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SUMMARY

Inspection	
Operation ID and Subject	293388: FY 25 Domestic and Foreign IFMF Inspections Schedule.

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

(KP)

This is a comprehensive inspection of an infant formula base powder manufacture conducted in accordance with the assignment, dated September 26,2024, "FY 25 Domestic and Foreign Schedule of Inspections/Sample Collections for Infant Formula and Medical Foods Compliance Programs", FACTS number 12388746, and eNSPect ID 249214; and Compliance Program Manuals 7321.006 Infant Formula Program-Inspection, Sample Collection and Examination, and 7303.040 Preventive Controls and Sanitary Human Food Operations. This inspection was unannounced and was conducted as part of the Critical Foods Cadre FY 25 Work Plan under eNSPect Operation ID 293388.

The firm only manufacture one infant formula bulk base powder (b) (4) under their brand ByHeart. All ingredients for the base powder is added at the firm except for the ingredient lactoferrin which is added by a sister facility in Portland, OR. The base powder is manufactured (b) (4) (b) (4) bulk packing.

The previous inspection was conducted by US FDA from 1/8/2024-1/30/2024; this was classified as NAI. There were no observations or discussion items from the inspection.

The current inspection focused on infant formula base powder, (b) (4) manufacturing (b) (4) which includes but not limited to receiving, storage, (b) (4) (b) (4) filling, and packing. In addition, we also covered cleaning and sanitation, environmental monitoring program (including (b) (4) testing), allergen controls, supply chain, internal audits, calibrations, hygiene zones and traffic patterns including air pressure and filters, food safety plan/hazard analysis, employee training program, process interventions/intrusion, water events, IT, recall procedures, complaint management program, and pest management program. During the inspection all associated procedures and documentations to the above-mentioned programs were reviewed along with batch records.

At the close-out of the inspection, a Form FDA 483, Inspectional Observations, was issued for 3 items, along with 2 "Additional Observations", and 7 "General Discussion with Management". The three 483 items included, receiving, and releasing (b) (4) ingredient used in infant formula base powder that was not held under conditions to prevent adulteration; not taking actions to eliminate all potential harborage areas when issues with rodent arose during the year 2024-2025; and not monitoring the floor conditions adequately at the dryer (b) (4) (level (b) (4) and level (b)) when there were findings of confirmed *Cronobacter Sakazakii*.

The two additional observations consists of the firm not having clear barriers separating hygiene

Summary

zones; and not monitoring baghouse differential pressures.

The seven discussion with management includes, the firm allowing for significant pest activity in (b) (4) areas; QA personnel missing final QA reviews and checks for records; not securing the double doors to the (b) (4) to not allow employee access; not collecting routine swabs during production; written procedures for environmental monitoring did not capture corrective actions and the event reports populated from deviations pertaining to environmental positives were not clear, nor included all information; the dryer (b) (4) floors had stains throughout; and the caulking placed on the propane storage tank due to an water event is not on a preventive maintenance program; and rust stains passing through open caulking on the ceiling on level [redacted] on the dryer (b) (4)

To the above-mentioned observations, the firm initiated some corrections, and for those that are pending corrections, the firm promised to make corrections in a timely manner and respond to US FDA in writing. The close-out meeting was joined by Mr. John van der Hulle (Plant Director), and other individuals from the firm management team as well as Corporate. These individuals were made aware that the inspectional observations on Form 483 do not represent a final Agency determination regarding the firm's compliance; these will be further reviewed by the Agency. Also, the firm was encouraged to make correction to all observations and respond to US FDA in writing. They were also encouraged to share objections, corrective actions, or concerns.

No refusals.

The following environmental samples were collected from the firm on 2/11/2025 and 2/13/2025, sample numbers INV 1250560-1250562, and INV 1287521 to analyze for *Cronobacter spp*. and *Salmonella spp*. ; all were classified by the lab as LC1.

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03040	FOOD CGMP INSPECTIONS
03040U	FOCUSED PCHF INSPECTIONS
03050N	DOMESTIC HUMAN FOOD ENVIRONMENTAL SAMPLES
21006	INFANT FORMULA SURVEY

Summary of Objectionable Conditions on FDA Form 483 - Current Inspection

CFR Number	Citation Text	Correction Status
21 CFR 106.40(f)(3)	You approved and released for use an ingredient that was not manufactured, packaged, labeled, or held under conditions to prevent adulteration.	Not Corrected
21 CFR 117.35(c)	You did not exclude pests from your food plant to protect against contamination of food.	Correction Requires Onsite Verification
21 CFR 106.20(a)	You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.	Not Corrected

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 117.20(b)	Your plant was not designed to facilitate maintenance and sanitary operations.	Correction Requires Onsite Verification
21 CFR 106.50(d)(2)	You did not include controls for the (b) (4) - (b) (4) process for a powdered infant formula.	Correction Requires Onsite Verification

Correction Statuses current at time report was signed.

Consumer Complaints Review

(SGM)
The firm's compliant SOP-Complaint Management Policy was reviewed with no concerns. The firm's complaint file from last inspection to the present was reviewed with no significant concerns. There were no reports of serious injuries or illnesses. All complaints are handled through the firm's corporate complaint response teams and then passed down to site QC managers. Blendhouse Allerton does not receive complaints directly because they make milk powder base which is sent to sister facility for finished product manufacturing.

Ms. Piepenhagen from HQ stated that the company received 1915 complaints related to products produced by the base powder. Complaints are sorted into 3 categories: Health; Quality; Sensitive/Serious. Health is related to gastro illnesses. Quality is related to tastes, smells, appearance, damages, and foreign materials. Sensitive is related to salmonella/pathogen illnesses. The firm stated there were reportedly 1915 quality complaints, 930 health related complaints, and 9 sensitive complaints. All sensitive complaint cases are reviewed by medical officer professionals during root cause investigations. All complaints trends are kept on charts and spreadsheets.

(b) (6)

[redacted]

Inspection Samples	
Sample Number(s)	1250560; 1250561; 1250562; 1287521

ADMINISTRATIVE DATA

Administrative Data	
Firm	Blendhouse Allerton,LLC
Physical Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Phone	641-221-2854
Fax	641-221-2932
Mailing Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008

Administrative Data	
Email Address	jvanderhulle@byheart.com
Website	byheart.com
Inspection Date(s)	2/11/2025, 2/12/2025, 2/13/2025, 2/14/2025, 2/17/2025, 2/18/2025, 2/19/2025, 2/20/2025

FDA Inspection Participants
Participant Name and Title
Kawshalya Pathiraja, Investigator
Joselin Baray-Alvarado, Investigator
Ron Pearson, Investigator
Lloyd Luapula, Investigator
Stephen Mclane, Investigator
Marc Balzarini, Investigator

FDA Team Members Not Present for the Whole Inspection

(KP)
The inspectional team included Investigators Kawshalya (NMI) Pathiraja, and Stephen G McLane. The members of the inspectional team was present for the entire inspection. The EIR is written by both Investigators Pathiraja and McLane, and in relevant EIR sections, this is indicated by the initials, KP (Kawshalya Pathiraja), and SGM (Stephen G. McLane).

The environmental sampling team included Investigators Joselin P Baray-Alvarado, Ron R Pearson, Lloyd M Laupula, and Marc Balzarini. The sampling team was present at the firm for sample collection on 2/11/2025 and on 2/13/2025.

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**
2/11/2025	John van der Hulle, Plant Director

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	John van der Hulle, Plant Director

FDA Form 483		
Description	**Date Issued**	**Issued To**
Original	Feb 20 2025 06:21PM	John van der Hulle, Plant Director

Additional FDA Forms Issued	
484 - Receipt for Samples	
Issued to	John van der Hulle, Plant Director

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	John van der Hulle, Plant Director	Industry Portal Representative and
Email Address	jvanderhulle@byheart.com	
*If a corporation		

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
Mailing Address	The same as the firm's mailing address.	FMD-145 Recipient
Phone Number	641-221-2854	
*If a corporation		

Guidance Documents Given to the Firm
(KP) We electronically provided the following handouts, information, and documents to Mr. Matthew Comer, Document Control Specialists electronically on 2/20/2025 for further distribution. -FDA Firm Resources -Redundancy Risk Management Plan Guidance -FDA Call to Action Letter, March 2023 -21 CFR Part 106 - Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications -21 CFR Part 107 - Infant Formula -21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food - 21 CFR Part 11 Guidance for Industry Part 11. Electronic Records; Electronic Signatures-Scope and Application The following document was provided via electronically on 3/25/2025 to Ms. Katie Whitesell, Ms. Julie Fry, and Mr. John van der Hulle. -Guidance for Industry: Establishing Sanitation Programs for Low-Moisture Ready-to Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event

HISTORY

Food Firm Registration Status	Current	
Hours of Operation	**(KP)** The firm manufactures (b) (4) [redacted]. Business hours (b) (4) [redacted] The warehouse receiving hours are from (b) (4) [redacted].	
New or Current Firm Legal Name	BlendHouse Allerton, LLC	
Legal Status	LLC	**(KP)** There are no changes to the firm's name since ByHeart, Inc. acquired the facility from Dairy Farmer's of America on 1/23/2023.
State of Incorporation	IA	
Year of Incorporation	12/15/2022	
Additional Information	**(KP)** The firm has not had any recalls or market withdrawals since the last US FDA inspection, with an ending date of 1/30/2024, and it was classified as NAI. Additionally, no prior Agency actions or significant inspection history pertinent to the current inspection.	

	Also, since the previous US FDA inspection (ending date 1/30/2024) no changes to the firm's parent company, affiliates, or subsidiaries. ByHeart Inc. (FEI 3022729623) is the parent company of BlendHouse, Allerton, LLC, and their corporate address is 131 Varick street, New York, NY 10013. The firm has sister facilities in Portland, OR (BlendHouse Portland, LLC; FEI 3013670080), and Reading, PA (BlendHouse Reading, LLC; FEI 3015728839). **(SGM)** Blendhouse Allerton, LLC is a (b) (4) . infant formula base powder manufacturer with (b) (4) employees. The firm was established in 01/23/2023 after being bought from Dairy Farmers of America by the parent company, ByHeart, Inc. Since the last inspection several significant facility improvement projects have been completed/started as part of capital investment commitments as the firm was newly acquired by ByHeart. Phase-1 warehouse projects have been completed by the firm between Oct-Dec 2024 which included warehouse roof structurally reinforced; ceiling insulation removed and replaced; vinyl membrane installed; interior circuitry and lights installed; applied coating on exterior to ensure interim leak remediation. Phase-2 projects were initiated Jan 2025 for completion at end of first quarter which includes exterior roof replacement of warehouse (b) (4) Furthermore, the firm completed facility improvement related to environmental monitoring protection, Oct-November 2024, which includes (b) (4) Room/If Packing Roof Replacement; Dryer (b) Level (b) Floor coating; (b) (4) Dryer Level (b) upgraded existing floor seals; Installation of (b) (4) Foyer; Replacement of exterior exhaust fan in Warehouse (b) (4) ; (b) (4) Replacement in (b) (4) Room; Floor coating in (b) (4) Room/ (b) (4) Room/QA Office; QA Lab/QA Office Room HVAC Ducting and Drop Ceiling Replacement; Replacement of exterior exhaust fan in Warehouse (b) (4) . Furthermore, the firm stated they have substituted all positive displacement pumps with (b) (4) due to age, efficiency/maintenance cost which will allow (b) (4) material. Lastly, the firm has stopped packaging base product in the (b) (4) bulk totes since October 2023. The firm provided a copy of detailed document with pictures and dates of all their improvement projects (refer to **Exhibit 1**).

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	**(SGM)** According to management, the firm receives approximately (b) (4) of ingredients (b) (4) through interstate commerce. The firm provided a copy of incoming BOL# (b) (4) for shipment of (b) (4) (b) (4) (refer to **Exhibit 2**). The firm ships its manufactured infant formula base blend via bulk totes to sister facility-

	Blendhouse Portland, located at 19217 Ne San Rafael St Portland OR 97230. The firm provided a copy of outgoing BOL#(b) (4) for shipment of base powder to BlendHouse Portland (refer to **Exhibit 3**).

Product Covered	**(KP)** Non-exempt infant formula base powder, (b) (4), in bulk totes for (b) (4).
Incoming	Yes
Received From	**(KP)** The firm receives (b) (4) from their approved supplier (b) (4) (b) (4) USA (refer to **Exhibit 2** for a copy of a bill of lading).
Outgoing	Yes
Sent To	**(KP)** The bulk infant formula base powder (b) (4) bulk totes are shipped from the firm (Allerton, IA) via 3 party logistics company (b) (4) to their sister facility BlendHouse Portland, LLC (Portland, OR), refer to **Exhibit 3** for a copy of a bill of lading. BlendHouse Portland, LLC (b) (4) the bulk infant formula base powder with lactoferrin and transfer the product into aluminum cans (retail can) with a plastic over cap. These finished product cans are then sent to a 3rd party owned facility (b) (4) for cap (metal lid) and collar (tamper evident seal) assembly with a plastic scoop, after which, product is distributed to customers.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	**(SGM)** The firm manufactures one powdered infant formula base powder (b) (4) (b) (4) to be blended/packed at sister facility, BlendHouse Portland, for the domestic market. The firm provided a copy of the bulk base powder label (refer to **Exhibit 4**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	John van der Hulle, Plant Director
Roles and Authorities	**(SGM)** Mr. John van der Hulle has been with the facility for over 40 years, serving as plant director for over 15 years. In his role, Mr. van der Hulle oversees overall facility management, personnel, and production operations. He possesses the authority to enact capital improvements and make decisions regarding personnel employment. Mr. van der Hulle reports to William Thomas, Senior Director of Manufacturing in corporate headquarters.

The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Industry Portal Representative, FMD 145 Recipient, Accompanied During the Inspection
Email Address	jvanderhulle@byheart.com
Mailing Address	The same as the firm's mailing address.
Phone Number	641-221-2854
Person #2	
Person's Name and Title	Katleen E Whitesell, Senior Director of Food Safety
Roles and Authorities	**(SGM)** Ms. Whitesell has been in current corporate role for 1.5 years and oversees food safety and quality operations at 3 sister BlendHouse facilities-Allerton, Portland, and Reading. In her role, she supports quality assurance teams at the firms and offers inspection and regulatory affairs support. **(KP)** During the inspection, Ms. Whitesell provided the organization charts for the Corporate Office (**Exhibit 5**, page 1) as well as for the inspected site (**Exhibit 5**, pages 2-6).
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #3	
Person's Name and Title	Julie L Fry, Director of QC
Roles and Authorities	**(SGM)** Ms. Fry has been in current role for 1 year and at firm for 13 years. In her role, she oversees onsite QC department and supports audits/inspections, and GMPs. She also oversees training programs. She reports to Ms. Whitesell.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person's Name and Title	(b) (6), Document Control Specialist
Roles and Authorities	**(SGM)** (b) (6) oversees the onsite lifecycle of document creation/changes, and archiving. He has been in current role for 1.5 years and reports to Ms. Fry.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #5	
Person's Name and Title	(b) (6), Internal Auditor
Roles and Authorities	**(SMG)** (b) (6) has been in current role for 1 year and supports audits/inspections/investigations and oversees document review, record verification, and certification/compliance dates. She also supports pest control and maintenance repairs/activities related to quality control/GMPs.
The following are applicable to this person	Interviewed, Accompanied During the Inspection

Person #6	
Person's Name and Title	Annie R Piepenhagen , Senior Director of Quality Compliance and Systems
Roles and Authorities	**(SGM)** Ms. Piepenhagen has been in current role for 4 months out of corporate HQ. She oversees supply quality, product regulatory compliance, complaints, CAPA programs and internal audits.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #7	
Person's Name and Title	Patrick W O'Dell, Quality Operations Manager
Roles and Authorities	**(SGM)** Mr. O'Dell has been in current role for 3 months and manages onsite laboratory operations, EMP coordination, and assists with quality control. He reports to Ms. Fry.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #8	
Person's Name and Title	(b) (6) Plant Engineer
Roles and Authorities	**(SGM)** (b) (6) has been in current role for 13 years and oversees day-to-day reliability operations and facility maintenance. He reports to Mike Honsberger, Director of Engineering in corporate HQ.
The following are applicable to this person	Interviewed, Accompanied During the Inspection

FIRM'S TRAINING PROGRAM

(SGM)
The firm's training program SOP (Training Management Policy-TRN-6900-POL) was reviewed with no concerns. Ms. Fry explained that all employees partake in initial new hire and (b) (4) refresher trainings. (b) (4)
(b) (4)
, food defense, employee hygiene, cleaning/sanitation, and CCPs. Training attendance logs are maintained at the facility and were reviewed during this inspection.

Three sets of employee training records were randomly selected and reviewed during this inspection with no concerns. The records reviewed were for a QA Release operator, packaging operator (metal detection CCP), and pasteurization operator (CCP). All training indicated role specific trainings and included extra CCP trainings.

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage
Facilities (KP) The facility sists on a (b) (4) , and the actual size of the facility (including the parking lot) is

Process Flow, Operations, and Product Coverage

(b) (4). Mr. Hulle stated the production site is approximately (b) (4) and the warehouses (warehouse (b) (4)) are approximately (b) (4). The plant includes office areas, raw material and finished product storage areas, raw material receiving area, processing areas, laboratory, and maintenance shop, for a copy of the floor plan refer to **Exhibit 6,** page 10.

Access to the facility is (b) (4) for authorized personnel only; all visitor entry is via the front office, (b) (4).

The firm has (b) (4) processing areas, which consists of (b) (4) dryers (b) (4) processing area along with its own (b) (4) side and (b) (4). These areas are known as their (b) (4) (b) (4)) and (b) (4) production area (b) (4) line (b) (4)), refer to **Exhibit 6**, page 10. Firm continues to manufacture food ingredients at the (b) (4) production line for their (b) (4) ; Ms. Whitesell stated these ingredients (b) (4) / "(b) (4) . Ms. Whitesell also stated that (b) (4) production area can be used for manufacturing food ingredients (i.e. (b) (4) (b) (4)) manufactured for (b) (4). For these ingredients, she said the packaging will be done at "Packaging Room (b) (4) (b) (4)) which is part of the (b) (4) production.

Firm manufactures (b) (4) infant formula base powder ((b) (4)) for their brand (ByHeart), which is manufactured on the (b) (4) production area.

During the inspection the firm provided two documents indicating their 2024 and 2025 production sales volumes for both (b) (4) lines, refer to **Exhibit 11** for 2024 data and **Exhibit 12** for 2025 data. For the (b) (4) production line in 2024, the listed total production sales volume is (b) (4) of product. Ms. Whitesell stated that firm does not manufacture any infant formula base powder (b) (4), the item listed on **Exhibit 11** (b) (4) (b) (4). In addition, in 2025 (January-February) the firm has manufactured a total production sales volume (b) (4) of product on the (b) (4) line.

Hygiene Zones and Traffic Patterns (KP)

The plant is divided into hygiene zones; (b) (4) (b) (4) (warehouse (b) (4) , and (b) (4) Dryer (b) (4) Dryer (b) (4) (b) (4) and critical zone (b) (4) room). These (b) (4) areas (b) (4) (b) (4) The firm maintains (b) (4) pertaining to infant formula production. The plant maintenance conducts (b) (4) checks and records are kept; last check was on 2/10/2025.

To enter the processing areas (b) (4) the (b) (4) (refer to **Exhibit 8**, (b) (4)). Firm provides (b) (4) has a captive shoe policy. Employees change clothes (b) (4) to a firm provided uniform and shoes. At the (b) (4) prior to (b) (4) entry point, employees change shoes/put on a pair of shoe covers, and wash hands and sanitize. There is also a (b) (4)

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(b) (4) . This (b) (4) , in addition to providing (b) (4) to (b) (4) prior to entering the packing area. In the locker rooms as well as in the (b) (4) adequate instructions are provided to employees per hygiene zone transitions requirements.

(b) (4) raw ingredients and finished product takes place there is a (b) (4) area from warehouses/weighing room or finished product bulk totes are transferred (b) (4) packing (b) (4) In addition, the (b) (4) system with a (b) (4) (b) (4) zones.

For more information on the firms GMP/employee practices including hygiene and health, and hygiene zoning and traffic control refer to SOP QUAL-6515.07-WI (**Exhibit 9**), and SOP QUAL-6524.02-SOP (**Exhibit 10**).

There are (b) (4) area on the (b) (4) . These doors are not used for employee entry; however, these doors were not properly secured, nor did it include a signage reminding employees to not use them for entry, refer to "**General Discussion with Management 3**". Additionally, the benches used at the (b) (4) were not easily cleanable or separates the hygiene zone, refer to "**Additional Observation 1**".

Moreover, throughout the facility the firm have floor/shoe treatment. They use (b) (4) (b) (4) for entryway control. This chemical is effective against *Listeria monocytogenes, Escherichia coli, Cronobacter sakazakii and Salmonella enterica.* The firm stated they (b) (4) ; however, they did not document this changeover. Ms. Whitesell stated the cleaning record will be updated.

Plant Report (KP)
For a copy of the plant report containing changes submitted to FDA for the infant formula, refer to **Attachment** 4. The changes listed on the plant report corresponds to changes provided by the firm during the inspection, for a copy of the changes, refer to **Exhibit 13.**

Production (KP)
Covered Product and Process (KP)
The non-exempt infant formula base powder, (b) (4) , manufactured on (b) (4) production area (b) (4) was covered during the inspection. The firm only manufacture (b) (4) infant formula base powder at the facility.

Food Safety Plan (KP)
The firm has a food safety plan signed by the plant director. The food safety plan provided for review was dated to 1/24/25. For a copy, refer to **Exhibit 14**.

Process Flow, Operations, and Product Coverage

For firms (b) (4) refer to **Exhibit 15.**

Overview of the Process Flow (KP)
Mr. Hulle stated since 2022, the firm has not made any process and equipment related changes to their infant formula manufacturing line. He stated, as part of their plant improvement project, they have replaced all (b) (4) on the (b) (4) side with new (b) (4) (b) (4) pumps for performance and efficiency reasons. This was done within the last year (2024). For all other facility improvements refer to **Exhibit 1** and EIR section under "History".

General overview of the process flow for infant formula base powder includes,

(b) (4)

Supply Chain (KP)
Ms. Piepenhagen stated there has been no changes to the supply chain program since the FDA 2024 inspection (refer to SOP QUAL-2505-SOP, for an overview of the supplier approval process, **Exhibit 17**). Suppliers are approved through a risk assessment performed on the supplier and the products they sell. (b) (4) system is used for supplier approval, management, and communication. Based on the risk assessment performed, (b) (4) Firm receives ingredients with vendor COA and for each new lot received, the firm will perform a confirmation testing to ensure the raw material meets the established specifications. Vendor deviations are monitored via non-conformance reports. Vendors performance is reviewed and evaluated for vendor maintenance. The firm maintains an approved supplier list. The firm's Quality team is responsible for all release decisions for raw material and finished bulk base.

Receiving (KP)
The firm can receive raw material directly from their supplier; however, due to the space constraints, the firm uses a third- party warehousing and logistics company (b) (4) in (b) (4) The firm has (b) (4) warehouses within the facility and for infant formula process, the firm stated they utilize warehouse (b) (4) raw material storage and finished product storage. Material procurement is performed by the Corporate office for all ByHeart facilities. All ingredients are released when ingredient specifications are met based on the vendor COA and raw material testing. The testing results are kept in (b) (4) system. The firm's Quality team is responsible for checking the (b) (4) laboratory systems to ensure same lot of material is not tested by a sister facility. As such, the inspected firm only test new lots of ingredients if it has not been tested prior by sister facilities or themself.

Ingredients are received in (b) (4). The firm's material handlers performs a truck inspections and maintains records of such inspections. The retain samples for the released ingredients are held for (b) (4); the ingredients rejected are quarantined and labeled as

Process Flow, Operations, and Product Coverage

"Rejected"/with a hold tag. Vendor lot is traceable, and the firm assigns a pallet tag upon receipt.

If an ingredient needs further evaluation prior to release, the firm complete Temporary Change Notification procedure (TCN, refer to **Exhibit 18** for a copy of the procedures QUAL-6509.03-WI). The review for ingredient release after a TCN is evaluated at the Corporate level. During the inspection, raw material release was reviewed for all raw ingredients used in manufacturing finished base, lot (b) (4) . The firm received an out of specification (OOS) lab results for (b) (4) The firm added the ingredient into a finished product base and released the base, refer to "**Additional Information**".

For a copy of the raw material specification for ingredients used in infant formula base powder, (b) (4) , refer to **Exhibit 19.**

The firm continues uses a cooler to store (b) (4) for shelf life and quality purposes (b) (4). The employees performs (b) (4) checks and keep records. During the inspection, due to time constraints we did not review the calibration of the temperature sensor nor verify whether the firm challenges the high temperature alarm.

Allergen Preventive Controls (KP)
The firm only handle milk allergens. Ingredients with milk are labeled with an allergen label and are stored away from ingredient not containing milk. Allergens are controlled through label reviews (at receipt and at finished base packaging), material segregation, and cleaning and sanitation. The firm conducts either (b) (4) swabs or perform rinse water samples to verify the effectiveness of the cleaning for allergen milk.

(b) (4) (KP)
In the (b) (4) , there are (b) silos for storage of (b) (4) both (b) (4)). Each is equipped with (b) (4) (b) (4) (b) (4) and last calibrations were on 9/3/2024 and 12/8/2024. The flow meter from the (b) (4) tank is calibrated by (b) (4) basis (calibrated on 10/17/2024). The (b) (4) at point of use at the (b) (4) are (b) (4) filters) and are changed (b) (4)

The (b) (4) capacity and consists of (b) (4) . It is (b) (4) (b) (4) The temperature (b) (4) were calibrated (b) (4) ; they were last calibrated on 9/3/2024 and 12/8/2024, respectively.

All powder ingredients are pre-weighed and staged for production. The (b) scales used for weighing ingredients in the minor ingredient weight up room are calibrated (b) (4) , the last calibrations were on 12/26/2024.

(b) (4) are added (b) (4) employees to (b) (4) . The (b) (4) (b) (4) and the last check was on 1/15/2025. This tank is (b) (4) (b) (4) . Then from the (b) (4) tank the (b) (4)

Process Flow, Operations, and Product Coverage

(b) (4) . The (b) (4) by the firm, and it was last inspected on 1/10/2025. The (b) (4) is calibrated by (b) (4) on (b) (4) basis (calibrated on 10/17/2024).

For vitamins, the ingredients are (b) (4) and employees (b) (4) is (b) (4) (b) (4) on (b) (4) basis and last inspection was on 1/13/2025.

(b) (4)

(b) (4) and the last check was on 12/26/2024.

(b) (4) are inspected (b) (4) last inspection was on 12/26/2024.

When (b) (4) basis, last inspection was on 10/17/2024.

Moreover, as the (b) (4) through a (b) (4)

The firm has a (b) (4) . The (b) (4) inspected (b) (4) , and it is part of their preventive maintenance program (last

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check was on 1/28/2025). The (b) (4) [redacted]

The (b) (4) [redacted] basis (calibrated on 1/21/2025).The (b) (4) [redacted] is inspected internally on (b) (4) [redacted]; last inspection was on 1/10/2025.

The (b) (4) [redacted]

(b) (4) [redacted] These are included with the batch records.

The (b) (4) [redacted] last test was on 1/23/2025.

(b) (4) [redacted]
There are (b) [redacted] levels to the dryer. The (b) (4) [redacted] The (b) (4) [redacted] were also calibrated internally (b) (4) [redacted] basis, last calibration was 1/18/2025.

There are (b) (4) [redacted] dryer.

(b) (4) [redacted] is not monitored, refer to "**Additional Observations 2**". The (b) (4) [redacted] present in the dryer, the (b) (4) [redacted]. These are inspected by (b) (4) [redacted] (b) (4) [redacted]; it is done (b) (4) [redacted] by the dryer operators and the last inspection was on 1/22/2025.

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Air Filters (KP)
For the (b) (4) the dryer, the (b) (4) (b) (4) filter. These are changed by the firm on (b) (4) basis. The (b) (4)

For the (b) (4) was insulated in late 2023 to prevent leaking water.

Additionally, (b) (4) Filter specifications were reviewed, and no discrepancies were noted. Firm also keeps a filter log, (b) (4) Facility Filter Log" (refer to **Exhibit 20,** page 1); and for filter specifications refer to **Exhibit 20** (pages 2-15).

Moreover, (b) (4) with (b) (4) .

Filling (KP)
After the (b) (4) last service was on 2/5/2025. The firm also have an (b) (4) .

For internal calibrations, (b) (4) For more information on the firm's calibration procedures and schedule, refer to **Exhibit 21.**

Finished Base Sampling (KP)
The infant formula base powder is packed in (b) (4) totes (b) (4) (b) (4) (b) (4) The firm collects samples from thei (b) (4) . (b) (4) Each of the sample bags (b) (4)

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(b) (4) testing.

There are (b) (4) and test.

The firm had not had any product positives since 1/1/2024. For the firm's finished powder base specification, refer to **Exhibit 22**. For micro testing including *Cronobacter* spp., and nutrient testing including fat, total carbohydrates, protein, ash, moisture, heavy metals (arsenic, lead, cadmium, mercury), and allergen testing (gluten and soy) are all conducted by (b) (4). For a copy of the COAs from indicating the testing method, refer to **Exhibit 23.**

For the (b) (4) filters are changed (b) (4), the last replacement was on 1/23/2025.

The QA reviews the batch records as a final review step, and if there are no deviations, releases the batch.

The firm also conducts in-process testing for fat, moisture, tap density, color, sensory particle size, and pH. These are done by their internal lab. Ms. Whitesell stated all these analysis are performed again by their third-party lab, (b) (4) as part of their finish base release criteria.
For a copy of the Attachment B, Infant Formula Nutrient Information Reporting Form filled out by the firm, refer to **Exhibit 24.**

Inspections of the Equipment (KP)
The firm have a third-party contractor, Mechanical Integrity Industrial Inspections, to (b) (4) inspect their (b) (4) dryer and the associated equipment ((b) (4), (b) (4) tank, (b) (4) tanks, (b) (4) tanks, silos (b) (4) tank, (b) (4) tank. (b) (4) ductwork, and dryer ductwork). The last inspections were completed by 10/31/2024.

During the inspection, inspection reports for the dryer, the (b) (4) tank (b) (4) tank (b) (4) and (b) (4) tank were reviewed. All the adverse \findings were addressed, repairs were made, and no discrepancies were found.

Deviations (SGM)
The firm's deviation records from last inspection and the Investigation and Root Cause Analysis SOP were reviewed with no concerns. A list of all current deviation reports, classified as either minor/major, were collected from the firm and reviewed with no concerns **(Exhibits 25-26)** The deviation reports include a summary, investigation findings including write-ups/pictures, root cause analysis, risk assessment, product disposition, and CAPAs. Each record is reviewed and approved by QC managers.

Batch Record Review (SGM)
Per 21 CFR Part 106.6, the firm maintains several written procedures, which cover all aspects of manufacture from incoming raw materials to finished product distribution; these procedures also

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cover many areas including ingredient, in-process and finished product testing, environmental sampling, allergen control and sanitation. In addition, a Manufacturing Batch Record is maintained for each batch per individual lot number.

The following (b)(4) batches records for production of (b) (4) ByHeart Infant Base Powder were reviewed during this inspection with no concerns: Lots (b) (4) ; (b) (4) Infant formula records are primarily (b) (4) entries of critical and operational parameters are documented. Charting systems are also used to capture critical and operational parameters; they are printed, reviewed, and included with the batch records.

Cleaning and Sanitation Program

Cleaning and Sanitation (SGM)

The firm's cleaning and sanitation procedures were reviewed with no concerns. The firm follows (b) (4) procedures. The firm no longer performs (b) (4) in hygiene zones. The firm has a (b) (4) sanitation schedule for (b) (4) and scheduled sanitation breaks for (b) (4) Chemical lists were reviewed with no concerns. (b) (4) cleaning/sanitation checklists/records and (b) (4) records were reviewed with no concerns. Cleaning/Sanitation records include (b) (4) legacy record printouts, circular charts and manually filled checklists/records. The firm has a dedicated washroom (b) (4) procedures including (b) (4) .

Environmental Monitoring Program (KP)

Surface Swabbing

During the inspection we focused on the environmental monitoring program (EMP) pertaining to the infant formula processing, which included Warehouse (b) (4) area and (b) (4) packing. The firm stated since the last inspection on January 2024, for the EMP program they have focused on controlling *Cronobacter* mainly through increase monitoring, repairing floors and insulations, implementing (b) (4) in the (b) (4) , and initiating collecting of before clean swabs for unplanned water events (initiated on 5/30/2024).

During the inspection the firm provided the following documentation for review pertaining to their environmental monitoring program.

- Environmental Monitoring Program, QUAL-6510-SOP- This is SOP describes the firm's environmental monitoring program, **Exhibit 27.**
- Environmental Monitoring Positive Response Action Plan, QUAL-6510.06-WI- This SOP describes the procedures for responding to a presumptive or confirmed findings, **Exhibit 28.**
- Additional EMP Testing, QUAL-6527.09-WI- this procedure refers to the additional swabs the firm collect during a (b) (4)). In the specific sites listed on the SOP **(Exhibit 29),** the firm is sampling for *Salmonella* spp., and *Cronobacter* spp.

The firm swabs zones (b) (4) zones. Currently, zone (b)(4) is swabbed (b) (4) for *Enterobacteriaceae* (EB), Aerobic Plate Count (APC), *Salmonella* spp., *Cronobacter* spp. and *Listeria* spp. At minimum, on (b) (4) basis, (b) (4) swabs each per *Salmonella* spp., and *Cronobacter*

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spp. is collected. A minimum of [redacted] swabs are collected for *Enterobacteriaceae* (EB) and *Listeria* spp. Zone [redacted] is swabbed (b) (4) for *Salmonella* spp., *Cronobacter* spp. and *Listeria* spp. Zone 4 is swabbed (b) (4) for *Salmonella* spp., *Cronobacter* spp. and *Listeria* spp. For a list describing of the swabbed sites, frequency, zone, and organism, refer to **Exhibit 30.** Firm collects both routine and investigational swabs. Investigational swabs can be collected as (b) (4) part of vector swabbing.

(b) (4)

.

(b) (4)

refer to **Exhibit 31**, page 4.

During the inspection, Investigator Pathiraja reviewed the EMP results for the infant formula base manufacturing line (including warehouse [redacted]) since January 1st, 2024-current. Firm provided a document with total number of swabs collected for each of the organisms in each of the (b) (4) (**Exhibit 32,** page 1). Firm has collected a total of (b) (4) swabs between 1/1/2024-2/11/2025.

The firm only had positive findings for *Cronobacter* spp., for a copy of a list with [redacted] positive findings since the last FDA inspection in January 2024, refer to **Exhibit 33.** The positive results are from a combination of swabs collected during routine swabs, or in response to positive finding, or for swabs collected during an unplanned water events. During the inspection all event reports were reviewed, and no major discrepancies were found. For some of the minor discussions pertaining to the firm's EMP program, refer to "**General Discussion with Management**" 4 and 5, and "**Additional Observations**" 1.

The positivity rate from June 2023-December 2024 (b) (4) and from January 2024-Decemebr 2024 was (b) (4) (**Exhibit 32**, page 2). The firm attributed the increase in positivity rate to longer collection period (June through December in 2023 vs. January through December in 2024), increase in number of investigational swabs collected, and the (b) (4) (b) (4) area. Firm believes that their implementation of (b) (4) has reduced the positivity rate (b) (4) in January and February 2025, for more information, refer to the presentation provided by the firm **Exhibit 34**.

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Ms. Whitesell stated they will discontinue taking swabs for EB and APC in the future mainly due to lack of correlation between these organisms and the presence of pathogens, refer to the statement provided for more information, **Exhibit 35**. For the EMP EB result for 2024-2025, refer to **Exhibit 36**.

Environmental Air Monitoring (KP)
Firm conducts air sampling using (b) (4) (refer to **Exhibit 37** for SOP QUAL-6527.04-WI). Samples are collected (b) (4) for Yeast & Mold, and APC, refer to **Exhibit 38** for sample locations. During the inspection Investigator Pathiraja reviewed the air sampling results from 1/2024-current, refer to **Exhibit 39** for results. For out of specification results (OOS) the firm would retake the tests the following week. If those results are exceeding the limits the firm would investigate. The firm has multiple OOS from September through October 2024. This was remediated by replacing the HVAC filters, see **Exhibit 40** for the firm's detailed explanation. Ms. Fry stated their environment monitoring program is reviewed at (b) (4) basis by the management at the firm as well as the corporate food safety team.

Water Events (SGM)
The firm's Unplanned Water Event Reporting and Process SOP was reviewed with no concerns. All water event records including RCAs and CAPAs were reviewed since last inspection. All investigations and corrective actions for each water event appeared thorough and adequate. The firm had 12 unplanned water events since last inspection. The firm documents findings and corrective actions with detailed write-ups and pictures. Also, environmental monitoring is conducted after each event in addition to cleaning and sanitizing areas around the water event.

Process Interventions/Intrusions (SGM)
The firm's Process Intrusions SOP was reviewed with no concerns. All intrusion records were reviewed since last inspection which included 28 reports. In each case the firm documents reasons for intrusion, need for any product concerns by QC, and preventive cleaning/sanitation steps. No concerns were noted.

Water Management Program (KP)
There has not been any changes to the water management program since the last inspection. The firm receives (b) (4) . The (b) (4) (b) (4) system. The (b) (4) system is (b) (4) . The firm's maintenance conducts checks on the (b) (4) for integrity, leaks, water hardness, and water softener operations. The firm also checks for pressure, conductivity, chlorine dioxide levels and pH of the (b) (4) system. Firm also monitors (b) (4) water. The most recent monitoring record dated to 2/17/2025 was reviewed, no discrepancies were noted.

The firm replaces the (b) (4) basis (last replacement was on 2/6/2025), conducts (b) (4) testing (last tests on the (b) (4) devices, for the (b) (4) , were done from 6/27/2024- 6/28/2024), and check filters (b) (4) (last check 2/4/2025). In addition, the (b) (4) system is inspected by its manufacturer, (b) (4) , the last report was provided, no discrepancies were noted. From the (b) (4) system the water is distributed to production. (b) (4) water is used at (b) (4) tanks, (b) (4) stations in the (b) (4) room, (b) (4) (b) (4) dryer. There are a set of (b) (4) after the (b) (4) line and (b) (4)

Process Flow, Operations, and Product Coverage

The firm conducts water sampling, for more information on water sampling refer to **Exhibit 41,** SOP QUAL-6527.07-WI). The firm is testing their (b) (4) water per 21 CFR 106.20 (f). The water testing results for the past year were reviewed and firm had one event report for OOS APC results found in the water tested in December 2024. Firm concluded that was due to a contaminated (b) (4) used in the sample bottle for sample collection (Event Number 2470), the firm has taken corrective actions to resolve the issue.

The firm uses the (b) (4) system to schedule maintenance work, and maintain inventory of equipment parts.

The (b) (4) additives used in the (b) (4) appeared to be in line with the FDA regulations, refer to **Exhibit 42**.

Pest Management Program (SGM)
The firm receives (b) (4) and as-need pest control services from (b) (4) (b) (4). The facility has 57 interior rodent traps, 3 insect zone monitors, 33 insect (b) (4) traps, (b) (4), 13 exterior rodent traps, and 15 exterior bait stations. Pest service tickets were reviewed from Jan 2024 through February 2025. A few elevated pest trap findings were discussed with firm management as areas of concern. Elevated thresholds of flying insects on (b) (4) traps were noted in (b) (4) from October 2024 through December 2024 during shut down for maintenance activities. It was discussed that no significant pest activity should ever be allowed in a (b) (4) zone. No significant pest activity was observed during facility walk-through at time of inspection.

Internal Quality Control and GMP (Hygiene) Audits (SGM)
The firm has (b) (4) audits conducted by a team of auditors from the corporate level (ByHeart Corporate Quality), covering GMP and quality control procedures. An internal audit memorandum for the most recently conducted audit was reviewed (11/19-21/2024). The firm's audit program SOPs were also reviewed: Self-Inspection CAP SOP; Audit Program SOP; Food Safety and Quality Self-Inspections SOP.

(b) (4) **Equipment (SGM)**
Firm management stated there have been no changes to (b) (4) programs. The firm continues to use the (b) (4) system control program. SOPs were reviewed with no concerns for: ByHeart (b) (4) Procedure; (b) (4) System.

MANUFACTURING CODES

(KP)
The firm only manufacture IF bulk base powder, the label is provided, refer to **Exhibit 4.** No changes to the lot code assigned.
For instance, for the lot code, (b) (4), see below for the breakdown of the lot code.
(b) (4)

(b) (4)

RECALL PROCEDURES

(SGM)
Firm management stated they have had no recalls since last inspection and no recall procedural changes. Recall procedure SOPs were reviewed with no concerns: Product Recall Procedure; Vendor Recall; Recall Management Policy; Mock Recall Procedure; Recall Process Flow. The firm conducts 3 mock recalls per year for trace backs on packaging, raw materials, and products.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Inspection Observations	
Observation	1
Citation Text	You approved and released for use an ingredient that was not manufactured, packaged, labeled, or held under conditions to prevent adulteration.
Observation Details	Specifically, your firm approved and released the use of (b) (4) (b) (4) ingredient for use in manufacturing infant formula base bulk powder, that was not held under conditions to prevent adulteration. On 12/27/2024, a truck load of (b) (4) pallets of raw ingredients were received from your third party contracted warehouse; these included (b) (4) pallets of (b) (4) ; lot (b) (4)). (b) (4) pallets of (b) (4) and (b) (4) pallets of (b) (4) ; lot (b) (4)). Your firm received/approved/released for use (b) (4) pallets in the manufacturing of infant formula base bulk powder, after 1 pallet of the shipment (b) (4) (b) (4)) contained evidence of rodent activity including torn bags and rodent excreta. After an initial evaluation, your firm destroyed and rejected this 1 pallet while using all others in the shipment prior to adequately investigating the root cause. Then on 1/13/2025, a truck load of (b) (4) pallets raw ingredients were received from your third party contracted warehouse; these included (b) (4) pallets of (b) (4) lots (b) (4) and (b) (4) pallet of (b) (4) - (b) (4) Upon receipt, your warehouse employees broke down one pallet from the shipment for inspection for rodents/rodent activity. During this inspection, your employees did not find any rodents and/or rodent activity, as such you accepted the shipment and stored it in your warehouse until need for use on 1/21/2025, and on 1/23/2025. On both 1/21/2025 and 1/23/2025, your employees pulled one pallet of (b) (4) (b) (4) on each day for use. Upon bag-by-bag inspection during staging, on each of the days, your employees found rodent activity in each of the two pallets. Your firm

Inspection Observations	
	received/approved/released for use (b) (4) pallets in the manufacturing of infant formula base bulk powder, after 2 pallets of the shipment (b) (4) (b) (4) contained evidence of rodent activity including loose powder and rodent excreta. Your firm rejected and destroyed these 2 pallets while using all others in the shipment prior to adequately investigating the root cause. The above-mentioned raw materials received on 12/27/2024 (BOL (b) (4)), and on 1/13/2025 (BOL (b) (4)) are used in the manufacturing of the following infant formula base powder lots. (b) (4) Additionally, on 2/20/2025, we observed your pre-weighing operations, and saw the exterior of the paper bags containing (b) (4) powder touched the employees' smock arms when lifting to pour the ingredients into another bag. The same employees' arm that was in contact with the exterior of the bags would go inside the milk bag for scooping. The employees did not change smocks, gloves, nor wash hands and/or sanitize hands in-between tasks.
Citation Reference	21 CFR 106.40(f)(3)
Supporting Evidence and Relevance	(KP) We explained to the firm that the firm should not have accepted the shipment if any part of the shipment showed signs of rodent activity, this is to prevent any potential food contaminations and any contamination of areas of the facility including the weighing room. The current staging of raw material does include a bag-by-bag visual inspection by employees. We could not observe this during the inspection. However, Investigator Pathiraja explained to the firm that microorganisms are not visible to the naked eye and that they may very well be on the exterior of the packaging of the raw material. Moreover, the weighing practice for raw materials in bags, such as (b) (4) (b) (4) cutting the bags with a knife, then weighing up the powder into another (b) (4) bag with a (b) (4). This operation uses two employees, and it requires one employee to lift the bag for pouring (the bag is held at elbow and shoulder level), then the same employee also placing the arms inside the bags for scooping. During these actions, the employees' gloved hands and smock sleeves contact the milk powder and the interior of the bag, the (b) (4). Any contaminants from the exterior of the bag (b) (4) could be on the employees' smock including the arms, gloved hands, and potentially be added to the ingredient, when scoping out ingredients. Refer to **Exhibit 45** for photo taken of the employees lifting the bag. This photo does not show the employee holding the bag at the elbow to shoulder level. The second photo shows the (b) (4) bags the firm use for weighing ingredients. The weighed (b) (4) bags are taken to hopper for dumping at a later time. Also, any partials are kept in the original bags.

Inspection Observations	
	Although, the firm claimed, the (b) (4) CSO Pathiraja observed during weighing operations on 2/20/2025 were not part of any shipments with observed rodent activity, it is still important to take note of the firm's weighing practices for identifying potential routes of contamination from bags, specifically from those bags that were part of a shipment with rodent activity. • For the (b) (4) and other ingredients received on 12/27/2024 from (b) (4), refer to **Exhibit 46,** BOL (b) (4) **please note on the 483, the BOL numbers were switched for the two dates, 12/27/2024 and 1/13/2024.* • For the (b) (4) and other ingredients received on 1/13/2025 from (b) (4), refer to **Exhibit 47,** BOL S21791. • For the most up to date "Event Reporting and Investigative Form" (event number 2483), refer to **Exhibit 48.** Please note, this event is still pending evaluation and investigation by the firm. The firm updated information on this report during the inspection to capture events from 2/17/2025 and 2/18/2025 and to include information requested by the CSOs. • Traceability exercise performed on the raw ingredients received on 12/27/2024 (BOL (b) (4)), and on 1/13/2025 (BOL (b) (4)), show that the ingredients were used in manufacturing (b) (4) infant formula base powder lots at Allerton Facility. Some of these lots were sent to Portland facility for (b) (4) and (b) (4). Refer to **Exhibit 49** for the traceability results. A lot number with a (b) (4) indicates it is a (b) (4) made at Allerton facility. A lot number with (b) (4) indicates a (b) (4) is at (b) (4) and (b) (4) • (b) (4) pest service reports from 1/3/2025-1/24/2025 documents the events pertaining to 12/27/2024-1/24/2025, refer to **Exhibit 50,** pages 1-28. These documents identify the pest activity found as rodent/mice activity. On 12/27/2024 when firm first encountered the pallet with (b) bags ((b) (4) (b) (4)) with tape in which, one bag had a hole with rodent droppings in the powder, refer to **Exhibit 48, page 2, figure 1**, in addition to notifying (b) (4) of the event, the firm also has scheduled an onsite audit at (b) (4) on 1/3/2025 , and implemented a 1 pallet breakdown rule for each shipment received from (b) (4) (b) (4) (for additional actions taken, refer to **Exhibit 48,** page 4-5 under "*Corrective Actions/Preventive Action Summary*"). On the same day, 12/27/2024, the firm's Corporate Supplier Quality Assurance contacted the (b) (4) the supplier for the (b) (4) (b) (4) to request for a root cause and corrective actions. Additionally, the firm stated the tape on the bags were applied by (b) (4) due to damages caused by a forklift on 11/25/2024.

Inspection Observations	
	On 2/17/2025, Ms. Anna M. Brennecke, Planning and Warehouse Manager stated, one pallet from the shipment, typically the first pallet off the truck is inspected and broken down per their new policy since the incident on 12/27/2024. She also informed us that for staging of materials for processing, the firm's employees always have performed a bag-by-bag visual inspection. Please note, that based on the information provided by the firm, on the 483, it was noted that the firm have used all pallets (b) (4) pallets; (b) (4) (b) (4) pallets, and (b) (4)) except for 2 in the production of infant formula base powder from the 1/13/2025 shipment. This was due to an oversight. However, firm did confirm that (b) (4) pallets/(b) (4) bags of (b) (4) was sent back to (b) (4) after rodent activity was found on 1/23/2025 (refer to **Exhibit 48,** page 7 under Risk Assessment and Product Disposition summary), although no documentation was provided CSOs to show this return. On 2/13/2025 and on 2/14/2025,we conducted a walkthrough of the warehouses (b) (4) and sample retain room. We found potential harborage sites within the warehouse (b) (4) and in the retain room. Moreover, during the pest control record review there were findings of rodents at the interior and along the exterior of the facility refer to **FDA 483 Observation 2** , and it's "Supporting Evidence and Relevance". During the inspection, the firm stated they will be receiving shipments from (b) (4) on 2/17/2025 and on 2/18/2025. On both occasions we observed the firm's receiving. On 2/17/2025, Ms. Katleen E. Whitesell, Sr. Director of Food Safety stated that after a discussion with the Corporate over the weekend, they have decided to inspect (with (b) (4) break down all pallets upon receipt, this is only for shipments coming in from (b) (4) . On 2/19/2025, Ms. Whitesell stated the firm will continue with this (b) (4) pallet break down up through March 19, 2025. On 2/17/2025, the firm received (b) (4) from (b) (4) , and no pests or pest activity were noted. We only observed shoe prints (dirt) on the pallet slips pertaining to pallets numbers (b) (4) . The bags on the bottom layer of the pallet were directly in contact with the shoe prints. Ms. Whitesell instructed the warehouse employees to hold these pallets until further evaluation. Prior to close-out, no other information was provided related to the disposition of these products from these pallets. In addition, on 2/18/2025, the firm received (b) (4) (b) (4) . During the pallet break down, we observed 2 pallets with pest activity (refer to **Exhibit 48,** page 3 for information; and **Exhibit 51,** page 1 for photos taken). The firm stated the entire truck load was rejected and was sent back to (b) (4) warehouse (refer to **Exhibit 52** , BOL

Inspection Observations	
	(b) (4). In addition, shoe prints on a pallet slip was also observed on pallet number 111 (**Exhibit 51,** page 2). On 2/13/2024, Ms. Annie Piepenhagen stated due to their findings on 12/27/2024, the firm has initiated a supply chain investigation to evaluate pest control activity. She stated, the supply chain includes (b) (4) (b) (4) supplier to BlendHouse, Allerton, and the (b) (4) supplier (b) (4) and (b) (4) for (b) (4) (contracted warehouse for (b) (4) is stored here prior to arriving to (b) (4) and (b) (4) (contracted warehouse for BlendHouse Allerton, all non-bulk ingredients are stored at this site). Because the rodent activities were found in pallets containing (b) (4) the firm stated they have identified the above-mentioned supply chain. For a copy of the supplier agreement, refer to **Exhibit 54.** Since 12/27/2024, the firm have received (b) (4) shipments from (b) (4) on 12/30/2024, 1/13/2025, 1/27/2025, 2/11/2025, and on 2/18/2025. The rodent activity were found on the shipments from 12/27/2024, 1/13/2025, and 2/18/2025. Also, the firm stated, they have conducted an onsite audit at (b) (4) (b) (4)s on 1/3/2025 and found no evidence of rodents or rodent activity (**Exhibit 48,** page 10). They stated there will be two other audits scheduled to be completed before the end of March 2025. Firm concluded that based on their review of pest control reports from (b) (4) (**Exhibit 48**, page 6), that (b) (4) was the potential culprit (**Exhibit 48,** page 12). As such, Ms. Piepenhagen stated the firm has delisted (b) (4) from supply chain as of 2/12/2025. This means (b) (4) will continue to supply (b) (4) to BlendHouse by shipping them directly from their facility to (b) (4). **Based on the information provided, it was difficult to say with certainty the pest activity arose from (b) (4), as such it is recommended that US FDA conducts an inspection at those warehouse facilities. The firm provided a BOL (b) (4) as a document to establish interstate commerce from (b) (4) (b) (4)), **Exhibit 53,** to (b) (4) (b) (4)*
Discussion With Management	During the closeout, the firm (Ms. Whitesell and Mr. Niall Mullane)

Inspection Observations	
	continue to reiterate that there is no food safety concerns, however, Investigator Pathiraja reminded the firm that although there may be a "kill step", it is not a good practice add to the microbial load prior to the kill step. During the inspection, the firm stated they will invest in (b) (4) for their inspections instead of (b) (4), refer to **Exhibit 73** for a copy of the purchase order and **Exhibit 76**, page 2 and page 3 for the list of corrections initiated by the firm. Firm promised to evaluate the situation and respond to US FDA in writing.
Correction Status	Not Corrected
Corrective Action Description(s)	For some of the actions taken by the firm refer to Exhibits 73 and 76.
Observation	**2**
Citation Text	You did not exclude pests from your food plant to protect against contamination of food.
Observation Details	Specifically, review of your pest management program from 1/16/2024-current, indicated a finding of a dead mouse on 1/22/2024 east of the QA Lab, seeing a live mouse in the compact baler on 12/3/2024, and catching mouse in a snap trap inside the (b) (4) Room on 12/15/2024. Moreover, there were rodent catches on the exterior premises, notably, in November 2024, and in December 2024 there were 11 and 8 catches in traps on the exterior premises, respectively. Also, currently, you are investigating rodent activity found in raw material, (b) (4). During our walk through, we found a potential harborage sites at Warehouse (b) (4) (b) (4) Room (b) (4) and Warehouse (b) (4). However, you have not taken actions to eliminate all potential harborage areas.
Citation Reference	21 CFR 117.35(c)
Supporting Evidence and Relevance	(KP) The firm had findings of mice inside the facility dating back to 1/2024 (**Exhibit 56,** page 1 and **Exhibit 57**, page 6). During the inspection, we only reviewed pest records dating back to January 1st, 2024. It appeared the pest service provider has identified potential ingress points on 1/2024 and on 12/2024. For instance, the pest service report dated to 1/26/2024 mentioned an open door near (b) (4) which could allow for rodent access (**Exhibit 57,** page 2 under "New Client Actions"). This report also mentioned (page 5) "[rodent] it had possibly fallen out of insulation that covers the walls and ceiling in this area". In addition, the pest service report dated to 12/20/2024 (**Exhibit 57,** pages 23 under "Updated Client Actions"), indicate a openings on dock plates to prevent rodent and insect entry (firm corrected this on 1/31/2025, **Exhibit 58,** page 30). During the inspection, we did not see any open doors or gaps on the dock plates. However, we did observe 3 potential harborage points, **Exhibit 59**. The firm cannot provide

Inspection Observations	
	information as to when these potential harborage points had appeared in the facility. The firm said the wall insulations were in the facility since 2022. However, knowing the rodent activity both inside and outside of the facility, the firm failed to identify these areas as potential harborage points and take additional actions to eliminate them. • Refer to **Exhibit 60** for a copy of the firm's "Pest Management" policy, "SAN-6811-SOP". This policy describes the firm's procedures, requirements, and responsibilities pertaining to the pest management program. • Refer to **Exhibit 55** for a copy of the summary of rodent catches on the interior and exterior of the facility. This document was created by the firm. Under (b) (4) for months November and December, the document lists the number of catches on the exterior bait stations. On the interior of the facility the firm "BlendHouse Allerton Interior Catch", there were two findings of mice on both 1/2024, and 12/2024. • Refer to **Exhibit 56** for a copy of the summary of events pertaining to "Pest Control Investigations and Actions" provided by the firm on 2/17/2025. • Refer to **Exhibit 57** for copies of the pest service reports from 1/26/2024 (pages 1-7), and 12/2024 reports (pages 8-46). Additionally, during the walkthrough of the Warehouse (b) (4) Room, we keep finding insulation material (refer to **Exhibit 61,** pages 3-6). To this, the firm responded that these pieces of insulation material may have been material left behind from December 2024, when they have placed the roof insulation throughout Warehouses [redacted] and [redacted] Although that maybe one possibility, it is difficult to rule out that these may not have been left behind as a result of rodent activity. Also, the insulation material found on the floor in the (b) (4) Room during out walk-through(**Exhibit 59,** page 6), is in proximity to where a mouse was caught in a snap trap inside the (b) (4) Room on 12/15/2024. Also, during our walkthrough we identified an apparent mud dauber's nest on the (b) (4) of Warehouse [redacted] **Exhibit 61,** page 1 (the firm identified the mud house as mud dauber's nest on 2/14/2025, refer to **Exhibit 62**). With consultation with their pest control service provider, the firm was able establish that the nest was possibly an abandoned nest without recent activity. Moreover, we found gaps under a (b) (4) in Warehouse [redacted], refer to **Exhibit 61,** page 2. The firm's maintenance confirmed the size of the gap was between 2mm-3mm in height and 4cm-5cm in width. On 2/19/2025 the firm stated they consulted with their pest service provider and concluded that this space does not provide enough room for rodent

Inspection Observations	
	ingress. However, it may be a potential entry point for small insects. The pest service report dated to 1/31/2025 (**Exhibit 58,** page 33) indicated a finding of a live insect inside Warehouse [redacted]
	During the inspection, the firm initiated the sealing of the 3 harborage areas, refer to **Exhibit 74** for photos of the correction made and for additional actions that will be taken by the firm, refer to **Exhibit 76**. Firm identified the mud nest as mud dauber nest and clean and inspected the area including the roof for entry points (refer to **Exhibit 76**). The firm fixed the gap under the (b) (4) in warehouse [redacted] (refer to **Exhibit 76 and Exhibit 74**, pages 21-24). These need to be verified as corrected at the next inspection.
	Correction Requires Onsite Verification
	For corrections taken, refer to Exhibit 74 and 76.
	You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.
	Specifically, on 2/14/2024, we observed on the floor of dryer level [redacted] near the exhaust fan, on multiple locations, rusty surfaces and the epoxy on the diamond plate surfaces was peeling. Also, the floor under the (b) (4) (b) (4) has rust on the floor. This creates a harder to clean surface thus leading to potential harborage areas for pathogenic microorganisms. Last time the level [redacted] floor near the exhaust fan was swabbed was on 10/10/24, one swab near (b) (4) was collected. Moreover, you had 8 confirmed Cronobacter *Sakazakii* positive findings at level [redacted] floor from 1/2/2024-2/6/2025. Also, you stated that the level [redacted] floor under the (b) (4) has not been swabbed in the past year (1/2/2024-current). You had 4 confirmed Cronobacter *Sakazakii* positive findings at level [redacted] floor from 1/2/2024-2/6/2025. Moreover, you were unable to provide information as to when the floor conditions have changed (rust and/or peeling) in dryer level [redacted] and in level [redacted]. This is a repeat observation from the previous inspection(s) conducted on 06/30/2022 (written observation).
	21 CFR 106.20(a)
	(KP) The firm had confirmed Cronobacter *Sakazakii* on both level [redacted] floor and level [redacted] in the last year, refer to **Exhibit 63 (3/2/2024, 3/6/2024, 3/9/2024, 4/3/2024, 4/11/2024, 4/13/2024, and 2 locations on 4/18/2024)** and **Exhibit 64 (2 locations on 8/22/2024, 9/14/2024, and 9/15/2024)**. Given that there were confirmed *Cronobacter Sakazakii,* it would be a

Inspection Observations	
	good practice for the firm to monitor these floor conditions (for rust, or peeling), to prevent any potential findings of such pathogens in the future. Additionally, refer to **Exhibits 65** and **66** for photos taken of the level [redacted] and [redacted] during the inspection. Moreover, **Exhibit 63, page 13** shows the area on level [redacted] that was last swabbed by the firm, on 10/10/24 (near the exhaust fan). **Exhibit 64, page 16** show the areas on level [redacted] that were last swabbed , page 16 refer to 12/19/24 (b) (4)); however, none encompasses the floor under the (b) (4)
Discussion With Management	Ms. Fry stated, on level [redacted], the rust on the floor is most likely is from a pressure valve on the exterior of the (b) (4) (not food contact) that is not (b) (4) . When the firm used to conduct (b) (4) in the area caused the rust to form. The firm stated the floor on Level [redacted] is repainted and resealed and the (b) (4) (b) (4) will be replaced with (b) (4) the future, refer to **Exhibit 76,** page 2 and **Exhibit 77**. These corrections needs to be verified as corrected at the next inspection. Firm promised to evaluate the situation and respond to US FDA in writing.
Correction Status	Not Corrected
Corrective Action Description(s)	For corrections made to Level [redacted] refer to Exhibit 76 and 77.

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	Your plant was not designed to facilitate maintenance and sanitary operations.

Observations Not Listed on FDA Form 483	
Observation Details	Specifically, (b) (4) (b) (4) for gowning PPE prior to entering the packing area, the (b) (4) dryer control room and the (b) (4) had steel benches that are harder to clean due to potential harborage areas, gaps between the legs and the floor and, underside of the bench.
Citation Reference	21 CFR 117.20(b)
Supporting Evidence and Relevance	(KP) Refer to **Exhibit 67** for photos of the benches in the controlled access points and refer to **Exhibit 8** for a copy of the floor map indicating employee access points for traffic control and hygiene zoning. The firm does have benches that goes all the way to the ground at the locker rooms (**Exhibit 8,** indicated on the map with a red arrow) where employees initially change their outside shoes and put on PPE before entering the processing areas, and their warehousing areas. However, when transitioning from (b) (4) areas (**Exhibit 67,**page 2, indicated with IMG_2660.JPG) or (b) (4) area (**Exhibit 67,** indicated with IMG_2646.JPG) the benches used are not solid barriers that separate floor contaminations between the hygiene zones and does not show clear control of hygienic entry point even though shoes are changed/shoe covers are put on. Also, the transition room in between the (b) (4) room to (b) (4) is in (b) (4) area (**Exhibit 67** indicated with IMG_2607.JPG). It has a bench that is not a solid barrier to prevent floor contaminations. Even though the hygiene zoning remains the same, it is important to establish clear barriers especially considering Environmental Monitoring data for 2024-2025, where there have been confirmed *Cronobacter Sakazakii* positives findings in the (b) (4) (**Exhibit 33)** . Also, **Exhibit 33** page 2, list for 9/12/2024, there was a *Cronobacter Sakazakii* positive swab collected from an employee's boots that they leave in the (b) (4) (same room as mentioned above with IMG_2607.JPG).
Discussion With Management	During the inspection the firm initiated to install new benches in the (b) (4) (b) (4) and in the (b) (4), refer to **Exhibit 75**. These need to be verified as corrected in the next inspection.
Correction Status	Correction Requires Onsite Verification
Corrective Action Description(s)	For correction taken refer to Exhibit 75.
Observation	**2**
Citation Text	You did not include controls for the (b) (4) process for a powdered infant formula.
Observation Details	Specifically, the baghouse differential (b) (4) (b) (4) are not calibrated. You (b) (4) (b) (4)) and replace the filters. However, they have not been calibrated to ensure they are working properly to detect any issues with the baghouse that may potentially impact dryer efficiency.

Observations Not Listed on FDA Form 483	
Citation Reference	21 CFR 106.50(d)(2)
Supporting Evidence and Relevance	The firm does not calibrate the baghouse (b) (4) sensors. (b) (6), Plant Engineer stated he has checked the differential pressure at least once using a reference gauge, but he did not have this check on a record. He also stated it is not currently on a Preventative Maintenance program. Investigator Pathiraja explained to the firm that it is a good practice to calibrate these instruments at the baghouse to ensure they are operating effectively.
Discussion With Management	(b) (6) created a new Preventative Maintenance schedule called (b) (4) to include (b) (4) (b) (4). He stated these will be calibrated (b) (4) starting 3/4/2025. He also showed me a calibration record which showed that he completed the calibration of the (b) (4) at the baghouse on 2/15/2025, after our conversation.
Correction Status	Correction Requires Onsite Verification
Corrective Action Description(s)	A new PM was created to include (b) (4) and was promised these will be calibrated (b) (4) starting 3/4/2025. A calibration of the sensors conducted during the inspection was reviwed on 2/15/2025.

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

(KP)
On 2/20/2025, at the close-out, the following individuals were present in person, John van der Hulle (Plant Director), Katleen E. Whitesell (Sr. Director of Food Safety), Julie L. Fry (Director of Quality Control), Annie R. Piepenhagen (Sr. Director of Quality Compliance and Systems), (b) (6) (b) (6) (Internal Auditor), Michele Otte (Quality Operations Manager from BlendHouse, LLC Reading, PA), Alicia Dickenson (Release Services Associate Manager, BlendHouse, LLC Reading, PA), (b) (6) (Document Control Specialist). Additionally, the following individuals were present via Microsoft Teams, Niall Mullane, PhD (Chief Quality Officer), Devon Kuehn, MD (Chief Medical Officer), Elias Aoukar (Chief Operating Officer), Georg Krause-Vilmar (Chief legal Officer), Bill Thomas (Sr. Director of Manufacturing),and Marcus Jordan (VP Supply Operations).
The FDA 483 was issued to Mr. John van der Hulle, Plant Director, who identified himself as the most responsible person for the facility inspected. Throughout the inspection and at the close-out, the firm was encouraged to make voluntary corrections to observations. The firm was

informed that the observations will be further reviewed by the Agency, before considering the firms' compliance. And can be considered violations of the FD&C Act or other statutes. Legal sanctions available to the FDA may include facility's products being refused, or detained upon entry, into the United States. Management was advised that if FDA receives an adequate response to the FDA-483, or other objectionable conditions, within 15 business days of the end date of the inspection, it may impact FDA's determination of the need for subsequent action. Firm conveyed they understood all the observations and promised to respond to the Agency within 15 business days.
During the close-out, the following discussion items in addition to the FDA 483 and Additional Observations were shared with the firm.

1. (SGM) Specifically, on 02/14/2025, we observed consecutive (b) (4) pest control service tickets between October 2024 and December 2024 that reported up to 200 large black flies caught in insect light traps in the IF (b) (4). Firm stated this was during a scheduled shutdown which included numerous maintenance activities that brought construction traffic through the bottom doors of the dryer.

   It was discussed that no significant pest activity should ever be allowed in a (b) (4) zone, even under shutdown/construction, due to concerns with extra environmental contamination potential.

2. (SGM) Firm QA personnel missed the final QA review check and signature of a completed process intrusion form from 01/24/2024.

   The importance of levels of quality control reviews and checks for records were discussed. Management stated that QA will reaffirm importance of review checks and stress concerns through retraining.
   (KP) For corrections made by the firm, review **Exhibit 76,** page 2 and **Exhibit 78.**

3. (SGM) Double doors to the (b) (4) area were not securely locked and were open/ajar without adequate signage for no access. These doors are only supposed to be used for taking in equipment and is not an employee access to (b) (4). The doors open to the (b) (4) (b) (4) where finished bulk powder totes are removed from the packing area and has foot traffic access to the warehouse**.**

   The importance of limiting access to (b) (4) zones without bypassing (b) (4) (b) (4) were discussed. It was discussed that non-routine-access doors should be properly locked with signage to prevent unwanted access to controlled areas. Firm management corrected the issue during the inspection and properly closed/locked the double doors and installed no-access signage.
   (KP) For corrections made by the firm, review **Exhibit 79.**

4. (KP) Environmental Monitoring Program:
   a. During the discussion of the firm's Environment Monitoring Program, CSO Pathiraja asked Ms. Fry when they collect the swabs. She stated their (b) (4) (b) (4) and their cleaning and sanitation can last (b) (4). She said typically,

the swabs are collected on a (b) (4) for (b) (4) collection; she also mentioned the day can vary. In addition, she mentioned about (b) (4) of the time, the swabs are collected (b) (4). As such, it was unclear whether the firm was routinely collecting their environmental monitoring swabs during production.

CSO Pathiraja explained, for routine swabs collected for environment monitoring, it is highly recommended that the firm collect these swabs during production to monitor and assess the overall conditions of the environment which includes but not limited to the facility, productions and employee practices, and equipment. Moreover, to evaluate the efficacy of cleaning and sanitation practices, the firm can collect additional swabs after cleaning and sanitation. During the close-out meeting, the firm promised to assess these practices.

b. The firm's procedures were unclear on the following/needed to include the following:

i. Corrective actions taken when vector swabs collected during (b) (4) clean are positive was not clearly explained in the procedures.
ii. Firm's procedures needed to include the (b) (4) of monitoring.
iii. Procedures need to include actions taken when vector swabs are cancelled due to lab not receiving them on time.

Per firm's current procedures, the firm conducts (b) (4) of cleaning and vector swabbing in the event of a presumptive/confirmed positive finding. For instances, when there is a presumptive positive swabs per routine (b) (4) collection, the firm would (b) (4) and its' surrounding, then collect swabs (b) (4). This is considered the (b) (4) and vector swabbing. Then collect additiona[illegible]wabs f[illegible] (b) (4) cleaning and sanitizing, which are considered (b) (4) vector and cleaning swabbing. Once all vector and cleaning swabs are negative, the firm would (b) (4). However, the written procedures do not include this (b) (4) of monitoring and what actions are taken by the firm when one of the cleaning and vector swabs are positive. In addition, the procedures do not clearly state the firm's action when swabs do not make it to lab on time. These practices are not clearly stated in their procedures, "Environmental Monitoring Program, QUAL-6510-SOP" (**Exhibit 27**), and " Environmental Monitoring Positive Response Action Plan, QUAL-6510.06-WI" (**Exhibit 28**).
During the close-out meeting, the firm provided an updated SOP, refer to **Exhibit 80.**

c. Event reports for Environmental Monitoring Program needed to be clear and easy to follow, contain detailed information and needed to capture all information including completion of any CAPA.

During the review of event reports, it was very difficult to follow the sequence of

events and the actions taken by the firm. Some corrective actions taken were not captured on the event report, for instance whether the firm had completed cleaning and vector swabbing for (b) (4) or capturing data on whether (b) (4) of monitoring was completed. Also, when the report lists CAPAs the firm writes the target date but does not include the CAPA completion date. As such, during the inspection additional time had to be invested in these reports to search for the missing information.
During the close-out meeting, the firm promised to evaluate their ways of documenting information on the event reports.

5. (KP) There were stains found throughout the (b) (4) floors. Specifically, on level (b) below a hoist, an oil drop and a stain were found (**Exhibit 43, page 2**). Also, stains/what appeared to be water mark was found on the floor of level (b) (4) (**Exhibit 43, page 3**). Dryer floors needs to be inspected regularly for cleanliness.

   The firm stated they cleaned the oil drop and the stain on level (b) (4) however, this was not verified during the inspection. Firm did not provide any additional information as to the stain found on level (b). Ms. Fry commented that that area where the stains were found was where the firm used to store their (b) (4). The firm promised to inspect the floors. Additionally, for other comments made during the walk-though related to the stains on the floor, the firm provided a document with corrections, refer to **Exhibit 81**.

6. (KP) As part of a CAPA #1 for EMP event (EMP-24AI-01), unplanned water event, a rain leak from the Warehouse (b) (4) storage tank (b) (4) compromised", refer to **Exhibit 44**, Event Report EMP-24AI-01) the firm has applied new caulking on open cracks found on the exterior of the (b) (4) through. Water from this event leaked "into the interior floor" of Warehouse (b) (4). However, this is not on a preventive maintenance program for future/continuous monitoring.

   During the close-out meeting, the firm promised to include this into their preventive maintenance program and to conduct inspections of the caulking starting 3/20/2025 at a frequency of every 6 months.
   The firm also reiterated the roof of the IF processing areas are under development, refer to **Exhibit 82** and **Exhibit 1**, pages 23-24.

7. (KP) During the walk-through, on the bottom of the ceiling on level (b), there were stains observed. Firm stated these are rust stains passing through the open caulking in the area (refer to **Exhibit 43, page 1**).

   Ms. Fry stated the rust is possibly from previous (b) (4) of the area. Firm promised to reassess caulking in the area.

ADDITIONAL INFORMATION

(KP)

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

(b) (5) [redacted]

The following are submitted for HFP review:

1. The firm has established specifications for their raw material (**Exhibit 19,** "ByHeart Ingredient Confirmation testing") and all raw materials are received against the vendor COA. In addition, each new lot of raw ingredient received is sampled by the firm. During the inspection CSO Pathiraja reviewed the receiving documents and testing done on raw ingredients for the infant formula base powder lot (b) (4) . For their infant formula base powder firm uses (b) (4) as an ingredient (refer to **Exhibit 19**). The supplier for this ingredient is (b) (4) (refer to **Exhibit 68,** page 10 for the COA supplied (b) (4)) and distributed by (b) (4) (b) (4) (refer to **Exhibit 68**, page 11). The supplier COA for (b) (4) (b) (4) (**Exhibit 68,** page 10) stated the specification levels for lead as (b) (4) (b) (4) and "results as <0.3 ppm". The firms' specifications for lead for this ingredient (b) (4) (b) (4) (**Exhibit 19**). However, when the firm tested the ingredient, their lab, (b) (4) , results for lead came to be 527 ppb (**Exhibit 68,** page 8). Firm's protocol when there is out of specification results is to have the lab test the same ingredient lot up to (b) (4) times. For this lot, the results were (b) (4) (**Exhibit 68,** page 8). As a result, the firm has opened a "Temporary Change Notification" number 24-0040A (**Exhibit 68,** pages 5-6) to evaluate the ingredient for use. The firm's Senior Technical Data Analyst, (b) (6) (b) (6) reviewed the historical data for this ingredient and determined that the levels indicated by the tests for raw ingredient will not impact the lead levels in their finished base. As such firm released the ingredient for use at normal usage rate.

   The finished infant formula base powder specification for lead is listed in the firm's "Infant Formula Canned Finished Product Release Specification-206-VA" (Refer to **Exhibit 22,** page 2), (b) (4) . The firm tested the finished infant formula base (lot (b) (4)) that the ingredient (b) (4) was used, and results provided by (b) (4) listed lead level of (b) (4) (refer to **Exhibit 68,** page 2). As such the firm has released this product.

   Investigator Pathiraja explained to Ms. Whitesell the documents will be collected and (b) (5) [redacted]

   The firm provided a statement by (b) (6) to support their reasoning (**Exhibit 69**). The firm further stated that they are in the process of removing (b) (4) .

   For a copy of the SOP QUAL-6509.03-WI Temporary Change Notification Procedure, refer to **Exhibit 18.**

Additionally, the firm was asked to update the hazard analysis and their supply chain preventive controls to include their evaluation of the hazard heavy metals. The firm already perform supplier verification activities for applicable raw materials. The firm promised to update the verbiage on the food safety plan.

2. The firm currently send their environmental swabs to Institute for Environmental Health (IEH) Laboratories & Consulting Group. Firm informed me they only collect (b) (4) swab to test 3 pathogens (*Cronobacter* spp. *Listeria* spp. and *Salmonella* spp.). They also informed me that the lab has told them that the lab (b) (4) to analyze Listeria, and the rest is used to analyze Cronobacter and Salmonella.

CSO Pathiraja asked the firm to provide validation studies performed to show that the recovery of the organism of interest is the same when using one swab per organism vs one swab for multiple organisms. The following documents were provided:

- Validation of IEH *Salmonella-Cronobacter* spp. and *Cronobacter sakazakii-Salmonella* PCR Assays for the Detection of *Salmonella* and *C. sakazakii on* Two Different Surfaces- **Exhibit 70**
- AOAC Test Method for *Listeria* spp. and *Listeria monocytogenes*- **Exhibit 71**.
- COA for month of February 2025 to show the methods used by the lab- **Exhibit 72.**

Ms. Whitesell stated that because the lab currently does not have a validated procedure for compositing three organisms, they will collect two swabs, one swab will be dedicated to *Listeria* spp. and the other will be tested for both *Cronobacter* spp. and *Salmonella* spp.

(b) (5) .

At the beginning of the inspection, Ms. Fry presented the "GMPs-Good Manufacturing Practices Visitors" (**Exhibit 6**) presentation and at the end we were asked to sign their "Training Attendance and Understanding" document (refer to **Exhibit 7**). Investigator Pathiraja explained to Ms. Whitesell that we cannot sign any documents that will give up FDA's authority, specifically usage of camera to document evidence and observations. As such we agreed that we can sign the document only to convey that we have reviewed the presentation with the firm. She stated the firm understands. Firm allowed us to take pictures during the inspection and the sample collection.

SAMPLES COLLECTED

Sample Number	INV 1250560
Description	(KP) The sample consist of 45 swabs and 4 closed controls. The sample was collected on 2/11/2025 and it is to be analyzed for *Salmonella spp*. The results received on 2/19/2025 from the US FDA lab classified the results as LC1, no *Salmonella spp.* detected.

Sample Number	INV 1250561
Description	(KP) The sample consist of 45 swabs and was collected on 2/11/2025. The sample is to be analyzed for *Cronobacter spp*. The results received on 2/19/2025 from the US FDA lab classified the results as LC1, no *Cronobacter spp.* detected.
Sample Number	**INV 1250562**
Description	(KP) The sample consist of 65 swabs. The sample was collected on 2/13/2025 and it is to be analyzed for *Salmonella spp*. The results received on 2/18/2025 from the US FDA lab classified the results as LC1, no *Salmonella spp.* detected.
Sample Number	**INV 1287521**
Description	(KP) The sample consist of 65 swabs and was collected on 2/13/2025. The sample is to be analyzed for *Cronobacter spp*. The results received on 2/20/2025 from the US FDA lab classified the results as LC1, no *Cronobacter spp.* detected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Facility Enhancements	24
2	BOL (b) (4)	4
3	BOL (b) (4)	5
4	Bulk Base Label	1
5	Org Charts	6
6	Visitors GMP presentation	18
7	GMP Training Attendance Log	1
8	Hygiene Zones and Traffic Control-Map	1
9	QUAl-6515.07-WI	8
10	QUAL-6524.02-SOP	21
11	2024 Sales Volume	1
12	2025 Sales Volume	2
13	FDA Submissions	1
14	Food Safety Plan	44
15	Day Code Summary	1
16	Process Flow	3
17	QUAL-2505-SOP	9
18	QUAL 6509.03	5
19	Ing. Specifications	6
20	Filters and Log	15
21	Calibrations	16

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
22	Base Powder Specifications	5
23	Base Powder Testing Methods	5
24	ATT B	1
25	Events and Deviations 2024	1
26	Events and Deviations 2025	1
27	QUAL-6510-SOP	19
28	QUAL-6510.06	7
29	QUAL-6527.09	3
30	Swab Schedule	24
31	(b) (4) Information	4
32	EMP Swab Count 2024-2025	2
33	EMP Positives 2024-2025	4
34	EMP Storyboard	20
35	APC and EB Removal	1
36	EB EMP Results 2024-2025	10
37	QUAL-6527.04	3
38	Air Sampling Sites	1
39	Air Testing Results	4
40	Corrective Actions to OOS Air Results	1
41	QUAL-6527.07	3
42	Boiler Chemicals	3
44	Event Report 24AI-01	15
45	Photo of (b) (4) Weighing	1
46	BOL 12-27-2024	1
47	(b) (4) BOL 1-13-2025	1
48	Event Report 2483	18
49	Trace Exercise Summary	3
50	Pest Service Report 1-2025	34
51	Photos of Rodent Pallets	1
52	BOL 2-18-2025	2
53	BOL (b) (4)	4
54	Supplier Agreement for (b) (4)	35
55	Rodent Summary	1
56	Pest Control Investigation and Actions	3
57	Pest Service Report Jan 2024-Dec 2024	46
58	Pest Service Report Jan 2025	34
59	Photos of the Potential Harborage Sites	6
60	SAN-6811-SOP	6
61	Photos of Other Findings	6
62	(b) (4) Roof FInding	5
63	(b) (4) Level	13
64	(b) (4) Level	16

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
65	Photos of Level [redacted]	4
66	Photos of Level [redacted]	1
67	Photos of the Benches	3
68	(b) (4)	11
69	(b) (4) Statement	1
70	Validation of (b) (4)	15
71	AOAC Listeria	6
72	COA Showing Methods	6
73	(b) (4) Light	2
74	FDA 483 Ob 2 CA	24
75	Update on Benches in (b) (4)	2
76	CA Summary	4
77	Level (b) (4)	12
78	QA Training	19
79	(b) (4) Door CA	1
80	QUAL-6510.06 Updated	8
81	Walkthrough CA	6
82	Roof Replacement	2

CAR Exhibits		
CAR Exhibit Number	**Description**	**Number of Pages**
1	(b) (4) CA	2
1	FDA 483 Ob 2	24
1	CA Summary	4
2	Level (b) (4)	12
1	(b) (4) Benches	2

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	Issued 483	5
2	482 was issued to the most responsible person present at the plant. Two copies of the forms are used to capture signatures of all investigators present.	8
3	Sample Receipt	2
4	FDA Plant Report	3
5	WB emo	3

M

SIGNATURE

Kawshalya Pathiraja
Investigator
Signed By: Kawshalya Pathiraja -S
Date Signed: 04-15-2025 16:05:00

Stephen G Mclane
Investigator
Signed By: Stephen G. Mclane -S
Date Signed: 04-16-2025 08:29:09

Ron R Pearson
Investigator
Signed By: 2003320308
Date Signed: 04-16-2025 08:53:53

Marc Balzarini
Investigator
Signed By: MARC A. BALZARINI -S
Date Signed: 04-16-2025 11:21:37

Lloyd M Luapula
Investigator
Signed By: Lloyd M. Luapula -S
Date Signed: 04-16-2025 11:05:32

Joselin P Baray-Alvarado
Investigator
Signed By: Joselin P. Baray-alvarado -S
Date Signed: 04-16-2025 11:50:00