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SUMMARY

Inspection	
Operation ID and Name	267913: FY 24 Domestic and Foreign Schedule of Inspections/Sample Co

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This surveillance infant formula and follow-up preventive controls inspection of an infant-formula-base manufacturer inspection was conducted in accordance with the FY24 HAFW2 workplan, Operation ID 267913, DFPG # 24-03 FY 24 Domestic and Foreign Schedule of Inspections/Sample Collections for Infant Formula and Medical Foods Compliance Programs and compliance program(s) 7321.006 Infant Formula Program - Import and Domestic, 7321.005 Domestic and Import NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements Program, 7303.040 Preventive Controls and Sanitary Human Food Operations.

The previous preventive controls human food inspection was conducted by FDA on June 27, 2023. That inspection was classified as NAI.

The previous infant-formula inspection was conducted by FDA on June 29, 2022. That inspection was classified as VAI.

The following observations were observed during the last infant-formula inspection:

- Not having a written sanitation preventive control, monitoring, corrective action and verification procedures appropriate to significantly minimize or prevent the hazard requiring a preventive control
- Having a person who conducted an audit relating to infant formula quality control procedures was directly responsible for matters that the person was auditing
- Measuring devices were not calibrated, which were used to verify that ingredient weights for infant formula bases were accurate
- Not maintaining a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

The firm does not qualify for 21 CFR 117 PC attestation

This inspection focused on the manufacturing of infant formula to include supply chain controls and the corrective actions implemented following the June 2022 inspection. This firm manufactures an unfinished-nutrient-deficient powdered-infant-formula base that is shipped to Blendhouse Portland located in Portland, OR. Local firm management stated Blendhouse Portland adds lactoferrin and packages the powdered infant formula for market.

Since the June 2022 inspection, the company has made significant facility improvements, including:

1. Replacing the steel floors of the (b)(4) tower with (b)(4).
2. Applying a more durable paint/coating to various areas
3. Relocating and replacing (b)(4) from dryer tower level (b) to the (b)(4) room.
4. Insulating the dehumidification section of the (b)(4) air supply, including the replacement of (b)(4) lines.
5. Replacing water service lines for dryer tower (b).
6. Stripping and re-roofing the roof of dryer tower (b), including reflashing.
7. Replacing the roofs of the (b)(4) foyer and (b)(4).
8. Replacing the overhead door into the (b)(4) foyer.
9. Installing an (b)(4) hygiene (b)(4), including boot change, garment change, and hand hygiene.
10. Replacing the walls and ceiling of the dryer tower (b)(4) hygiene entrance with (b)(4)
11. Excavating the north side of the facility and installing larger tiles to redirect water away from the facility into the local watershed area.
12. Installing airlocks in (b)(4) packing tower.
13. Replacing the non-infant formula packaging area and equipment with (b)(4) system, including hygiene

Summary

areas and a (b)(4) system.

Refusals were not encountered. (b) (3) (A) . Samples were collected ; INV1240167 to be analyzed for Cronobacter and INV1240166 to be analyzed for Salmonella. A reconciliation exam was not conducted.. An FDA 483 was not issued. Verbal observations were not issued to the firm. A verbal warning was given to the firm and corporate management, emphasizing the need for compliance with the FD&C Act. During this interaction, consequences for non-compliance were clearly communicated to underscore the importance of adhering to the Act.

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03040	FOOD CGMP INSPECTIONS
03040U	PCHF FOLLOW-UP INSPECTIONS
03050N	DOMESTIC HUMAN FOOD ENVIRONMENTAL SAMPLES
21006	INFANT FORMULA SURVEY
21005	DOM & IMP NLEA, NUTR SMPL ANAL & GEN'L LBING PROG

Correction Statuses current at time report was signed.

Consumer Complaints Review

I reviewed the firm's complaint file from June 2023 to the present. There were numerous complaints regarding product quality and some specifically mentioning issues like spitting-up and diarrhea. Complaints related to these health concerns are investigated by corporate headquarters. The ages of the infants involved in these complaints were 71 days and 90 days. There were no reports of serious injuries or illnesses.

Additionally, there were complaints related color and flavor. Ms. Fry explained that the infant formula is (b)(4) . The color variation depends on how long the wet mix sits in the tank, with the wet batch maintained at (b)(4) degrees F for (b)(4) .

Inspection Samples

Sample Number(s)	1240166; 1240167

ADMINISTRATIVE DATA

Administrative Data

Firm	ByHeart Inc dba Blendhouse Allerton
Physical Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Phone	641-873-4121
Fax	641-873-4574
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)	1/8/2024, 1/16/2024, 1/17/2024, 1/18/2024, 1/30/2024

FDA Inspection Participants
Participant Name and Title
Michael Feingold, Investigator
Alicia Frees, Investigator
Joselin Baray-Alvarado, Investigator
Raymond Anderson, Investigator

FDA Team Members Not Present for the Whole Inspection
CSO Joselin P Baray-Alvarado was present on 01/17/2024 CSO Raymond T Anderson was present on 01/17/2024 CSO Alicia Frees was not present on 01/30/2024

Non-FDA Inspection Participants			
Participant	**Agency**	**Purpose for Being Present**	**Dates of Participation**
Kurt Rueber, Small Food Processing Lead	IDIA		1/8/2024; 1/16/2024; 1/17/2024; 1/18/2024; 1/30/2024

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**
1/8/2024	John van der Hulle, Plant Manager
1/16/2024	John van der Hulle, Plant Manager
1/17/2024	John van der Hulle, Plant Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	John van der Hulle, Plant Manager
Person's Name and Title	Julie L Fry, QA & Regulatory Compliance Manager
Person's Name and Title	Katie Whitesell, Senior Director of Food Safety

FMD 145 Recipient	
Person's Name and Title	John van der Hulle, Plant Manager
Email Address	jvanderhulle@byheart.com
Mailing Address	The same as the firm's mailing address.

Guidance Documents Given to the Firm
I provided Ms. Julie Fry the FDA QR Handout and guidance documents which contains the following factsheets and reference materials: • FDA Food Safety Modernization Act (FSMA)

Guidance Documents Given to the Firm
• Reportable Food Registry (RFR) At A Glance Fact Sheet • KEY REQUIREMENTS: Accredited Third-Party Certification • KEY FACTS: Preventive Controls for Human Food • KEY REQUIREMENTS: Preventive Controls for Animal Food • KEY REQUIREMENTS: Foreign Supplier Verification Programs • KEY REQUIREMENTS: Intentional Adulteration Mitigation Strategies • KEY REQUIREMENTS: Sanitary Transportation • Human and Animal Food • KEY REQUIREMENTS: Produce Safety • FACT SHEET: Voluntary Qualified Importer Program • (b) (3) (A) • Technical Assistance Network Contact Information • HAFW2 FDA 483 Response Email Address

HISTORY

(b) (3) (A)	
Additional Information	The infant formula attachment B was completed for this inspection; however, not all nutrient information could be entered into the attachment. A complete nutrient analysis is completed at the Blendhouse Portland Facility. An FDA 484 was issued to the firm on January 30, 2024, at the close of the inspection; however, it was dated the day the samples were collected. The firm received the FDA484 during the official closeout meeting on January 30, 2024; however, the form was dated January 17, 2024, which was the date the samples were collected. Mr John van der Hulle signed the FDA 484 on January 30, 2024 acknowledging the samples were provided to the FDA at "no charge".

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	The firm ships it manufactured infant formula blend to Blendhouse Portland located at 19217 Ne San Rafael St Portland OR 97230.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	The firm manufactures powdered infant formula to be blended at Blendhouse Portland. See product label (exhibit 29).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	John van der Hulle, Plant Manager

Roles and Authorities	Mr. John van der Hulle has been with the facility for over 41 years, serving as plant manager for the past 16 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.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, FMD 145 Recipient, Accompanied During the Inspection
Email Address	jvanderhulle@byheart.com
Mailing Address	The same as the firm's mailing address.
Person #2	
Person's Name and Title	Julie L Fry, QA & Regulatory Compliance Manager
Roles and Authorities	Ms. Julie L Fry has been employed by the firm for over 10 years, holding her current position for the past 3 years. In her role, Ms. Fry is responsible for overseeing and co-developing the firm's quality and food safety programs, which includes managing procedures, work instructions, and audits. She also holds the authority to make decisions regarding capital improvements and personnel employment decisions.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #3	
Person's Name and Title	Katie Whitesell, Senior Director of Food Safety
Roles and Authorities	Ms. Whitesell is responsible for the site quality and sanitation report, collaborating with various groups to establish and develop local and corporate safety programs. She oversees six direct reports and has held her current position in the company since mid-June. With the authority to hire and fire, Ms. Whitesell reports directly to Niall Mullan.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection

MANUFACTURING/DESIGN OPERATIONS

Other Areas Covered

ASSESSMENT OF COMPLIANCE WITH INDIVIDUAL CGMP REQUIREMENTS SUBPART B CURRENT GOOD MANUFACTURING PRACTICE

PRODUCTION AND IN-PROCESS CONTROLS SYSTEM

The company has established a production and in-process control system, documented through written procedures. Additionally, they have a comprehensive food safety plan, including a hazard analysis that identifies ingredient hazards, processing hazards, as well as physical, chemical, and radiological hazards inherent to infant formula manufacturing.

The firm has implemented specifications with active monitoring and a corrective action plan for any deviations. Qualified individuals conduct reviews leading to material disposition decisions. However, it was noted that the packaging specifications, available in exhibit 18 & 19, lack information on how the firm prevents packaging from contaminating the finished product with pathogens. Ms. Julie Fry mentioned that the packaging manufacturer (b)(4) , and I suggested incorporating this treatment into the hazard analysis, food safety plan, and product specification.

The company maintains comprehensive documentation and records for monitoring at every control point in the production process. This includes specifications, actual values, deviations, corrective actions, and details of responsible individuals. The firm's process flow (exhibit 2) highlights (b)(4) Critical Control Points (CCPs): (b)(4)

Other Areas Covered

To ensure quality, a (b)(4) is in place (exhibit 5), preventing the use of articles failing specifications until a documented review and decision are made.

CONTROLS TO PREVENT ADULTERATION BY WORKERS

CSO Frees and I conducted a thorough review of training records for three randomly selected operators and supervisors. All records were found to be complete, and it was confirmed that all personnel had received training in infant formula good manufacturing practices. Furthermore, CSO Frees, IDIA Small Food Processing Lead Kurt Rueber, and I examined the production records for lots (b)(4) , and (b)(4) . The master manufacturing record documented pasteurization temperatures and metal detection records, with no deviations observed. Additionally, lot and product verification checks were adequately recorded and reviewed.

During our observations, all personnel directly involved in working with infant formula demonstrated good personal hygiene practices as required by the firm's SOP (exhibit 7). This included wearing clean outer garments, hair, and beard nets. Employees were observed following proper hygiene protocols, such as washing and sanitizing their hands, as well as changing their boots and outer garments in designated (b)(4) hygiene areas.

A summary of the firm's Hygiene Zoning and Traffic Control Program (exhibit 7) is explained as such:
The hygiene zoning requirements are (b)(4)

(b)(4)

Other Areas Covered

(b)(4)

CONTROLS TO PREVENT ADULTERATION CAUSED BY FACILITIES

The buildings used in the manufacture, processing, packing, or holding of infant formula were observed to be in a clean and sanitary condition. Infant formula operations are conducted (b)(4), as depicted in exhibit 7 page 7. Raw materials are (b)(4) (b)(4), and the manufacturer has ample space for the separation of incompatible operations.

The company utilizes (b)(4) in warehouses (b)(4). Ingredients and raw materials are labeled with (b)(4).

Additional lighting has been installed in the warehouses, facilitating easy identification of raw materials, packaging, labeling, in-process materials, and finished products released for use in infant formula production. The lighting in processing areas is sufficient for reading instruments and controls necessary for processing, packaging, and laboratory analysis. Fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished products have protective measures to prevent broken glass from contaminating the products.

The firm appears to have adequate ventilation to minimize odors and vapors in areas where they may contaminate raw materials, in-process materials, final product infant formula, packing materials, and surfaces in contact with infant formula. During our inspection, we did not observe conditions where rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents could contaminate infant formula.

Other Areas Covered

Per the firm's SOP (exhibit 8), water sampling at the Allerton plant is conducted by the Allerton QA staff, employing (b)(4) to prevent cross-contamination during the sampling process. (b)(4) . Each sample is labeled with its location and date, and subsequently transported to the Allerton lab for shipment to an approved third-party lab.

The frequency of water sampling varies depending on the location and production. During (b)(4) production, (b)(4) tests for APC, Coliform, Odor, and Flavor are conducted. Similar tests are conducted for the (b)(4) , either (b)(4) , depending on production. The (b)(4) undergoes (b)(4) during production, with additional (b)(4) tests for various parameters, including APC, Coliform, sediment, solids, color, odor, flavor, fluoride, lead, TTHM's, and EPA drinking water parameters.

Established action limits include Coliform (b)(4)), and guidelines for acceptable pH, chlorine levels, clarity, and color. (b)(4) .

The water supplied is (b)(4) that appeared to be free of defects, and there is no backflow from, or cross-connection between, piping systems that discharge wastewater or sewage. I reviewed the firm's water sampling records and was provided a summary of the firm's results (exhibit 9); no deviations or food safety concerns were observed.

The boiler water additives were not reviewed during this inspection.

The manufacturing site has readily accessible toilet and hand washing facilities that include hot and cold water, soap, and single-service towels. The facilities appeared to be sanitary and in good repair.

CONTROLS TO PREVENT ADULTERATION CAUSED BY EQUIPMENT OR UTENSILS

The equipment and utensils utilized in the production, processing, packaging, and storage of infant formula appear appropriately designed, installed, and maintained to facilitate their intended functions, as well as for ease of cleaning. Processing equipment is primarily constructed of (b)(4) or its non-toxic equivalent. Our observations indicate the manufacturer uses easily cleanable equipment and utensils that can withstand their intended environment, minimizing the risk of contamination of infant formula.

A detailed report of the firm's crack testing with images can be viewed in exhibits 10-13. A summary of the firm's crack testing is summarized below. All cracks were welded or remediated.

In October 2023, (b)(4)) performed inspections specifically targeting dryer cracks at the facility. The contractor's methodology (detailed below) and accompanying documentation (exhibits 10-13) represent a substantial improvement compared to the previous inspection. During the prior inspection, the remediation details for dryer cracks were lacking, making the recent inspection a significant and voluntary correction in terms of thoroughness and clarity.

(b)(4) utilizes the (b)(4) system, an inspection test method designed for detecting various defects such as cracks, incomplete welds, cavities from corrosion, porosities, and other issues that may lead to cross-contaminations or bacterial presence in the final product. The (b)(4) system consists of (b)(4)

(b)(4)

To ensure accuracy and reliability, the (b)(4) equipment undergoes testing and calibration (b)(4) adhering to the requirements of our quality management system. The inspectors, responsible for utilizing the

Other Areas Covered

(b)(4) system, undergo training and certification, including an internal examination to qualify for its usage. The period of validity for inspections conducted using (b)(4) is (b)(4) from the date of examination.

(b)(4) inspection on the (b)(4) revealed several issues that required correction. The inspection identified one crack, measuring 1/8" in length, (b)(4), specifically in the (b)(4) (b)(4) Notably, there were instances of excessive weld reinforcement with overlap and cold roll observed in the (b)(4)

Additionally, large areas of denting were observed on the (b)(4), and weld spatter was noted on the (b)(4). A crater crack was identified on the (b)(4) of the (b)(4). Furthermore, a crack measuring 1/8" was detected on the top of the (b)(4) (Exhibit 10)

During the inspection of the (b)(4) Dryer (exhibit 11), several issues were identified. Specifically, a 1/2" crack was observed on the (b)(4). Another 1/2" crack was noted on the (b)(4), situated on the dryer shell. Additionally, a 1" crack was found (b)(4)

Furthermore, internal surfaces of the dryer exhibited damage in the form of denting and gouging. (b)(4) recommended continuous monitoring of these deficiencies at the next inspection interval to assess any potential changes or developments. Various cracks were observed throughout the (b)(4) Dryer, with the assessment starting from the (b)(4) and progressing in a clockwise direction.

(b)(4) **Dryer Main Chamber (exhibit 11) Findings**

- Sugaring was observed 4" above the blast doors, positioned at 20degrees from the (b)(4) (b)(4).
- A crater crack with product leakage was identified on the middle shell, located 100degrees from the (b)(4).

- A 1/2" crack was noted on the shell, situated 100degrees from the (b)(4) and 10' from the dryer roof.
- Porosity was observed on the upper (b)(4), positioned 100degrees from the (b)(4) and 8' from the dryer roof.
- Another 1/2" crack was found on the (b)(4), located 135degrees from the (b)(4) and 10' from the dryer roof.
- A 1/4" crack was noted on the (b)(4) positioned 180degrees from the (b)(4) and 14' from the dryer roof.
- Three cracks, measuring 1/2", 1", and 3" in length, were identified on the bottom of the (b)(4) door. These were located 190degrees from the (b)(4) and 6' from the dryer roof.
- Two 1/4" cracks were observed on the (b)(4), 240degrees from the (b)(4) and approximately 18' from the dryer roof.
- Six small gouges/holes were found on the (b)(4) located 250degrees from the (b)(4) and approximately 10' from the dryer roof.
- Porosity was noted on the (b)(4) positioned 260degrees from the (b)(4) and 10' from the dryer roof.
- A 2" crack was observed on the (b)(4) (b)(4) in the top left corner, located 250degrees from the (b)(4) and 7' from the dryer roof.
- Four 1/4" cracks were noted just above the (b)(4), positioned 350degrees from the (b)(4) and approximately 14' from the dryer roof.
- Three cracks, each measuring 1" in length, were identified on the (b)(4), located 30degrees from the (b)(4) and approximately 24' from the (b)(4) roof.
- A 1/4" crack was found on the (b)(4), positioned 35degrees from the (b)(4) and approximately 24' from the dryer roof.
- A 1" crack was noted on the s(b)(4), located 90degrees from the (b)(4) and approximately 24' from the dryer roof.
- A 1.5" crack was identified on the (b)(4), pc(b)(4) 135degrees from the (b)(4) and approximately 24' from the dryer roof.

Other Areas Covered

- Four cracks, measuring 1/4" and the other three measuring 1/2" in length each, were observed on the (b)(4) . These were located 190degrees from the lower manway door and 24' from the dryer roof.

Internal examination of the (b)(4) Oven revealed the following findings:

- Two cracks, measuring 1" and 3" in length respectively, were identified at the floor (b)(4) (b)(4) situated in the north region of the dryer.
- A crack measuring 2" in length was noted at the floor (b)(4) , located in the (b)(4) of the dryer.
- A crack measuring 1/2" in length was observed on the (b)(4) at the nine o'clock position.
- A crack measuring 1" in length was detected at the floor (b)(4) positioned in the (b)(4) of the dryer.
- Another crack measuring 1" in length was found at the floor (b)(4) , situated in the (b)(4) of the dryer.

(b)(4) External Findings (exhibit 12):

- A crack measuring 2" in length was observed on the (b)(4) .
- A crack measuring 3" in length was identified on the (b)(4) .
- A 6" crack was noted on the (b)(4) down leg.
- A 3" crack was observed on the (b)(4) down leg, specifically on the (b)(4)
- Cluster porosity was detected just below the (b)(4) down the (b)(4), corresponding to a previous weld repair on the (b)(4)
- A 3" crack was found on the bottom of the (b)(4) motor housing, located below the (b)(4)
- A 6" crack was identified on the bottom of the (b)(4) motor housing, located below the (b)(4).
- A 4" crack was noted on the bottom of the (b)(4) motor housing, located below the (b)(4).
- A 4" crack was observed on the 2"x4" steel tubing used to support the (b)(4) on the bottom (b)(4) side next to the stairs.
- Three cracks, measuring 2", 4", and 6" in length, respectively, were identified on the 2"x4" steel tubing supporting the (b)(4) on the bottom (b)(4) side next to the stairs.
- A 10" crack was noted on the 2"x4" (b)(4) supporting the (b)(4) on the (b)(4) , just below the stairs.
- A 1" crack was identified on the 2"x4" (b)(4) supporting the (b)(4) on the (b)(4) , just below the catwalk.
- A 1" crack was found underneath the (b)(4) of the (b)(4) on the bottom of the c (b)(4)
- Two cracks, each measuring 2.5" in length, were observed on the 2"x4" (b)(4) supporting the (b)(4) on the (b)(4) .
- A 3/8" crack was noted on the 4"x4" (b)(4) supporting the (b)(4), located on the (b)(4) of the (b)(4).

(b)(4) Internal Findings:

Below (b)(4)

- A 1/4" crack was identified on the (b)(4) support member located just above the (b)(4) for the (b)(4) . The crack is positioned at the two o'clock position adjacent to the (b)(4)
- Coloration from an external weld repair was noted on the north (b)(4) air duct.
- Coloration was observed on the center divider between the (b)(4) (b)(4)

Below (b)(4) South Side:

- Coloration was noted on the center divider between the (b)(4) (b)(4)
- Coloration was observed on the center divider between (b)(4) (b)(4).

Other Areas Covered

- Sugar residue was detected from an external weld repair located on the south (b)(4) air duct.

Above (b)(4)

- 1" crack was identified on the (b)(4) of the (b)(4) where the (b)(4)(b)(4) down toward the (b)(4)

(b)(4) **(Exhibit 13) Findings:**

- A crack measuring 4.5" in length was identified on the (b)(4) CIP line standoff.
- A crack measuring 1" in length was noted on the (b)(4) CIP line standoff.
- A crack measuring 1 1/4" in length was found where the ductwork enters the (b)(4) on the (b)(4) side of the (b)(4)
- A crack measuring 3/4" in length was observed at the ductwork (b)(4) where the duct separates to the (b)(4) and (b)(4) .
- A crack measuring 1/2" in length was noted on the ductwork coming from the baghouse at the top of the (b)(4) where the duct separates to the (b)(4) and (b)(4) .
- Two cracks measuring 1" and 1/2" in length were identified on the (b)(4) located on the (b)(4) in the (b)(4) .
- (b)(4) was noted from an external weld repair on the (b)(4) in the (b)(4)
- A crack measuring 1" in length was noted on the (b)(4) , located in the (b)(4)
- A crack measuring 1/4" in length was observed on the (b)(4) located in the (b)(4)
- (b)(4) was noted on the (b)(4) ball located in the (b)(4) region of (b)(4)
- A crack measuring 1" in length was noted on the (b)(4) approximately 18" from the roof in the (b)(4) region of (b)(4)
- A crack measuring 1/4" in length was identified on the (b)(4) in the (b)(4) region of (b)(4) e
- (b)(4) was noted on the (b)(4) , located in the top left corner
- A crack measuring 2" in length was identified on the (b)(4) , located in the (b)(4)

Upon reviewing the firm's sanitation Standard Operating Procedures (SOP), six months' worth of sanitation records corresponding to production runs and conducting a facility walkthrough our observations indicate the manufacturer ensures equipment and utensils involved in the production of infant formula are regularly cleaned, sanitized, and maintained. A newly appointed sanitation manager oversees sanitation procedures, reviews documentation, and implements corrective actions as needed. However, the records lack specific details regarding the timing of cleaning, sanitizing, and the aggregate production number of each infant formula processed between equipment startup and shut down for maintenance.

The sanitizing agents employed on the equipment and utensils appear to comply with the Environmental Protection Agency's regulations, and a list of the firm's detergents and sanitizers is available in exhibit 14.

During the facility walkthrough and environmental monitoring, no substances such as lubricants or coolants were observed contacting formula ingredients, containers, closures, in-process materials, or the infant formula product during the manufacturing process.

The manufacturer has implemented procedures and controls to ensure the accuracy, readability, and maintenance of instruments used for measuring, regulating, and controlling temperature and product flow. Following the June 2022 FDA 483 citation regarding pump calibration, the firm has since calibrated all pumps/flow meters (exhibit 16), scales (exhibit 15), and thermometers (exhibit 17) in the infant formula process. Additionally, a review of the firm's temperature verification for lots (b)(4) , and (b)(4) indicates routine calibration of thermometers and scales against a proper reference. The records specify the instrument, date of the accuracy check, standard used, calibration method, results found, corrective actions taken if out of calibration, and the initials of the individual conducting the test.

Other Areas Covered

The manufacturer does not engage in thermal processing of infant formula packed in hermetically sealed containers. The firm maintains a cold storage area, though it was not observed during this inspection.

Procedures and controls are in place to ensure that (b)(4) introduced into infant formula does not contaminate the product. The firm sources (b)(4) from a (b)(4), which provides a Certificate of Analysis (COA) guaranteeing its freedom from contaminants. I reviewed the most recent COA from 2023; the gas was free from contaminants.

CONTROLS TO PREVENT ADULTERATION DUE TO AUTOMATIC (MECHANICAL OR ELECTRONIC) EQUIPMENT

I reviewed the manufacturer's written procedures ensuring that the equipment used in the production of infant formula adheres to a scheduled preventive maintenance plan. Thermometers and pumps undergo (b)(4) validation by a third-party contractor. Additionally, I examined the validation of the firm's electronic system, last validated in 2009. The management team assured me that the automated system has remained unchanged since its 2009 validation. When inquiring about equipment maintenance, they mentioned that some pumps had been replaced with the exact version in a "like-for-like" manner.

Furthermore, it was noted that the study had been conducted under previous ownership. I advised the management team to consider revalidating the automated system, considering the current hardware, change in ownership, and the age of the study.

The manufacturer previously challenged the electronic system, documenting the accuracy of input and output during its initial test in 2009. The management team disclosed that their corporate office employs an individual designated to modify software.

The manufacturer maintains records for both mechanical and electronic equipment used in infant formula production. I verified these records to include a comprehensive list of systems, describing computer files, defined capabilities, and inherent limitations of each system. The four-binder manual and validation include copies of all software used, along with records demonstrating installation, calibration, testing, validation, and maintenance of the systems.
However, I identified a gap in the records as they lack a valid list of individuals authorized to create or modify software. Furthermore, there are no documented records of software modifications, including the identity of the person responsible. I suggested that the firm engage in discussions with their corporate office to assess whether the validation requires updating or reevaluation.

The binder also lacked records documenting retesting or revalidation of modified systems, given that the system had only undergone testing once. Additionally, there were no backup files of data entered into computers, such as duplicate electronic records, tapes, or microfilm. I emphasized the importance of addressing these gaps in the records and ensuring comprehensive documentation for future assessments.

CONTROLS TO PREVENT ADULTERATION CAUSED BY INGREDIENTS, CONTAINERS, AND CLOSURES

The manufacturer has written specifications for ingredients and containers (exhibit 18). Infant formula is packaged in 750kg super sacks/totes manufactured by (b)(4). The totes are (b)(4) The firm provided their supplier's micro analysis and process flow (exhibit 19)

Ms. Julie Fry, qualified through education, training, and experience, is tasked with conducting and documenting material disposition decisions, including the options to reject, reprocess, or recondition, or to approve and release the ingredient, container, or closure.

Other Areas Covered

The manufacturer (b)(4) which clearly designate materials pending release for use, released for use, or rejected for use in infant formula production.

According to the firm's Infant Formula Supply Chain Release SOP (exhibit 20), a (b)(4) This preventive measure remains in effect until a thorough documented review and a corresponding material disposition decision are made.

The firm's procedures are designed to ascertain whether the system stipulates that any rejected ingredient or container must be unmistakably identified as rejected and subjected to quarantine to prevent its usage. Additionally, the procedures aim to determine if the system specifies criteria to ensure that any ingredient or container not manufactured, packaged, labeled, or stored under conditions preventing adulteration is appropriately addressed.

CSO Frees and I conducted a review of the records for lots (b)(4) These records outlined the identity and quantity of each lot of ingredients and containers, along with details such as the supplier's name, their lot numbers, the date of receipt, the specified receiving code, and the Certificate of Analysis (COA) results.

Furthermore, the name and location of the manufacturer of the ingredients and containers were documented within the firm's approved supplier documentation.

CONTROLS TO PREVENT ADULTERATION DURING MANUFACTURING

CSO Frees and I conducted a review of the written master manufacturing orders for lots (b)(4) . The examination revealed that the firm has established controls and procedures governing the production of infant formula. Specifically, the records indicate a process wherein each raw or in-process ingredient required by the master manufacturing order undergoes scrutiny and dual verification, ensuring accurate addition of the correct ingredients and adherence to specified weights or measures.

The manufacturer has implemented a systematic identification system for processing lines and major equipment utilized in the production process. The manufacturer has established controls and follows their SSOP to ensure that the nutrient levels required by 21 CFR 107.100 are maintained in the formula and that the formula is not contaminated with microorganisms. The Master Batch Record (exhibit 26) outlines critical parameters - mixing time, speed, and temperature - that guarantee the homogeneity of the formula.

While reviewing the master manufacturing records, it was observed that the firm consistently documents the closure of each container. However, the records lacked information regarding the filtering of intake air before heating and the removal of air from the finished product. Documentation for intake air filtration is available in the firm's maintenance records. *It is recommended that future inspections address the inclusion of this record within the Master Manufacturing Record (MMR).*

The manufacturer has also established specifications and controls for in-process materials. In our examination of the firm's discrepancy reports issued by Ms. Fry, records for Lot (b)(4) indicated that tote number (b)(4) had fat content outside the firm's specifications (exhibit 21). Ms. Fry, in response, made a material disposition decision to reject the affected in-process material, which was subsequently held in quarantine until the (b)(4) totes were destroyed.

CONTROLS TO PREVENT ADULTERATION FROM MICROORGANISMS

The manufacturer has established a system of sanitation controls, environmental monitoring, and process controls aimed at preventing the adulteration of infant formula due to the presence of microorganisms in the processing environment.

The firm operates with two Critical Control Points (CCPs), with CCP 1 requiring the (b)(4) to a (b)(4) for (b)(4) . A review of processing records for lots (b)(4)

Other Areas Covered

(b)(4), conducted by CSO Frees, IDIA Small Food Processing Lead Kurt Rueber, and me, revealed that while the documentation on the recording chart did not strictly adhere to the Pasteurized Milk Ordinance (PMO), the records indicated proper testing of the milk product-flow controller and bypass system through cut-in and cut-out tests. The charts for each lot confirmed that the product was adequately pasteurized at an operating temperature of (b)(4) F for (b)(4).

The firm maintains a written Environmental Monitoring Program (EMP) (exhibit 27), with environmental zones (b)(4) defined that aligns with FDA's zoning guidance. The program includes a (b)(4) (b)(4) The SOP dictates the frequency of swabbing for *Salmonella*, *Cronobacter*, and *Listeria* in different zones, with specific requirements for (b)(4).

I reviewed the firm's June 2023 to January 2024 environmental monitoring records, detailing the collection of approximately (b)(4) environmental samples. During this time, (b)(4) zone (b)(4) swab locations tested positive for *Cronobacter*, (b)(4) in air handling units after (b)(4) filtration. The affected lots underwent thorough clean and sanitize cycles both before and after the production run, with no other products impacted. The firm voluntarily destroyed (b)(4) (b)(4) ensuring that no product entered interstate commerce or left the positive release quarantine location.

The firm's environmental monitoring investigation confirmed the isolated nature of these locations, with no impact on product safety. Further, the firm's samples were subjected to (b)(4)) at (b)(4) , and the discrepancy report detailed these findings (exhibit 22 Page 10).

> *A review of the fastq files was performed by* (b)(4) (b)(4) *sent* (b)(4) *sets of* (b)(4) *files from Cronobacter sakazakii isolates sequenced by* (b)(4) *for analysis. The analysis demonstrated clustering of the* (b)(4) *with* (b)(4) *isolates obtained during environmental sampling and three taken by the FDA from a PIF and a "dairy" facility in May (PIF) and June (dairy) of 2022. The FDA samples were uploaded and are posted on NCBI (SNP Cluster PDS000112222.2). Below is a* (b)(4) *of the* (b)(4) *internal* (b)(4)*, including the* (b)(4)*, and the* (b)(4) *FDA* (b)(4).

(b)(4)

Additionally, the firm identified (b)(4) zone (b) *Cronobacter* positives on a dryer door handle and an ingredient shelf. Corrective actions, including cleaning, sanitization, and vectoring, were promptly implemented.

The firm ensures the microbiological quality of each production aggregate of powdered infant formula at the final product stage (prior to distribution) through representative sample testing. According to the firm's SOP, (b)(4) Ms. Julie Fry and Ms. Katie Whitesell confirmed that every manufactured tote of infant formula undergoes sampling and testing for *Salmonella* and *Cronobacter* (CB).

CSO Frees, IDIA Small Food Processing Lead Kurt Rueber, and I reviewed the sample records for lots (b)(4) All tested products demonstrated negative results for pathogens and met the firm's microbiological (yeast/mold) limit specifications.

CONTROLS TO PREVENT ADULTERATION DURING PACKAGING AND LABELING OF INFANT FORMULA

The manufacturer has established procedures and controls to inspect packaged and labeled infant formula during finishing operations. This is documented in the master manufacturing record. CSO Frees, IDIA Small Food Processing

Other Areas Covered

Lead Kurt Rueber, and I reviewed the records for lots 217323181Z1, (b)(4) and (b)(4) ; the firm had documentation for every tote and lot.

The manufacturer has implemented a quarantine system ((b)(4)) designed to prevent the distribution of each production aggregate of infant formula until a thorough evaluation ensures that the production aggregate aligns with all the specifications set by the manufacturer. Lot (b)(4) of infant formula included (b)(4) totes (b)(4) that failed to meet the specified fat content requirements. In response, (b)(4) totes were immediately placed in quarantine and subsequently underwent destruction.

TRACEABILITY

The manufacturer codes each production aggregate with a sequential number that identifies the product and the establishment where the product was packed and that also permits tracing of all stages of manufacture. (See Manufacturing Codes)

AUDITS OF CURRENT GOOD MANUFACTURING PRACTICE

The manufacturer conducts routine audits to assess compliance with CGMP regulations. Voluntary corrections have been made since the last inspection, where the auditor and the individual responsible for approving the audit are now distinct individuals. Although the firm did not furnish a copy of the audit, they did provide the SOP (exhibit 24) and documentation confirming that the audit took place on August 22, 2023 (exhibit 23).

INSPECTION FOR COMPLIANCE WITH INFANT FORMULA QUALITY CONTROL PROCEDURES REQUIREMENTS SUBPART C - QUALITY CONTROL PROCEDURES

GENERAL QUALITY CONTROL

The firm tests or reviews the Certificate of Analysis (COA) for every ingredient in each nutrient premix utilized in the production of infant formula. Following the manufacturing process, (b)(4) (exhibit 28). (b)(4)

AUDITS OF QUALITY CONTROL PROCEDURES

The manufacturer conducts routine audits to assess compliance with CGMP regulations. Voluntary corrections have been made since the last inspection, where the auditor and the individual responsible for approving the audit are now distinct individuals. Although the firm did not furnish a copy of the audit, they did provide the SOP and documentation confirming that the audit took place on August 22, 2023.

SUPPLY CHAIN CONTROLS

SUPPLY-CHAIN PREVENTIVE CONTROLS

(Written by Alicia R Frees)
The firm has transitioned supply-chain preventive controls from Dairy Farmers of America (DFA) to ByHeart. I reviewed ByHeart's Supplier Quality Management SOP (Exhibit 1) which outlined the supplier quality management process. The SOP covers suppliers, manufacturers, brokers of raw materials, sanitation chemicals, packaging components, warehousing, distribution facilities, contracted laboratories, and other services (electrical, mechanical, etc.) purchased for or provided to ByHeart, and or ByHeart facilities in Reading, PA, Allerton, IA, or Portland, OR.

The SOP also outlines the responsibility for initial selection of ingredients and approval and assessment for suitability.

Other Areas Covered
New suppliers are set up in the (b)(4) and a request for documentation is sent to the supplier for review by QA. Once a supplier is approved, suppliers are added to the Approved Supplier List (Exhibit 2) maintained by the firm. Supplier assessments are conducted via (b)(4) and an annual verification process is conducted for ingredients. The most recent on-site audit was conducted 12/2023 at (b)(4) and covered Item (b)(4). The firm does not directly import any products. I reviewed two Incoming / Outgoing Transport Inspection Reports for (b)(4) Lot #(b)(4) received 12-20-23 (Exhibit 3) and (b)(4) Lot #(b)(4) received 12-4-23 (Exhibit 4). Both reports were compared to the Review and Release of Materials procedure (Exhibit 5) detailing the incoming process for ingredients and how they are deemed safe for use. Materials received in Exhibit 3 were received prior to third party testing and were held until results were received. Materials received in Exhibit 4 were received with an expiry date of 10OCT23 on 12-4-23. After verification testing the shelf life was extended to 01JAN2024. Product for the current campaign was manufactured on 1/16/2024. I asked for and was provided an additional expiration date extension (Exhibit 4, pgs 6-8) to review. The expiration date was extended until 31MAR2024.

MANUFACTURING CODES

The firm's lot code system has not changed since previous inspections:

(b)(4)

(b)(4)

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

The inspection concluded with the following individuals present and connected virtually:

Virtual
Katie Whitesell- Senior Director of Food Safety
Devon Kuehn - Chief Medical Officer
Niall A Mullane - Chief Qty Officer

William Thomas - Senior Dir of Ops and Manufacturing

Present
John van der Hulle - Plant Manager
Julie Fry - QA & Regulatory Compliance Manager
(b) (6), (b) (7)(C) - Document Control Specialist
Lance Burnette - Sanitation Manager

I expressed gratitude to everyone for their cooperation and voluntary corrections made since the last inspection. I reminded everyone present that this inspection represents a snapshot in time. Although I did not uncover any significant negative findings during this inspection, the next investigator may discover issues or conditions that were not addressed during this inspection. Additionally, I provided a verbal warning to all present individuals, emphasizing the importance of compliance with the FD&C Act and highlighting the consequences for non-compliance.

SAMPLES COLLECTED

Sample Number	INV1240166 & INV1240167
Description	(Written by Raymond T Anderson) Environmental swabbing was conducted by Investigators Alicia R Frees (ARF), Raymond T Anderson (RTA), and Joselin P Baray (JPB). Mr. Kurt Rueber, Small Food Processing Lead, Food & Consumer Safety Bureau - Iowa Department of Inspections & Appeals, was present under State of Iowa authority and assisted with transporting supplies, transferring completed swabs to the cooler, and supervising the cooler during swabbing. Swabs for *Salmonella spp* (INV1240166) and *Cronobacter* (INV1240167) were collected concurrently from the same location. JPB collected all subs using (b)(4) technique with either a hydrated sponge or Q-tip. ARF handled supplies, labeled samples, and placed samples in the cooler. RTA sanitized the gloved hands of ARF and JPB between each sub using (b)(4) (Prepared: 03/31/2023; Expiry: 02/22/2024), took photos, and documented each sample location. Subs (b)(4) are environmental swabs aseptically collected from the firm. Subs (b)(4) were collected from the (b)(4). Subs (b)(4) were collected from (b)(4) (b)(4) were collected from the (b)(4) room (b)(4). Swabs (b)(4) were collected from the (b)(4) room. After swabbing using aseptic technique, each sub was placed into their original container then placed into a new, sterile 24oz Whirl Pak bag, and identified with a printed white adhesive label as "INV1240166 1/17/24 RTA" followed by SUB number prior to being placed in a plastic lined hard-sided cooler with ice packs. Q-tip swabs were each placed in a small Whirl Pak bag prior to being placed into the cooler.

VOLUNTARY CORRECTIONS

The firm has implemented several corrective actions following previous inspections, aiming to enhance hygiene, eliminate potential sources of contamination, and improve overall facility conditions. The key corrective actions from

exhibit 25 are as follows:

1. Mild Steel Painted Floors Replacement:

- Replaced mild steel painted floors with stainless steel checker plate on Level (b)(4) Level (b), and the Chamber exterior roof and inlet air snail.
- Reason: Eliminated potential foreign material and microbiological harborage by transitioning to a more durable material that supports required cleaning protocols.
- Completed on 11/6/23 by (b)(4)

2. Surfaces Recoating:

- Paint recoating projects on various surfaces, including East foyer walls and ceiling, (b)(4) room walls, Dryer tower walls, ceilings, and understructure, including lift well, and Indirect (b)(4) room.
- Reason: Eliminated flaking paint that could lead to potential foreign material or microbiological harborage.
- All paint recoating projects completed on 11/23/23 by (b)(4)

3. Floor Recoating Projects:

- Recoated all cementitious floors in Dryer tower, (b)(4) packing tower, (b)(4) room, (b)(4) Alleyway, point drain upgrade, (b)(4) room, (b)(4) room, WH 2 and ramp, (b)(4) room, and Dryer (b)(4) Room floor with point drain upgrade.
- Reason: Eliminated potential foreign material and microbiological harborage by transitioning to more durable material supporting required cleaning protocols.
- All floor recoating projects completed on 12/3/23 by (b)(4)

4. Relocation/Replacement of (b)(4) Heaters:

- Relocated/replaced (b)(4) heaters from Dryer tower (b)(4) to the (b)(4) room.
- Reason: Eliminated a potential water source in the dryer tower.
- Completed on 10/30/23 by (b)(4).

5. (b)(4) Section (b)(4) Air Supply:

- (b)(4) section (b)(4) air supply, including replacement of (b)(4) lines.
- Reason: Mitigated potential condensation associated with the (b)(4) section.
- Completed on 11/30/22 by M(b)(4)

6. Replace Water Service Lines:

- Replaced water service lines throughout Dryer tower with (b)(4), replacing aged copper service lines.
- Reason: Eliminated potential for unplanned water due to deteriorating lines.
- Completed by 11/17/23 by (b)(4).

7. Roof and Roof/Wall Flashings Replacement:

- Replaced (b)(4) Dryer Tower Roof and roof/wall flashings.
- Reason: Eliminated potential (b)(4) Dryer Tower rain leaks.
- Completed on 10/20/23 by (b)(4).

8. Replacement of (b)(4) and (b)(4) Roof:

- Replaced (b)(4) foyer and (b)(4) roof with a new membrane to eliminate leaks and potential new leaks.

- Completed on 1/8/24 by (b)(4)

9. Replacement of Overhead Door into (b)(4)

- Replaced overhead door into (b)(4) to enhance traffic patterns, decrease microbiological cross-contamination, and further separate the East Plant from the (b)(4) Plant.
- Completed on 11/18/23 by (b)(4)

10. Installation of (b)(4) :

- Installed (b)(4) (boot change, garment change, handwashing, and sanitizing) to further minimize the potential of environmental microbiological cross-contamination.
- Completed on 7/7/23 by Allerton Maintenance Project Team.

11. Replacement of Dryer Tower (b)(4) Hygiene Entrance:

- Replaced dryer tower (b)(4) hygiene entrance with a (b)(4) version, eliminating potential microbiological harborage locations.
- Completed on 11/1/23 by (b)(4)

12. (b)(4) Drainage Project:

- Conducted (b)(4) drainage project to eliminate potential groundwater ingress into the facility along the (b)(4)
- Completed on 12/5/23 by (b)(4)

13. Installation of (b)(4) Exiting (b)(4) Packing Tower:

- Installed (b)(4) exiting (b)(4) Packing Tower to provide enhanced separation of (b)(4) hygiene area to (b)(4) hygiene area (best practice).
- Room completed on 12/8/23 by (b)(4)).

14. (b)(4) Room (b) Updates:

- Recoated floors, walls, and ceilings to update the area to current best practices.
- Established a dedicated (b)(4) hygiene room for the bag filler, including an anteroom entrance, (b)(4), and materials passthrough, along with (b)(4) temperature/humidity and pressure control.
- Implemented a (b)(4) to separate filling (b)(4) hygiene) from palletizing (b)(4) hygiene area) and provide an anteroom and pass-through space.
- Completed project on 11/3/23 by BP&R and Morice Engineering.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	SOP Supplier Quality Management	
2	Infant Formula Approved Supplier List	
3	(b)(4) Transport Inspection Report	
4	(b)(4) Transport Inspection Report	

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
5	SOP Material Release	
6	Process Flow Diagram	
7	Hygenic Zoning	
8	SOP Water Testing	
9	Water Test Report	
10	Crack Test and Repair	
11	Crack Test and Repair	
12	Crack Test and Repair	
13	Crack Test and Repair	
14	Sanitation Chemicals	
15	Scale Calibration	
16	Flow Meter Calibration	
17	Thermometer Calibration	
18	Packaging Specification	
19	Packaging Specification	
20	SOP Positive Release	
21	Product Specification	
22	Discrepancy Report	
23	QA System Check	
24	SOP QA Audit	
25	Voluntary Corrective Actions	
26	MMR	
27	SOP Environmental Monitoring	
28	COA	
29	Product Label	

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FDA 482	
2	FDA 482	
3	FDA 482	
4	FDA 484	
5	Infant Formula Attachment B	

SIGNATURE

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Investigator
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