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SUMMARY

Inspection	
Operation ID and Name	283562: FY 24 Domestic and Foreign Schedule of Inspections/Sample Co

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'24 Schedule of Inspections/Sample Collections for Infant Formula (7321.006) and Medical Foods (7321.002) Programs, DFPG #24-03, FACTS #12313588, and eNSpect OP ID #283562. The inspection included coverage of 21 CFR 117, subpart G – Supply Chain Program.

This was the initial inspection of BlendHouse Portland. The inspected facility was previously operated as "Cascadia Nutrition". The previous inspection of Cascadia Nutrition was conducted from 06/04/18-06/05/18, and it was the initial inspection of the firm. The previous inspection revealed Cascadia Nutrition operated as a manufacturer of powered infant formula for export only. At the close of the pervious inspection, no Form FDA-483, Inspectional Observations was issued to the firm. On 01/09/23, ByHeart purchased the business, including the facility, and at no time did ByHeart operate as, or commercialize any of Cascadia Nutrition's products.

At the time of the inspection, the firm was in the second of a (b) (4) scheduled shutdown. The firm stopped operations on 04/05/24 and planned to resume operations on (b) (4). The purpose of the shutdown was for (b) (4) line for powdered infant formula. The firm management explained they plan to pilot the (b) (4) (b) (4) line and estimates that commercial production could begin in the next (b) (4) months. Firm management stated they are aware a (b) (4) format for infant formula may constitute a major change that is required to be reported to FDA.

BlendHouse Portland currently manufactures (b) (4) infant formula product for the firm's parent company ByHeart (New York, NY). 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 facilities (BlendHouse Allerton, IA and BlendHouse Reading PA) (b) (4) the base powder with lactoferrin, and filling cans. The canned product is sent to the firm's co-packer, (b) (4), for the addition of a cap, collar, and scoop. The finished product is sent from (b) (4) to (b) (4) for distribution to stores, and to 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 (b) (4). BlendHouse Portland anticipates they will resume receiving base powder from BlendHouse Reading in (b) (4) of (b) (4).

The inspection included a review of the following: complaints/complaints procedure; sanitation; environmental monitoring; deviations; water events; supply chain controls; product release and distribution; finished product microbiological and nutrient testing; transportation and storage of base powder and finished product; internal audits; water quality; air and gases; expiration dating; stability testing; retained

Summary

samples; equipment calibration; blending validation; allergens; and pest control. The inspection also included a comprehensive review of seven batch production records. The inspection also included a follow up to consumer complaint #170282 received by FDA on 09/21/21 when the facility was owned and operated by Cascadia Nutrition.

No Form FDA-483 – Inspectional Observations was issued at the close of the inspection. There was one discussion item related to the following: The point of use (b) (4) for air used at the "(b) (4)" (b) (4) and the point of use (b) (4) for the (b) (4), were equipped with (b) (4). The firm immediately corrected this discussion item by replacing both (b) (4) with (b) (4), and on 05/17/24, the firm also provided a written response to this discussion item.

Sample #1199544, consisting of 60, 24-ounce subs of ByHeart powdered infant formula, was collected on 04/24/24 for microbiological analysis (Cronobacter and Salmonella). Sample #1199545, consisting of 12, 24-ounce subs of ByHeart powdered infant formula, was collected on 04/24/24 for nutrient analysis.

There have been no major changes to the production process, equipment or product since the firm submitted its 90-day pre-market notification.

Attachment B - Infant Formula Nutrient Information Reporting Form, was completed.

(b) (3) (A) . FDA guidance material were provided to firm management.

There were no refusals, and a reconciliation exam was not conducted.

This establishment inspection was written by Gerard D. DiFiore, Jeff J. LeClair (JJL) and Miles D. Foster. The following subsections were written by Jeff J. LeClair (JJL): Sanitation; Internal Audits; Water Quality; Firm's Training Program; Air Quality Monitoring. The following sections were written by Miles D. Foster (MDF): Recall Procedures; Manufacturing Codes; Pest Control. All other sections of this EIR were 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 Discussion Items Not on FDA Form 483 - Current Inspection

CFR Number	Citation Text	Correction Status
21 CFR 106.30(g)	You did not install a (b) (4) capable of retaining (b) (4) is used at a product filling machine.	Corrected & Verified

Correction Statuses current at time report was signed.

Consumer Complaints Review

Follow-up on FDA Received Complaints

The inspection included a follow up to FDA Consumer Complaint 170282 received on 09/21/21. The complainant reported purchasing a product called Dose & Co Pure Collagen unflavored collagen peptides. The ingredient label says the serving size is 2 teaspoons and it provides 11 grams of protein. The complainant believes this is false and that the product is mislabeled. Complainant believes this because other similar products reflect (b) (4) grams of protein per (b) (4) of product. A discussion was held with firm management who explained that ByHeart purchased the firm, including the facility, on 01/09/23 and at no time did ByHeart operate as, or commercialize any of, Cascadia Nutrition's business or products and therefore, individuals interviewed explained they could not provide a response to this complaint.

ByHeart Complaints

Complaints are received by ByHeart corporate. ByHeart 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 (**EX. 4**).

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 initiated through ByHeart’s Parent Experience Team. 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 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.

Complaints are initiated through ByHeart Customer Experience Group and are reviewed by ByHeart’s Pharmacovigilance Group (PVG). 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.

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, which were described by the Director of Pharmacovigilance as health-related complaints that include the following: hospitalization; prolongation of hospitalization; death; life threatening; disability; or anything that would require significant medical intervention.

Consumer Complaints Review

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

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 Pharmacovigilance Group identifies (b) (4) complaint records with a relatedness assessment of related or possibly related to a particular batch, then the Pharmacovigilance Group will notify Quality that the threshold has been met and the batch may require further investigation.

(b) (4) per (b) (4) the Chief Medical Officer, or designee, reviews all health-related complaints received to identify any possible aggregate safety signal.

From 07/31/23 – 04/23/24, ByHeart received a total of (b) (4) health-related complaints of which three complaints were categorized at serious. All three of the complaints involved hospitalization. Two of the three complaints were categorized as milk protein allergies and one complaint was categorized as an allergy (not otherwise specified).

The firm trends the number of complaints per (b) (4) units sold. From 07/31/23 – 04/23/24 there were (b) (4) health related complaints per (b) (4) units sold ((b) (4)) and there were (b) (4) quality complaints per (b) (4) units sold (b) (4)).

BlendHouse Portland Complaints

BlendHouse Portland has a written procedure titled "Complaint Management Program" (QUAL-4514-SOP) that describes ByHeart's procedure for receipt, handling and investigating complaints (**EX. 5**).

From 07/31/23 – 04/23/24, there were (b) (4) complaints forwarded from ByHeart to BlendHouse Portland that required further investigation. (b) (4) of the complaints were related to reports of foreign material in the finished product and (b) (4) complaint was related to rust on the can collar. None of the complaints were health related.

The following four complaints were selected for review of the BlendHouse Portland's complaint investigation reporting:

Complaint 24-015 (batch code 232641P2).

The complainant reported finding a green, paper like material in a container of infant formula. The firm conducted a root cause analysis and investigation into the complaint. The firm was unable to determine the source of the foreign material and determined it was unlikely to have come in on the base powder, or that it was introduced into the product during blending/packaging at BlendHouse Portland, as the foreign material would have been collected at the (b) (4) in the (b) (4) room where bulk bags are unloaded or at the (b) (4) located at the filler.

Complaint 24-018 (batch code 232631P2)

The complainant reported finding a "mold like" foreign material at the bottom of a can of infant formula. The firm conducted a root cause analysis and investigation into the complaint. BlendHouse Reading received the foreign material, inspected it, and sent it to a laboratory ((b) (4)) for identification and

Consumer Complaints Review
analysis. The laboratory reported the substance to be a blue, sugar based gummy candy like product. The firm was unable to determine the source of the foreign material and determined it was unlikely to have come in on the base powder, or that it was introduced into the product during blending/packaging at BlendHouse Portland, as the foreign material would have been collected at the (b) (4) in the (b) (4) room where bulk bags are unloaded or at the (b) (4) located in the (b) (4) room at the filler. **Complaint 24-019 (batch code 232371P2)** The complainant reported observing rust around the can collar upon opening a can of infant formula. The firm's investigation included reviewing can receiving records, can storage conditions, and general condition of the facility, which is dry. The firm was unable to determine the source or cause of the rust on the can collar. There were no similar complaints received by the firm. **Complaint 24-022 (batch code 232831P2)** The complainant reported finding a "moon-shaped" plastic particle in a can of infant formula. The firm's investigation included reviewing the batch production records to determine that the foreign material controls were working as intended. Foreign material controls include, but are not limited to, (b) (4) (b) (4) (b) (4) (b) (4); a (b) (4) located in the (b) (4) room where bulk bags are unloaded and a (b) (4) located in the (b) (4) room at the filler that are visually inspected (b) (4). The firm concluded the source of the foreign material as "unknown" and that it was unlikely the source of the foreign material was from inside within BlendHouse Portland given the foreign material controls that are in place in the manufacturing process.

Inspection Samples	
Sample Number(s)	1199544; 1199545

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)	4/22/2024, 4/23/2024, 4/24/2024, 4/25/2024, 4/26/2024

FDA Inspection Participants
Participant Name and Title
Jeffrey Leclair, Investigator
Jose Caraballo Rivera, Investigator
Miles Foster, Investigator
Gerard Difiore, Investigator

FDA Team Members Not Present for the Whole Inspection
Jose O. Caraballorivera was present on 4/23/24.

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**
4/22/2024	Robert Esquer, Plant Manager
4/23/2024	William Thomas, Senior Director Manufacturing

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

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Ron Belldegrun, CEO/Owner	Industry Portal Representative and FMD-145 Recipient
Email Address	(b) (6)	
Mailing Address	ByHeart 131 Varick St. 11th Floor. New York, NY 10013.	
Phone Number	503-288-6502	
*If a corporation		

Guidance Documents Given to the Firm

The following documents were provided to firm management:

- What to Know About the New Requirement for Manufacturers of Critical Food (Including Infant Formula) to Develop a Redundancy Risk Management Plan (October 2023).
- FDA Firm Resources: General Human and Animal Food (Form JA-000048, Rev01).
- 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.

HISTORY

(b) (3) (A)	(b) (3) (A)

Status	
Hours of Operation	(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

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	(b) (4) percent of components and ingredients used to manufacture the infant formula are received from (b) (4) and (b) (4) of finished product is shipped (b) (4). Lactoferrin is supplied by (b) (4) Base powder is supplied by BlendHouse Reading, PA and is initially shipped to (b) (4) before being shipped to (b) (4) where the product is held for BlendHouse Portland. Base powder supplied by BlendHouse Allerton, IA 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. The canned infant formula is shipped on (b) (4) 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) where collars and lids are placed on the product and the product is case packed and palletized. Pallets of the infant formula are shipped from (b) (4), to (b) (4) (b) (4). (b) (4) for distribution to select (b) (4) stores to and customers who order from the firm's website www.byheart.com; (b) (4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	The firm operates 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” (**See EX. 6 for product label**). The firm's operations consist of receiving infant formula base power from BlendHouse Allerton, IA and BlendHouse Reading PA, (b) (4) the base powder with lactoferrin, and filling cans. The firm’s products are regulated as foods by the FDA under the FFD&C Act.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Ron Belldegrun, CEO/Owner
Roles and Authorities	According to firm management at Blend House Portland, Mr. Belldegrun is the CEO and most responsible person of ByHeart. Mr. Belldegrun was not present during the inspection and was not interviewed during the inspection.
The following are applicable to this person	Industry Portal Representative, FMD 145 Recipient
Email Address	(b) (6)
Mailing Address	ByHeart 131 Varick St. 11th Floor. New York, NY 10013.
Phone Number	503-288-6502
Person #2	
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. He has worked for the firm for eight months.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #3	
Person's Name and Title	Robert Esquer, Plant Manager
Roles and Authorities	Mr. Esquer is responsible for overseeing the entire production process from inbound of raw material through final packaging of the product and he is the most responsible person of the firm on a day-to-day basis and he has the authority to hire and fire employees. The Production Manager and Maintenance Manager's report to him. He reports to the Senior Director of Operations. He has worked for the firm in his current position since August 2023.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #4	
Person's Name and Title	Kathleen "Katie" Whitesell, Senior Director - Quality & Food Safety

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, Accompanied During the Inspection
Person #5	
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 Senior Director of Food Safety. 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
Person #6	
Person's Name and Title	Joseph Doscherd, Regulatory Compliance Manager
Roles and Authorities	Mr. Doscherd is responsible for ensuring the firm is in compliance with the Code of Federal Regulations, (b) (4) and the firm's internal quality standards. The Document Control Specialist and Internal Auditor Reports to him. He reports to the Director of Quality. He has worked for the firm in the current position since November 2023.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #7	
Person's Name and Title	Consuela Bolanos, EHS Manager
Roles and Authorities	Ms. Bolanos is responsible for environmental health and safety, workplace safety, environmental responsibilities and injury and illness reporting. She has worked for the firm in the current position since January 2024.
The following are applicable to this person	Accompanied During the Inspection
Person #8	
Person's Name and Title	Dhru Patel, Director of Pharmacovigilance
Roles and Authorities	Mr. Patel is responsible for receiving and reviewing health complaints and working with the Customer Experience Group. Mr. Patel is a (b) (6) and he reports having nine years' experience in drug safety case processing and medical information. He reviews all complaint records, and he performs an assessment of complaints and conducts periodic reviews of complaints. During the inspection Mr. Patel answered questions and provided a detailed explanation of the firm's procedure for conducting investigations of health related complaints. The Senior of Safety Assurance report to him and he reports to the Chief Medical Officer. He has worked for the firm for nine years. Ms. Patel joined the inspection remotely to discuss the firm's procedure for handling complaints.
The following are applicable to	Interviewed

this person	
Person #9	
Person's Name and Title	Kristen Fallon , Senior Manager Quality Compliance
Roles and Authorities	Ms. Fallon is responsible for overseeing the firm's complaint program, deviations and release of finished goods. During the inspection she provided an explanation of the firm's procedure for conducting complaints. She reports to the Chief Quality Officer. She has worked for the firm for 2.5 years. Ms. Fallon joined the inspection remotely to discuss the firm's procedure for handling complaints.
The following are applicable to this person	Interviewed
Person #10	
Person's Name and Title	(b) (6), Maintenance Manager
Roles and Authorities	(b) (6) is responsible for maintenance of the building and equipment. During the inspection he showed me that the (b) (4) for the air for the (b) (4) and (b) (4) for the (b) (4) were replaced with (b) (4). Mr. Burt has worked for the firm for one year. he reports to the Senior Engineer and the Maintenance Supervisor report to Mr. Burt.
The following are applicable to this person	Interviewed
Person #11	
Person's Name and Title	Devon Kuehn, Chief Medical Officer
Roles and Authorities	Ms. Kuehn is responsible for overseeing Innovation, R&D and clinical research. She has been with the firm since August 2020. R&D; Nutrition Science & Research; and Pharmacovigilance report to her. Ms. Kuehn was present at the close out meeting via video conference call.
The following are applicable to this person	Interviewed
Person #12	
Person's Name and Title	Niall Mullane, Chief Medical Officer
Roles and Authorities	Mr. Mullane reported he is responsible for end to end quality and food safety for ByHeart. He has been with the firm since 01/02/24. The Senior Director - Quality & Food Safety report to Mr. Mullane and Mr. Mullane reports to the CEO. Mr. Mullane was present at the close out meeting via video conference call.
The following are applicable to this person	

FIRM'S TRAINING PROGRAM

(JJL)
The firm has a formal training program, with policies contained in Training Management Policy TRN-4800-POL (**EX. 7**). Training is accomplished (b) (4), when dictated by the training matrix (schedule), and when needed for example to correct observed deficiencies. Topics include Good Manufacturing Practices (GMP), Good Documentation Practices (GDP), hygienic areas, allergens, sanitation, HACCP, CCP, pest control, (b) (4), food defense, food fraud, and the FSPCA Food Defense Awareness for the IA Rule

/ Intentional Adulteration. There is also job qualification training specific to responsibilities for each employee which may include reading specific SOP documents, work instruction documents, policies, records within the document control system, and procedures that related directly to their specific responsibilities. Quizzes are issued for evaluation of understanding, with an (b) (4) pass requirement. All training is recorded for each individual employee on the (b) (4) Assessment Form and with training certificates and kept with the HR file.

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

The firm operates from a (b) (4) storied, (b) (4) square foot facility. Manufacturing operations consist of (b) (4) (b) (4) bulk base powder (b) (4)) with lactoferrin ((b) (4)) and canning the finished infant formula powder as a continuous process. The facility currently has (b) (4). Production areas are designated as (b) (4) hygiene and (b) (4) hygiene areas (**See EX. 8 for "Hygiene Area and Traffic Pattern Program" for floor plan and hygienic zoning**).

The firm has written procedures that cover each point, step, or stage in the production process; the firm has implemented production and process controls at various points, step, or stages throughout production process; and the firm conducts monitoring and verification of the production and process controls.

The facility has (b) (4) for shipping and receiving. Components received include bulk base powder; lactoferrin; (b) (4) metal cans; can ends; can lids. Material Handlers inspect the seals on delivery vehicles and inspect the conditions and cleanliness of the delivery vehicle prior to offloading. The receiving of product/components is documented in the "Inbound Material Inspection" form. Material Handlers enter the product/component into the firm's (b) (4) system ((b) (4)) and the product/components are automatically put on hold in the (b) (4) system. The (b) (4) system notifies QA who is responsible for conducting a review of the COA's against component specifications and making a disposition decision. Product/components that meet the firm's specifications are release by QA in the (b) (4) system and "(b) (4) " stickers are placed on each container of the received component(s). The status of rejected components is changed from "hold" to "rejected" in the (b) (4) system and the rejected component(s) are identified with a (b) (4) sticker.

The firm receives an Authorized Release Certificate (ARC) from the suppliers of base powder.

Each component is assigned a unique product code. The firm does not assign its own lot numbers to any components, but instead, uses the supplier lot number.

Material Handler are responsible for picking and staging components for manufacturing. Ingredients and components, including base powder, lactoferrin, metal can ends and plastic lids transferred from the warehouse to the (b) (4) Room are recorded in the document titled "(b) (4) Room (b) (4) -Warehouse". Cans that are transferred into (b) (4) Room are recorded in the document titled " (b) (4) -Warehouse (b) (4)

(b) (4) the firm conducts a visual verification that the warehouse, (b) (4) room, (b) (4) room and (b) (4) room are clean and documents on (b) (4) checklist.

Process Flow, Operations, and Product Coverage

(b) (4) a supervisor will walk-through and inspect the equipment and document on the "Supervisor (b) (4) Checklist"

Pre-printed empty cans ((b) (4) cans) are depalletized (b) (4) at a time and are fed onto a conveyor and are inverted. The inverted cans enter an (b) (4) conveyor where they pass through an air rinse before passing through a (b) (4) and then through a (b) (4) system (b) (4) that inspects the inside of empty cans for scratches, dents, punctures, out of round/misshapen. The cans then enter the (b) (4) room to be filled with infant formula powder.

Material Handlers stage base powder and lactoferrin in the (b) (4) adjacent to (b) (4) Room (b) The (b) (4) is (b) (4) relative to the warehouse and (b) (4) Room (b) is (b) (4) relative to the (b) (4). The outer container (cardboard box) of the lactoferrin is removed, and the plastic bags are sanitized with (b) (4). The base powder is brought to the (b) (4) with a forklift. The outer shroud (plastic or cardboard) is removed, and the bulk container of base powder is wiped down and sanitized with (b) (4). The forklift is positioned in place so only the forks break the plane between the (b) (4) and the (b) (4) room, while the wheels of the forklift stay in the (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 under a hoist and hoisted to the top of the bulk bag unloader. The throat on the bottom of the bag is opened and sanitized with (b) (4) and gravity fed through a (b) (4) sifter into a receiving hopper at the top of the blender. The powder is (b) (4) through a (b) (4) system equipped with a (b) (4) into a (b) (4) before being deposited into the blender. The bag of lactoferrin (b) (4)), and the (b) (4) addition port on the blender, are sanitized with (b) (4), and the lactoferrin is (b) (4) deposited on top of the base powder through the (b) (4) port. The base powder and lactoferrin are blended at (b) (4) RPM for (b) (4). The firm conducted a validation of the blending time and speed (**See section titled "Blending Validation**"). The blender is a (b) (4) auger, (b) (4) blender with (b) (4) on (b) (4) augur ((b) (4) Mixer) with a (b) (4) capacity. The start and end time for blending is documented in the " (b) (4) ". The operators record the blending time and weight of components in the blender (as detected by the load cells) in the " (b) (4) (b) (4) " document. The firm uses the (b) (4) for documenting/recording the lot numbers of components (base powder and lactoferrin) used. The (b) (4) for the blender is set to only allow the blender to proceed if the weight of the components in the blender meets the pre-programed settings. The input data in the program is based on the charge weight of the components in the blender as detected by the load cells the blender sits on. Each blend 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) Each blend has a sequential blend number for the (b) (4) The blended material is deposited into a (b) (4) (b) (4) hopper and is (b) (4) through a (b) (4) system to a (b) (4) located at the can filling line. The powder passes through a (b) (4) sifter, past a (b) (4) and into a (b) (4) (b) (4) hopper. (b) (4) cans are filled at a time. The cans pass through a (b) (4) then through a check weigher before passing through a (b) (4) seamer where can ends are affixed to the cans. The sealed cans pass through an (b) (4) can rinse that blows clean air on the (b) (4) of the cans to (b) (4) (b) (4). The cans pass through an (b) (4) coder that (b) (4) the product number, lot code, time stamp, expiration date on the bottom of the cans before passing through a (b) (4) coder. The cans are (b) (4) flipped and conveyed to a station where temporary plastic lids are placed on top of the can. The cans pass

Process Flow, Operations, and Product Coverage

through a (b) (4) that inspects cans for scratches and dents, and for presence of a lid. The cans then pass through an (b) (4) then onto an accumulation table. The cans are (b) (4) boxed ((b) cans to a box). A case label is affixed to each box and the boxes are palletized and wrapped in plastic for shipment under quarantine to the firm's (b) (4) before being shipped to (b) (4). (b) (4) removes the temporary plastic lid and affixes a cap, collar, and scoop to the cans.

The firm documents can filling in the document titled, "(b) (4) Room (b) (4) ". An operator verifies the filler and check weigher settings are set to the amounts specified in the master manufacturing order/batch production record; documents the expiration date is (b) (4) from the date the base powder was manufactured; verifies the readiness of the (b) (4), (b) (4), (b) (4) coder, (b) (4) coder, (b) (4).

The firm verifies the codes are set up and documents in the document titled "Lot/Date/Exp. Code Inspection". The firm documents the readiness of the packaging equipment in the "Final Packaging (b) (4) ". This includes a readiness check of (b) (4) that checks the cans for dents, scratches, missing lids, out of round. The firm affixes a copy of the case pack label on the back page of the "Final Packaging (b) (4) " document.

(b) (4) of every production shift the firm conducts a foreign material inspection by inspecting the (b) (4) (at the blender sifter) and (b) (4) (at the filler) for foreign materials and documenting in the "Foreign Material Detection System Check sheet (PROD-4314.01) (b) (4) located at the blender and filler are inspected at (b) (4) (b) (4).

The (b) (4) located at the filler checked (b) (4).

(b) (4), which checks the inside of empty cans for scratches, dents, punctures, out of round/misshapen is challenged (b) (4) and is the check is documented in the Empty Can (b) (4) Challenge Verification Sheet PROD-4308.04-FM. All cans rejected by the (b) (4) during operations are recorded in the Product Examination (b) (4) (b) (4) Rejection Log (PROD-4308.01-FM).

A lot code verification inspection is conducted (b) (4) to verify the (b) (4) and (b) (4) systems are functioning properly and the check is documented in the "Lot/Date/Expiration Code Inspection" sheet (PROD-4306.34-FM).

(b) (4), which checks filled cans for scratches, dents and for presence of a lid, is challenged (b) (4) which is documented in the Product (b) (4) (b) (4) Challenge Verification Sheet (PROD-4308.06-FM). All cans rejected by the (b) (4) (b) (4) during operations are documented on the Product Examination (b) (4) Rejection Log (PROD-4308.03-FM).

The (b) (4) is challenged (b) (4) by (b) (4) which is documented in the (b) (4) Verification Sheet (PROD-4307.02-FM). Rejected cans are recorded in the (b) (4) Rejection

Process Flow, Operations, and Product Coverage

Log (PROD-4307.02-FM). Rejected cans are passed through the (b) (4) times, and if rejected again, QA will open the can and sift the powder through a (b) (4) and review the (b) (4) for presence of foreign material/metal.

(b) (4) of can filling, QA will verify can label against the work order instruction and documents the inspection in the (b) (4) Product Label Verification form (QUAL-4515.02-FM).

(b) (4) the firm conducts a verification of the scales production (except for the blender load cells) using calibrated weights. The verification is documented in the (b) (4) Scale Verification form (QUAL-4511.07.02-FM).

(b) (4) **controls and tests conducted on canned product**

(b) (4) cans are collected at the check weigher (b) (4) and weighed on a calibrated scale to check the variance between the checkweigher at the filler (variance must be (b) (4)) which is documented in the Product Weigh Verification Form (PROD-4319.01-FM).

Loose and tapped density of finished product powder is conducted (b) (4) (b) (4) documented in the Loose and Tapped Density Sheet (QUAL-4513.47-FM).

Scoop weight is conducted (b) (4) documented in the Scoop Weigh Check Sheet (QUAL-4513.38-FM).

A reconstitution test is conducted (b) (4). The reconstitution test checks for weight; flavor, odor and undissolved particles by passing the reconstituted material through a (b) (4) (b) (4) and is documented in the Infant Reconstitution Sheet (QUAL-4513.38-FM).

(b) (4) from each filler head is collected (b) (4) (b) (4) and tested for leaks using the (b) (4) leak detector (b) (4) which is documented on the ByHeart Infant Formula: Leak Test form (QUAL-4513.48-LM).

(b) (4) the (b) (4) leak detector (b) (4) is challenged using (b) (4) (b) (4) control which is documented in the (b) (4) leak detector challenge verification (QUAL-4513.42-FM).

(b) (4) cans are checked for residual oxygen which is documented in the ByHeart Infant Formula: Residual Oxygen Analysis Daily Verification Sheet (QUAL-4513.39-FM).

(b) (4) cans are collected from (b) (4) and tested for residual (b) (4) (b) (4)

(b) (4) cans are collected (b) (4) (b) (4) operators will scoop the powder from each can (b) (4) and check the weight of each scoop to determine the scoop weight is within the acceptable range. Documented in the ByHeart Infant

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Formula: Determination of Scoop Weight form (QUAL-4513.38-FM).

(b) (4) cans are collected (b) (4) seamer head to conduct a (b) (4) can seam evaluation of the cans for the following: Countersink; seam thickness; body hook; body hook butting; cover hook; overlap; and tightness. Documented in the (b) (4) Seam Evaluation form (QUAL-4513.50-FM).

(b) (4)
can is checked for head space and weight and documented in the ByHeart Infant: Fill Weight, Head Space, Verification Log (QUAL-4513.37-FM).

Other Areas Covered

Sanitation

(JJL)
The firm utilizes detailed standard sanitation operating procedures (SSOP's) dedicated for each piece of equipment at the facility, and for non-food contact surfaces. Examples of these SSOP documents are Filler (b) (4) Cleaning Procedure SAN-4713-SOP (**EX. 9**) and BBU and Blender Disassembly and Cleaning Work Instruction (**EX. 10**). Sanitation frequencies are (b) (4) for non-food contact surfaces, floors, and walls. (b) (4) sanitation is accomplished for areas such as the warehouse, the shoe racks, (b) (4) room (though not in use), door frames, the chemical cage, the laboratory floor, (b) (4), and the inner/outer perimeter.

A sanitation clean break for manufacturing equipment with food contact surfaces is conducted (b) (4) . The sanitation clean break consists of disassembly of each piece of manufacturing equipment, removal of the powder through (b) (4) (b) (4)" techniques like (b) (4), then sanitizing by wiping the surfaces with (b) (4) from (b) (4). Parts that can be removed are (b) (4) separately. After every sanitation clean break cleaning, which is considered an intervention (an entry into the product contact zone of the manufacturing process), and before the equipment is reassembled:

- (b) (4) swabs of the (b) (4) are taken.
- Sanitation Break Verification Testing is conducted, which is environmental sampling of the (b) (4) with analysis for the presence of *Cronobacter*, *Salmonella*, *Listeria*, *Enterobacter*, aerobic plate count (APC), and coliforms.

See the Master Sanitation Procedure SAN-4700-SOP for details (**EX. 11**).

I addition to the environmental monitoring as part of the clean break procedures, the firm has developed and implemented an environmental monitoring program that verifies the effectiveness of the sanitation program and provides information needed to prevent possible contamination of food products. **See EX. 12 "Environmental Monitoring Program" QUAL-4510-SOP**. The environmental monitoring program is focused on the equipment and air in the production environment. Environmental surfaces are swabbed and air is monitored as described in their respective SOP documents.

Other Areas Covered

The firm utilizes specific procedures for actions to take when environmental sampling leads to a presumptive or confirmed pathogen finding. The procedure, Environmental Monitoring Positive Response Action Plan QUAL-4510.06-WI (**EX. 13**), states that upon a pathogen finding, the identity and location of the pathogen will be documented, vector swabbing of the area per Environmental Surface Sampling QUAL-4510.07-WI (**EX. 14**) will be conducted before cleaning and sanitizing operations take place. After cleaning and sanitizing, the area will be vector swabbed again. These actions will occur for (b) (4). If any vector swabs reveal a positive, a root cause analysis will commence to identify the need for further cleaning, swabbing and/or more intensive monitoring. Procedures also state that any confirmed pathogens are identified using (b) (4)

The firm has a procedure ((b) (4) Event Escalation Process QUAL-2525-SOP) for escalating a (b) (4) event for findings that could cause the product to violate the Food, Drug, and Cosmetic Act or any other applicable law, where the violation could cause the product to be subject in a Class I or Class II recall, or otherwise cause the product to be injurious to health (**EX. 15**). The team consists of plant management personnel and corporate management. Timing and frequencies for various events are summarized including positive environmental results, out of specification label claims analyses, intentional adulteration, facility events such as leaks, and many other situations. Kathleen Whitesell, Senior Director of Quality and Food Safety stated that any positive result for a pathogen in the plant from environmental sampling for any reason would trigger the (b) (4) event escalation process. Event escalation would include the following actions:

- The affected product would be (b) (4).
- (b) (4) systems in the warehouse would include (b) (4) being applied to the product.
- (b) (4) system controls which usually would allow creating of the bills of lading for shipping, would not allow employees to create the paperwork.
- Upon any positive, the environmental action plan would be activated, triggering the vector swabbing, intensive cleaning, and sanitary break activities. The amount of (b) (4) swabs taken upon clean break sanitation activities is decided by the (b) (4) event escalation team.

Chemicals used to clean manufacturing equipment include (b) (4) cleaner and sanitizer (b) (4) and (b) (4) cleaner and sanitizer (b) (4) (b) (4)., also used for walls). Floors are cleaned with (b) (4) Sanitizers include (b) (4) (b) (4) and (b) (4) **See EX. 16 for a full approved chemical list**.

There were no sanitation issues observed during this inspection.

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. 12**).

The firm monitors the environment for Salmonella, Cronobacter spp., Listeria spp., Enterobacteriaceae (EB), APC, Yeast and Mold. The firm also monitors water quality (See section titled, "**Water Quality**" for water quality monitoring).

Other Areas Covered

The firm collects (b) (4) swabs from (b) (4) for Salmonella spp., Cronobacter sakazakii, Listeria spp. and EB; and the firm collects (b) (4) swabs from (b) (4) for Salmonella spp., Cronobacter sakazakii, Listeria spp. A minimum of (b) (4) swabs are collected for Salmonella; (b) (4) swabs are collected for Cronobacter spp.; and (b) (4) swabs are collected for Listeria spp. during (b) (4) swabbing. 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. 17**). All areas are to be swabbed (b) (4). For routine environmental monitoring, most swabs (unspecified) are collected from (b) (4) and fewer swabs are collected from (b) (4)

The SOP "Environmental Monitoring Positive Response Action Plan" (QUAL-4510.06-WI) describes the action plan taken by the firm in the event of a presumptive positive or positive finding (**EX. 13**). 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." The initial swabbing is followed by cleaning and sanitizing the area and vector swabbing is repeated for (b) (4) (b) (4) with a minimum of (b) (4) environmental swabs taken over the (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.

The work instruction titled, "Environmental Surface Sampling" (QUAL-4510.07-WI) describes the instructions for collection and testing of sponge and swab samples from environmental surfaces for detection and analysis of microbial pathogens (**EX. 14**). This 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 APC or EB).

(b) (4) sponge swab is used for both Salmonella spp., and Cronobacter sakazakii; (b) (4) sponge swab is used for both EB and APC; and (b) (4) sponge swab is used for the collection of Listeria spp.

Swabs are collected with a (b) (4) and are sent to (b) (4) (b) (4)

From July 2023-March 2024 the firm collected the following swabs:

Cronobacter sakazakii: (b) (4)

Listeria spp.: (b) (4)

Salmonella spp.: (b) (4)

The firm has had no positive swabs for pathogens since the firm began swabbing in July 2023 (**See EX. 18 for table of environmental swabbing results**). The firm had one presumptive positive in a (b) (4) tank drain (b) (4)), which is designated as a low care area due to the fact the (b) (4) room has never been used by the firm since manufacturing operations were initiated. After receiving the results of the presumptive positive for Cronobacter, the firm conducted precleaning and post cleaning investigational swabbing (vector swabbing). The results of the initial presumptive positive came back from the lab as "negative for Cronobacter spp." so the firm cancelled the testing of the investigational swabs that were collected.

The lab provided certificate of analysis (COA) for the environmental monitoring for APC, EB, Cronobacter spp., Salmonella and Listeria spp. results for the month of March 2024 were reviewed. The review revealed that Quality documented the reviewed of the COA.

Test methods were reported by the lab as follows:

Aerobic Plate Count: (b) (4)

Listeria spp. (swab): (b) (4)

Other Areas Covered

Enterobacteriaceae Count: (b) (4)

Cronobacter spp. detection (swab): (b) (4)

Salmonella spp. detection (swab) (b) (4) .

(b) (4) **Swabbing**

The firm conducts (b) (4) swabbing of the equipment in (b) (4) Room 1 during a sanitation breaks (**See section titled, "Sanitation" for information on sanitation breaks**). The firm has a visual aide for (b) (4) swabbing of the (b) (4) Room 1 (**EX. 19**).

No product is released until the results of all environmental monitoring, including (b) (4) environmental monitoring, is complete. In the event of a (b) (4) positive, collected during a sanitary break, the product is (b) (4)

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

Environmental Monitoring Program (QUAL-4510-SOP) states "Confirmed pathogens must be identified using (b) (4) (**EX. 12**).

Environmental Monitoring Program (QUAL-4510-SOP) also states "In the event of a confirmed pathogen findings in a product sample, swabs from the environment shall be collected for the root cause investigation both before and commencing cleaning and sanitizing activities" (**EX. 12**).

The firm has never had an environmental sample, in-process material, or finished product test positive for Salmonella or Cronobacter.

(JJL)

The firm uses (b) (4) to sample the ambient air in the (b) (4) room, (b) (4) room, (b) (4) room, (b) (4) room, and (b) (4) . The samples are collected (b) (4) and sent to (b) (4) (b) (4) for APC and Y&M analysis. Test results dated 3/6/2024, 3/20/2024, 3/26/2024, and 3/27/2024 were within tolerances.

Deviations

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. 35).** The Plant Manager and Director of Quality (or designee) are responsible for reviewing and approving completed complaint investigation reports and the Director of Quality (or designee) is responsible for tracking and trending events.

Events are categorized as (b) (4) .

(b) (4) 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.

(b) (4) events are events or conditions which will likely adversely affect the SIPQN of a product, function of

Other Areas Covered

a system, adequacy of a process, or adequacy of documenting, if allowed to continue.

(b) (4) 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. (b) (4) 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.

A list of event reports for 2023 and 2024 were reviewed. There were (b) (4) events between 07/28/23 – 12/31/23. During this period there were (b) (4) events classified as (b) (4); (b) (4) events classified as (b) (4); and (b) (4) events classified as (b) (4). There were (b) (4) events between 01/01/24 - 04/23/24. During this period there were (b) (4) events classified as (b) (4); (b) (4) events classified as (b) (4); (b) (4) events classified as (b) (4) and (b) (4) events where the final classification is pending. **See EX. 20 for a list of events that includes a summary description of each event**.

The following is a summary of the 2023 (b) (4) deviations that were review:

Event Number: E-23-16
Date of Event: 11/13/23
Description of Event: Start-up check of (b) (4) revealed (b) (4) was not functioning.
Root Cause Analysis and CAPA: The decided to process product without (b) (4). All product was held until the (b) (4) was repaired and re-run through the (b) (4) on 10/18/23.

Event Number: E-23-17
Date of Event: 03/07/24
Description of Event: (b) (4) rejector was not hitting (rejecting) cans.
Root Cause Analysis and CAPA: The timing of the ejector was off by 0.5 seconds. All product since the last (b) (4) verification was held and passed through the (b) (4) once the malfunction of the (b) (4) was corrected.

The following is a summary of the 2024 (b) (4) deviations that were review:

Event Number E-24-009
Date of event report: 03/12/24
Description of Event: (b) (4) identified two cans in a case that were missing the (b) (4) code but did have the (b) (4) code.

The firm's immediate action was to place the lot on hold pending investigation.

Root Cause Analysis and CAPA: The (b) (4) lot coder did not function as expected. QA pulls over (b) (4) samples during a production run for QA testing, and Operations verifies the (b) (4) code every (b) (4), all of which were found to have both the (b) (4) codes on the cans. The firm reviewed the entire days production. There were no reported issues with the (b) (4) codes during production. The (b) (4) was performed, and no issues were reported. Samples pulled throughout production for (b) (4) testing were not missing (b) (4) codes. No definitive root cause was identified. Possible, but unlikely, root causes include (b) (4) malfunction; personnel interference with the line; cans too close to one another causing the (b) (4) to identify the two cans as one and only placing an (b) (4) code on one can. The firm's corrective action is to validate and implement the use of (b) (4) that will verify (b) (4) coding on all cans and will reject cans missing a code. The target date for installing and verifying the (b) (4) (b) (4) is June 30, 2024.

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Event Number E-24-023
Date of event report: 04/08/24
Description of Event: (b) (4) identified (b) (4) cans that were missing the (b) (4) code but did have the (b) (4) (b) (4) code.

The firm's immediate action was to place the lot on hold pending investigation.

Root Cause Analysis and CAPA: The (b) (4) lot coder did not function as expected. QA pulls over (b) (4) samples during a production run for QA testing and Operations verifies the (b) (4) code every (b) (4), all of which were found to have both the (b) (4) codes on the cans. The firm reviewed the entire days production. There were no reported issues with the (b) (4) codes during production. The (b) (4) was performed, and no issues were reported. Samples pulled throughout production for (b) (4) testing were not missing (b) (4) codes. No definitive root cause was identified. Possible, but unlikely, root causes include (b) (4) malfunction; personnel interference with the line; cans too close to one another causing the (b) (4) to identify the two cans as one and only placing an (b) (4) code on one can. The firm's corrective action is to validate and implement the use of (b) (4) that will verify (b) (4) coding on all cans and will reject cans missing a code. The target date for installing and verifying the (b) (4) (b) (4) is June 30, 2024.

Event Number E-24-010
Date of Event: 03/07/24
Description of Event: During batch record review, the Release Services Team observed that the lot codes for lactoferrin and base powder were not properly documented in the '(b) (4) Room Batch Record – Warehouse" record.

Root Cause Analysis and CAPA: The operator responsible for transferring components from the warehouse to the (b) (4) room didn't properly record lot codes for the component base powder and lactoferrin in the '(b) (4) Room Batch Record – Warehouse" record. The operator failed to notice a lot number change-over in base powder, and the operator failed to accurately record the lot number for lactoferrin, leaving a digit off of the lot code (wrote lot '(b) (4)" but was supposed to be (b) (4)). The individual who entered the lot code was covering for an absent employee and was not properly trained in the Material Handler's position. The lot numbers were able to be verified by the lot numbers recorded on the batch sheet at the blending step where two operators verify the lot numbers added to the blender at the blending step. The root cause was identified as failure to train. The corrective action is the bolster warehouse staffing and have capable and proficient backups available in the event of future staff shortages.

Water Events

There have been (b) (4) water events since the firm began operating in 2023. There were (b) (4) water events in (b) (4) areas where water seepage occurred at (b) (4) doors in (b) (4) areas and water event where water entered the facility from a roof like into a (b) (4) area.

A review of the firm's root cause analysis and preventive/corrective actions for the (b) (4) water events that occurred at the (b) (4) doors in (b) (4) areas revealed the events occurred because of water infiltration/seeping through the seals in the (b) (4) doors a result of heavy wind and rain.

The events were non-flooding type events with minor infiltration/seepage past the seals on the (b) (4) doors. The firm's corrective action on "day 0" (day of the event) consisted of cordoning off the area; collecting (b) (4) swabs for Cronobacter, Listeria and Salmonella *prior to cleaning*; applying (b) (4)

Other Areas Covered

" (b) (4) " to the area; scrubbing the area with brush; applying (b) (4) Sanitizer; followed by treating the area with (b) (4). On the day after the event ("day 1), the firm collected a minimum of (b) (4) swabs from the affected area, and on the second day after the event ("day 2") the firm collected a minimum of (b) (4) swabs from the affected area. The swabs were sent to a third-party lab and tested for Cronobacter, Listeria and Salmonella and all swabs were found to be negative.

Water Event 24-002
A roof leak from a penetration over the (b) (4) of the (b) (4) room which was not in use at the time and is still not in use caused water to enter the facility near the (b) (4) room (a (b) (4) area). The firm was not operating at the time of the event due to icy conditions preventing employees from going to work. This was a non-flooding type event and the area of water on the floor was (b) (4)'. The firm's CAPA was to direct the leak to a (b) (4) drum and erect absorbent barriers around the water on the floor to prevent foot traffic in the area. The firm swabbed the area prior to cleaning and sanitizing. After swabbing, the firm applied full strength (b) (4) and scrubbed the area with a deck brush and removed the liquid with a mop. The firm then applied (b) (4) to the area followed by (b) (4). The firm collected additional swabs from each day for (b) (4) days for a total swabs of (b) (4) swabs. The swabs were sent to a third-party lab and tested for Cronobacter, Listeria and Salmonella, and all swabs were found to be negative. The firm repaired the area of the roof where water was leaking into the facility.

Supply Chain

The firm receives the following components for manufacturing its infant formula: base powder; lactoferrin and metal cans.

The firm's hazard analysis did not identify any potential physical, chemical or biological hazards associated with the components it receives for manufacturing infant formula (**See EX. 21 for firm's written food safety plan including the hazard analysis**).

The firm maintains a list of approved suppliers of ingredients and components. The firm 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 (**EX. 22**).

The firm has written specifications for the ingredients and components it receives. The firm receives a certificate of analysis or certificate of compliance each time it receives an ingredient or component and the COA and/or COC are reviewed by Quality before the ingredient or component can be released for use. BlendHouse Portland receives an authorize release certificate from BlendHouse Reading and BlendHouse Allerton with each shipment of base powder. BlendHouse Portland collects a sample from (b) (4) of lactoferrin it receives and sends the sample to (b) (4) for testing for protein, minerals, vitamin B12 and lactoferrin.

Finished Product Release and Distribution

The firm has a written procedure titled, "ByHeart Infant Formula Supply Chain Release" (QUAL-2510-SOP) that describes the requirements for the release of ingredients, packaging components and product at all ByHeart facilities and third-party manufacturers (**EX. 22**).

For the release of the canned infant formula from ByHeart Portland, Batch Auditors at ByHeart Portland will conduct an initial review and a site level release of the canned product. A review of the Master Batch Record is conducted that includes the following: Results of all environmental monitoring for the (b) (4) (b) (4), and (b) (4), the date of manufacture; cleaning and sanitation and (b) (4) inspections; review of all events, deviations, and interventions; CCP compliance; (b) (4) lab results; COA's for microbiology and nutrients and heavy metals; investigation reports (as applicable). After reviewing the Master Batch Record, BlendHouse Portland Quality will then determine the disposition of the product (released or rejected). **See EX. 23, page 2 for "BlendHouse Portland Master Batch File**

Other Areas Covered

Checklist" document. For released product, a Release Services Manager issue an "Authorized Release Certificate" (ARC) and COA's for microbiology and nutrients and release the product in the firm's (b) (4) system ((b) (4)). 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. The product is first shipped to one of BlendHouse Portland's third-party warehouses (b) (4) under a hold status. According to the firm, (b) (4) has access to BlendHouse Portland's (b) (4) system and (b) (4) (b) (4) cannot not ship product without a bill of lading from BlendHouse Portland's Supply Chain. The product is then shipped from (b) (4) to (b) (4) for addition of the cap, collar, and scoop. ByHeart Corporate Quality is responsible for the final release and/or rejection of the finished product from the contract manufacturer (b) (4) to the distribution centers. For released product, an ARC to authorize the release of the finished product from contract manufacturer (b) (4) to the distribution centers. Rejected product is (b) (4) and an Authorized Rejection Notice (ARN) is issued, and a (b) (4) (b) (4) is required for all rejected finished product.

The firm does not release any finished product until results of (b) (4) swabbing collected during a sanitary break have been completed.

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 canned infant formula powder manufactured at BlendHouse Portland (**EX. 24**).

(b) (4), the firm collects (b) (4) cans for the following microbiological testing: (b) (4) cans pulled (b) (4) for *Cronobacter* spp. and *Salmonella* spp. (b) (4) cans are (b) (4) for microbiological testing for Listeria spp., Coagulase positive *Staphylococcus aureus; E. Coli*/Coliform; *E. coli* – Enrichment; *Bacillus cereus;* and aerobic plate count.

A review of the finished product microbiological and nutrient testing for (b) (4) batches of product covered during the inspection was conducted (see section titled, "**Batch Record Review**" results of the review). According to firm management, the firm has never had (b) (4) material or finished product test positive for *Salmonella* spp. *Cronobacter* spp.

(b) (4), the firm collects (b) (4) cans for nutrient testing per 21 CFR 107.100, including added nutrients (lactoferrin, arachidonic acid, docosahexaenoic acid and galactooligosaccharides). A composite sample is sent to (b) (4) for testing.

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 (**EX. 25**).

Master Manufacturing Order/Batch Record Review

The firm currently processes (b) (4) The firm follows a written master manufacturing order (MMO) that covers each point, step, or stage in the manufacturing process ((b) (4) filling; packaging). Batch production records are issued to operators at each, point, step, or stage in manufacturing operations to record in-process controls and parameters. The firm also has standard operating procedures that contain instructions for each point, step or stage in the manufacturing process for operators to follow. Manufacturing and packaging operations are documented in

Other Areas Covered

the (b) (4) Batch Record (PROP-4312.01-MI); (b) (4) Log (PROD-4312.02-FM); (b) (4) (b) (4) Room BR, (b) (4) Room BR; Final Packaging Batch Record and the Final (PROD-4312.05-MI); Packaging Batch Record (PROD-4312-06-MI).

During the inspection a review of the complete batch production records for the following batches were reviewed without comment or observation:

(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4));
(b) (4) (date of manufacture (b) (4)).

A complete batch production record for batch (b) (4) (date of manufacture (b) (4)) was collected (**EX. 23**).

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, chemical, and biological hazards, including temperature and humidity excursions (**EX. 26**).

Base powder from BlendHouse Reading, PA is shipped in totes to (b) (4) (b) (4) for intermediate storage before being shipped in (b) (4) trucks to (b) (4) (b) (4) facilities located at (b) (4) (b) (4). Base powder from BlendHouse Allerton, IA is shipped in totes in (b) (4) trucks to (b) (4) facilities located at (b) (4) (b) (4).

(b) (4)' facilities are not climate controlled, however, the temperature (but not humidity) at both facilities is monitored, and BlendHouse Portland receives (b) (4) updates from (b) (4) on the temperature monitoring of both facilities.

The base powder is transported in (b) (4) trucks from (b) (4) to BlendHouse Portland.

Canned product is transported on (b) (4) trucks from BlendHouse Portland to one of the (b) (4) facilities in (b) (4).

The canned product is normally shipped from one of the (b) (4) facilities to (b) (4) on (b) (4) trucks. If the product is shipped in (b) (4) 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.

Internal Audits

(JJL)

Other Areas Covered

The procedure for the accomplishment of audits is Audit Program QUAL-4504-SOP (**EX. 27**). Audits of the production and in-process control system are conducted to include observation of the production of infant formula and comparing this observation to the written production procedures, reviewing records of the monitoring of points, steps, or stages where control is necessary to prevent adulteration, reviewing records of how deviations from specifications were handled, and a review of a representative sample of all records maintained. The procedure states that these audits are conducted by an individual or a team of individuals who as a result of education, training, or experience is knowledgeable and have no direct responsibility for the matters that such individual or team is auditing and shall have no direct interest in the outcome of the audit. The procedure states that the results of the audit are discussed with Management during the (b) (4) Quality Review and corrective actions are communicated to employees as needed by changes to procedures, training, employee meetings, and briefings as applicable. These audits are conducted (b) (4) see Plant (b) (4) Auditing Program QUAL-4504.01-WI (**EX. 28**). Kathleen Whitesell, Senior Director of Quality and Food Safety provided a Statement of Assurance for Completion of Regularly Scheduled GMP Audits (**EX. 29**), which was an attestation serving as a statement of assurance that the regularly scheduled audits are being conducted. The firm also has third parties conduct audits of their infant formula operations. See **EX. 30** for the cover letter of an audit conducted by (b) (4) from March 19 through March 21, 2024, and the cover sheet for the FDA QRC Audit Report related to this audit.

Water Quality

(JJL)

The firm implements a water analysis program for process water at the facility (**See EX. 31 for the Water Analysis Program QUAL-4508-SOP**). Water at Blendhouse Portland is used for handwashing and some utensil cleaning. It is not used as part of the product or for cleaning equipment where dry powder is processed. The source is (b) (4) water from the (b) (4) . Samples are collected (b) (4) from areas of the plant such as the (b) (4) Samples are tested inhouse using the (b) (4) test kit ((b) (4)) for aerobic plate count (APC), coliforms, *E. coli*, and yeast and mold (Y&M). The test results are periodically verified by sending water samples to (b) (4) Test results were examined for sampling on 3/11/2023, 9/8/2023, 10/6/2023, 11/14/2023, 1/5/2024, 2/2/2024, 3/1/2024, and 4/4/2024. All results were absent for coliforms, *E. coli*, and Y&M, and within the tolerance of (b) (4) for APC. The water is further tested (b) (4) for organic contamination, inorganic contamination, microbiology, disinfection by-products, residual disinfection, PFAS/SDWA, and radionucleotides. A test result for radionucleotide testing from water sampled at the (b) (4) and the (b) (4) was *None Detected*, dated 11/16/2023. A test result dated 12/1/2023 from water sampled at the (b) (4) was within tolerances for a large list of chemicals tested.

Air and Gases

The air in the (b) (4) room is (b) (4) air (b) (4) through a series of (b) (4). The (b) (4) are (b) (4) (b) (4)

(b) (4) air for use in cleaning difficult to reach areas inside the blender has (b) (4) (b) (4).

(b) (4) gas for use in canning is supplied by (b) (4). The firm receives a certificate of analysis from the supplier with each lot it receives. The COA reports on carbon monoxide; water, oxygen, total hydrocarbons and odor. During the inspection, it was observed that the (b) (4) installed. This was brought to the attention of firm management and the (b) (4) was changed to a (b) (4) filter (**see section titled "Additional Observations"**).

Other Areas Covered

During the inspection, it was observed that the "(b) (4)" air rinse air used for cleaning the inside of the empty cans had a (b) (4) installed. This was brought to the attention of firm management and the (b) (4) were changed to a (b) (4) (**see section titled "Additional Observations"**).

Expiration Dating, Stability Testing, Retained Samples

Expiration Date

The base powder comes in with a date of production and a best by date. The firm sets the expiration date of the finished product at (b) (4) from the base powder production date.

Stability Testing

The firm collects (b) (4) for stability testing at time "0" and (b) (4) (end of shelf life). The firm has ongoing stability testing on nutrients in the first lot of product produced at BlendHouse Portland (lot (b) (4)). The product was tested at time "0", (b) (4) and (b) (4) (**See EX. 32. for results of time "0", (b) (4) and (b) (4) stability testing**).

Retained Samples

The firm collects (b) (4) as a retained sample. Retained samples are held for (b) (4) past the expiration date and are stored under ambient conditions.

Equipment Calibration

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 (**EX. 33**).

The following equipment calibrations were reviewed during the inspection:

- The load cells on the blender were initially calibrated 7/20/23 (b) (4) calibration) and on 1/12/21.
- The QA scale used to verify the check weigher at the can filling step was last calibrated on 4/1/24.
- The (b) (4) was last calibrated on 11/01/23.

Blending Validation

The firm conducted a trial to validate the blend uniformity of the infant formula (b) (4) process at BlendHouse Portland (**See EX. 34**). The study was used to establish the blending process (time and equipment parameters) and confirm its repeatability. In summary, (b) (4) batches of finished base infant formula powder were (b) (4) with lactoferrin. Samples were collected from each batch at (b) (4) intervals and analyzed for physical attributes, nutrient content, and organoleptic attributes. The results in nutrient content were uniform and remained homogenous and within specification at approximately (b) (4) (b) (4) of blending and there were no changes to the physical properties throughout the entire (b) (4) of blending time. The tech trial recommended blending time be established at (b) (4) (b) (4).

Allergens

The only major food allergen handled by the firm is milk. The finished product is a cow's milk based infant formula and the product label has a "**CONTAINS**: MILK" statement (**See EX. 6 for product label**).

Pest Control

(MDF)

The firm has a written pest control procedure. (b) (4) is contracted on a (b) (4) basis to

service the firm's (b) (4) traps, (b) (4) traps, (b) (4) traps, (b) (4) (b) (4), and exterior spraying on an as needed basis. The firm's sanitation manager will meet with the technician before and after the service to review trends or to discuss the firm's service. I inquired with firm management as to their level of involvement in regard to scheduling service or placement of traps. Management informed me that the company will express dissatisfaction if they start to notice trends or service is not up to their quality. They informed me that in January of 2024, they were dissatisfied with the service of their previous technician from (b) (4) and they requested a new one. When the new technician began, the firm implemented a "verification" in which they leave a business card on a random trap in the facility every (b) (4), which the technician brings back to them. If the technician fails to retrieve the card, the firm will file a non-conformance report with (b) (4). The firm logs this activity on the "Business Card Retrieval Log" which was reviewed from 01/25/24-04/12/2024.

When a technician is done servicing the facility, they file a report in (b) (4) online portal and discuss their findings with the sanitation manager. The (b) (4) reports from July of 2023 to April of 2024 were reviewed with no results or comments of concern from the technician. The firm is also provided with (b) (4) trending reports of activity in their facility by (b) (4) which shows the firm the trends of each species of pests in their facility. Firm management stated that they use these reports and work with (b) (4) to adjust treatment if necessary. The (b) (4) trend reports were reviewed from July of 2023 to April of 2024 with no results of concern. The firm does not conduct additional pest control on their own. No pest activity was observed during the inspection.

MANUFACTURING CODES

(MDF)
The firm has a written procedure for product coding. The firm is using an (b) (4) System (b) (4)) developed by (b) (4) that generates product identifiers, job numbers, and assists in the firms manufacturing.

Warehouse Supervisors are responsible for managing product identifiers, while Quality Assurance (QA) Technicians are responsible for ensuring the coding information is correct in the (b) (4) as well as the packaging labels. It is the responsibility of the process and packaging operators to ensure the correct coding information is used in manufacturing as well as ensuring QA approved labels are applied.

In the (b) (4) stage, work order numbers automatically populate in the (b) (4) and the bulk product bag lot, bag number, weight, time of operation, and the operators name are also recorded inside the system.

The added Lactoferrin lot number is added manually on the batch record. In the canning stage, the bottom of every can is (b) (4), and (b) (4) with the following information:

(b) (4): Line 1: (b) (4). Line 2: (b) (4). Line 3: (b) (4) 4: (b) (4)

(b) (4): (b) (4) (b) (4).

For example: the coding on the products that were sampled on 04/23/2024 read: "USE BY 1OCT 2025 BYHEART (b) (4)"

RECALL PROCEDURES

(MDF)
The firm has a written procedure for both stock recovery and recalls which highlights responsibilities and procedures in the event of either occurring. The firm has never initiated a recall at this facility, nor have they been part of recall. Should the firm be involved in a recall, the Director of Quality, Vice President of Quality, and Plant Manager will assess the need and viability of product withdrawal and recovery. It is the responsibility of the Quality department to initiate a recall or withdrawal, assess the effectiveness, and communicate with the FDA. The warehouse supervisor is responsible for conducting interactions with customers during a recall, and the Plant Manager us ultimately responsible for handling the recall process and implementing corrective actions.

Should the firm be made aware of the need for a recall, they would first conduct an investigation to determine if the reason for recall is an issue that came from the Blendhouse Portland facility, another facility in the supply chain, or an outside supplier. The firm will determine the extent of fault so that they can narrow down how much inventory and batch records that need to be reviewed. The firm will compile all the affected lot numbers and conduct a health hazard analysis in which they will assess the impact to public health. All production relating to the hazard will be immediately halted and the extent of the affected products will be documented. The firm will use all of this information to develop a recall strategy, and the information will be reported to the FDA via the Reportable Food Registry (RFR). The firm will notify their district office and conduct the recall. The warehouse supervisors have the responsibility of individually contacting the affected consignees to alert them of the recall and after they have done so, the firm's corporate office will issue a public statement which will highlight the product information, hazards to public health, request for return or destruction, extent of contact to consumers, and a request to cease distribution. The firm considers the recall to be "completed" when all product is in its final state of reconciliation, the root cause of the problem was identified, and records of all action are completed.

The firm is conducting (b) (4) mock recalls. A random product or component is picked, and the firm has (b) (4) to identify the extent of distribution and production to be considered "successful". The firm most recently conducted a mock recall on 12/15/2023 and was able to successfully identify the finished product in (b) (4).

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	You did not install a filter capable of retaining particles 0.5 micrometer or smaller when compressed gas is used at a product filling machine.
Observation Details	Specifically, the (b) (4) for air used at the "(b) (4)" (b) (4) and the (b) (4) for the (b) (4) that provides (b) (4) at can filling step were observed to be equipped with a (b) (4).

Observations Not Listed on FDA Form 483	
Citation Reference	21 CFR 106.30(g)
Correction Status	Corrected & Verified
Corrective Action Description(s)	During the inspection, on 04/26/24, I verified the firm replaced both the (b) (4) (b) (4) for the (b) (4)" (b) (4) and the (b) (4) for the (b) (4) (b) (4) used for can filling with (b) (4). See EX. 1 for spec sheet for air system (b) (4) (b) (4) (b) (4). See EX. 2 for spec sheet for (b) (4) system (b) (4). See EX. 3 for spec sheet for (b) (4) (b) (4).

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

A close out meeting was held on 04/26/24.

The following personnel were present at the firm during close out meeting: Katie Whitesell, Senior Director - Quality & Food Safety; Robert Esquer, Plant Manager; Lori Boyd, Director of Quality; Joseph Doscherd, Regulatory Compliance Manager; and Consuela Bolanos EHS Manager. The following personnel joined the close out meeting via video conference call: Devon Kuehn, Chief Medical Officer; and Niall Mullane, Chief Quality Officer.

A discussion was held with firm management regarding the use of (b) (4) at the (b) (4) (b) (4) and for the (b) (4) and the requirement to use a (b) (4) at these locations. I acknowledged that the firm implemented a corrective action by installing suitable (b) (4) at these locations immediately after this was brought to the attention of plant management.

ADDITIONAL INFORMATION

The firm does not (b) (4).

SAMPLES COLLECTED

Sample Number	1199544
Description	Sample consists of 60, 24-ounce subs of ByHeart powdered infant formula collected on 04/24/24 for microbiological analysis (Cronobacter and Salmonella).

Sample Number	1199545
Description	Sample consists of 12, 24-ounce subs of ByHeart powdered infant formula collected on 04/24/24 for nutrient analysis.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Spec Sheet for Air System (b) (4) (b) (4) (b) (4) . 1 pg.pdf	1
2	Spec Sheet for (b) (4) (b) (4) .	1
3	Spec Sheet for (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) .	2
4	ByHeart Complaint Managment Policy.	13
5	BlendHouse Portland Complaint Managment Program.	5
6	ByHeart Whole Nutrition Infant Formula Label.	4
7	Training management policy.	7
8	Hygiene Area and Traffic Program.	16
9	Filler (b) (4) Cleaning Procedure.	7
10	BBU and blender disassembly and cleaning work instruction.	32
11	Master Sanitation Procedure.	11
12	Environmental monitoring program.	8
13	Environmental Monitoring Postive Response Action Plan.	7
14	Environmental Surface Sampling.	11
15	(b) (4) Event Escalation Process.	6
16	Approved Chemical List.	12
17	Master Environmental Site List.	9
18	EMP Swab Results Table June 2023 to March 2024.	1
19	(b) (4) Room (b) (4) Swab Locations Visual Aid.	42
20	List of Deviations.	1
21	Food Safety Plan.	52
22	ByHeart Infant Formula Supply Chain Release SOP.	7
23	Complete Batch Production Record.	155
24	Canned Infant Formula Powder Microbiological Sampling Plan.	5
25	Infant Formula Canned Finished Product Release Specifications.	4
26	Requirements for Storage and Transport.	26

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
27	Audit Program.	8
28	Plant (b) (4) Auditing Program.	6
29	Statement of Assurance for GMP Audits.	2
30	IEH and QRC Audit Cover Sheets.	2
31	Water Analysis Program.	6
32	Stability Data for Lot (b) (4) .	1
33	Calibration Procedure.	4
34	Blending Validation.	15
35	Event Reporting Investigation Procedure.	4

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	Form FDA 482 - Notice of inspection dated 4.22.24 Issued to Plant Manager Robert Esquer.	3
2	Form FDA 482 - Notice of Inspection dated 4.23.24. Issued to Senior Director - Manufacturing William Thomas.	3
3	Attachment B	3

SIGNATURE

Gerard D. Difiore -S
Digitally signed by Gerard D. Difiore -S
Date: 2024.06.18 07:21:28 -04'00'

Jeffrey J. Leclair -S
Digitally signed by Jeffrey J. Leclair -S
Date: 2024.06.12 13:36:06 -07'00'

Jose O. Caraballo Rivera -S
Digitally signed by Jose O. Caraballo Rivera -S
Date: 2024.06.12 13:46:41 -07'00'

Miles D. Foster -S
Digitally signed by Miles D. Foster -S
Date: 2024.06.12 15:15:18 -07'00'