies to calibration and validation variations (**see EX. 45**). I asked Ms. Boyd how Maintenance would know to notify Quality Assurance if a critical device was found to be out of calibration if the firm does not maintain a list of critical devices. On 03/26/25, Ms. Boyd agreed that the calibration procedure was not clear in categorizing what equipment is considered critical and non-critical and she stated that, based on the discussion on 03/25/25, the firm had started revising the Calibration Procedure.

A close out meeting was held with firm management on 03/27/25.

The following personnel were present at the firm during close out meeting: William Thomas, Senior Director of Manufacturing; Katie Whitesell, Senior Director Quality & Food Safety; Robert Esquer, Plant Manager; Lori Boyd, Director of Quality; Jennifer Rigby, Quality Compliance Manager and Byron Bean.

The following personnel joined the close out meeting via video conference call: Niall Mullane, Chief Quality Officer; Marcus Jordan, Vice President and Head of Supply Chain for ByHeart; Annie Piepenhagen,

Senior Director of Quality Compliance and Systems.

During the close out meeting I reiterated the discussion I had with Ms. Boyd regarding the firm's calibration procedure. And I read aloud 21 CFR106.100(f)(2), which states, in part:

> *"If calibration of an instrument shows that a specification at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and any actions that need to be taken with respect to that product, must be made".*

Firm management explained that they would respond to this discussion item in writing.

During the close out meeting, I also explained to firm that infant formula manufactures are required to develop a risk management plan and I reminded them that the document titled, "What to Know About the New Requirement for Manufacturers of Critical Food (Including Infant Formula) to Develop a Redundancy Risk Management Plan (October 2023)" was provided to the firm during the previous inspection.

SAMPLES COLLECTED

Sample Number	**1223862**
Description	Sample #INV1223862, collected on 03/18/25, consists of 25 environmental swabs collected in the (b) (4) room and (b) (4) room. Sample analyzed for *Cronobacter*.
Sample Number	**1223863**
Description	Sample #INV1223863, collected on 03/18/25, consists of 25 environmental swabs collected in the (b) (4) room and (b) (4) room. Sample analyzed for *Salmonella*.
Sample Number	**1290948**
Description	Sample #INV1290948, collected on 03/19/25, consists of 75 environmental swabs collected in the (b) (4) room, (b) (4) room entrance hallway, (b) (4) room, secondary gowning area, and gowning and handwash area. Sample analyzed for *Cronobacter* species.
Sample Number	**1290949**
Description	Sample #INV1290949, collected on 03/19/25, consists of 75 environmental swabs collected in the (b) (4) room, (b) (4) room entrance hallway, (b) (4) room, secondary gowning area, and gowning and handwash area. Sample analyzed for *Salmonella* species.
Sample Number	**1290950**
Description	Sample #1290950, collected on 03/20/25, consists of eight, 17-gram stick packs of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months*. Sample analyzed for HPAIV.
Sample Number	**1291577**
Description	Sample #1291577, collected on 3/20/2025, consists of 60 cases (each containing approximately 200, 17-gram stick packs), of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months*. Sample analyzed for Cronobacter and Salmonella.
Sample Number	**1291578**
Description	Sample #1291578, collected on 03/20/25, consists of 300, 17-gram stick packs, of *Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 months.* Sample analyzed for Nutrients.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Complaint Investigation Complaint Tracking Code 24-040.	8
2	Firms Complaint Investigation Complaint Tracking Code 24-059.	25
3	Pouch Outer Package Label_Stick Pack Foil Stock Label.	4
4	ByHeart Marketing Material.	2
5	Hygiene Area and Traffic Pattern Program QUAL-4530-SOP.	16
6	Food Safety Plan. 73 pgs.pdf	73
7	DrySan Tri-O technical data sheet.	2
8	Environmental Monitoring Program QUAL-4510-SOP.	8
9	Environmental Surface Sampling QUAL-4510.07-WI.	16
10	Environmental Monitoring Master Site List.	9
11	Visual Aid for Stick Pack Swab Locations.	18
12	Environmental Monitoring Postive Response Action Plan QUAL-4510.06-WI.	7
13	Environmental Positive Investigation Form EMP 24-002.	16
14	Environmental Positive Investigation Form EMP 24-004.	24
15	Event Reporting and Investigation Procedure QUAL-4509.05-WI.	8
16	EX. 16. List of Deviations Since Previous Inspection. 6 pgs.pdf	6
17	EX. 17. Event E24-089. 7 pgs.pdf	7
18	Event E24-076.	37
19	Facility Water Leak Control and Cleaning MAIN-4414-SOP.	5
20	Event L-24-005.	29
21	Event L-24-006.	33
22	ByHeart Approved Supplier List - Ingredients and Components.	4
23	Ingredients and Packaging Material Receipt and Handling WHSE-4201-SOP.	4
24	Inbound Outbound Load Inspection Checklist.	3
25	Material Inspection Checklist.	1
26	EX. 26. Batch Record Review QUAL-4531-SOP. 7 pgs.pdf	7
27	By Heart Infant Formula Supply Chain Release. QUAL-2510-SOP.	8
28	Finished Product Release QUAL-2510.03-WI.	9

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
29	Sample Pull Spread Sheet Finished Product_Retains_Stability.	1
30	Infant Formula Canned Finished Product Release Specifications 206-VA.	4
31	Batch Record (b) (4) .	352
32	Ongoing Stability Testing of Lot 232071P2.	1
33	Process Qualification Report for (b) (4)	23
34	Requirments for Storage and Transport.	5
35	(b) (4) Lactoferrin Product Data Sheet.	1
36	EX. 36. Temperature Monitoring Device Locations for Temp Mapping Study. 1 pg.pdf	1
37	Aggregate Temp of All Monitoring Devices.	3
38	Audit Program.	8
39	(b) (4) Register of Area GMP Audits.	20
40	Calibration Procedure MAIN-4400-SOP.	7
41	Event E24-017.	8
42	(b) (4) Air Quality Sampling.	5
43	Product Coding And Traceability SOP.	4
44	Product Recall Plan QUAL-4526-SOP.	14
45	Investigation and Root Cause Analysis SOP QUAL-2532-SOP.	29

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
	Inspection Narrative Report (Uploaded)	30
	Coversheet PDF Document for Inspection= 293389	
1	Form FDA 482 - Notice of Inspection.	3
2	Blend House Portland Plant Report FEI 3013670080.	3
3	Attachment A BlendHouse Portland FEI 3013670080.	5
4	ATT. 4 Attachment B for ByHeart Stick PAcks 206-VA-BP.	15
5	Consumer Complaint 188454 Memorandum.	1

SIGNATURE

Gerard D Difiore
Investigator
Signed By: Gerard D. Difiore -S
Date Signed: 06-03-2025 16:05:03

Desiree C Iya
Investigator
Signed By: 2001641778
Date Signed: 06-03-2025 13:43:32

Delanie M Browning
Investigator
Signed By: Delanie M. Browning -S
Date Signed: 06-04-2025 09:21:13

Jeffrey J Leclair
Investigator
Signed By: Jeffrey J. Leclair -S
Date Signed: 06-04-2025 09:31:01