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SUMMARY

Inspection	
Operation ID and Name	275380: FY 24 Domestic and Foreign Schedule of Inspections/Sample Co

Summary Data	
This is a comprehensive report.	
Inspection Basis	F/U to Warning Letter

Summary

This compliance follow up inspection of BlendHouse LLC, a manufacturer of an infant formula base powder, was conducted as a follow up to a Warning Letter issued to the firm on 08/30/2023. The Warning Letter was issued due to significant violations of Title 21, Code of Federal Regulations, Part 106 (21 C.F.R. Part 106), Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications ("the Infant Formula Rule").

This inspection was in accordance with Compliance Policy Guidance Program (CPGM) 7321.006, Infant Formula Program- Import and Domestic under PAC 21006, Compliance Policy Guidance Program (CPGM) 7303.040 Preventative Controls and Sanitary Human Food Operations under PACs 03040/3040L, and Compliance Policy Guidance Program (CPGM) 7321.005 Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Program under PAC 21005. This assignment is documented under eNSpect Op ID 275380 and FACTS ID #12313588.

The production facility for BlendHouse is located at 61 Vanguard Drive, Reading, PA and is owned by the parent company, ByHeart Inc. The production facility is approximately (b) (4). The (b) (4) building is approximately (b) (4) of the (b) (4) and is (b) (4) high. The warehouse and offices are located next door at 51 Vanguard Drive, Reading, PA and is leased. The warehouse facility is approximately (b) (4).

ByHeart Inc.is the parent company of BlendHouse and their corporate address is 131 Varick Street, New York, NY 10013. No product is manufactured at the corporate office, this location is offices only.

The previous FDA inspection conducted 12/21/2022-02/17/2023 was classified Official Action Indicated (OAI) with FORM FDA 483- Inspectional Observations was issued for the following reasons: 1. Firm did not establish a system of process controls covering all stages of processing that was designed to ensure that the infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment. 2. Firm did not ensure that equipment or a utensil used in the manufacture, processing, packing or holding of an infant formula were of appropriate design to facilitate their intended function.

There were also several discussion items from the previous inspection which included the following. Review of the firm's production records for the time period associated with the firm's recall revealed numerous instances of crossed out and re-written data for such items as lot numbers and dates. Due to the amount of crossed out information that needed correction; production records were often delayed as being reviewed by QC. QC does not sign off on the review until all information has been corrected which can take several days up to several weeks due to the shifts employees work and if an employee is off. Review of the firm's SOPs and event records revealed the firm does not consistently use the same language when describing an item. For example, a SOP called a sampling tool a "vial" but in the event record it was referred to as a "sample cup" and a "plastic cup". Also noted during our review of these records was that some forms do not document the time an activity was performed. For example, "Pre-Op (b) (4) Checklist-Special Testing QUAL-510.03.03-FM", does not document the time the activity was performed. Lastly, it was noted that the firm does not consistently document downtime on the production records. All of these items were discussed with firm management throughout the inspection and management acknowledged they would look into these items and address as necessary.

At the end of the current inspection, FORM FDA483- Inspectional Observations **(Attachment # 3)**was issued to Jonathan Fenstermacher, Plant Manager for the following:

- You did not ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source.
- You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and

Summary

sanitary condition.

- You did not exclude pests from your food plant to protect against contamination of food.
- You did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration.
- You did not implement a system of production and in-process controls for an infant formula.
- You did not minimize the potential for contamination of raw materials through the use of appropriate measures.

The firm did not provide any voluntary corrections at the closeout meeting. The firm was advised they can respond to the FORM FDA 483- Inspectional Observations in writing within 15 business days. Ms. MacNaughton was provided with the email address: ORAHAFEAST2FIRMRESPONSES@fda.hhs.gov to send the firm's response.

Discussion items for the current inspection included the following:

- You did not prepare a written master manufacturing order that establishes controls and procedures for the production of an infant formula.
- You did not establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order was examined by one person and checked by a second person or system.
- You did not conduct and document your hazard analysis.
- You did not review your annual (b) (4) Analytical Report ((b) (4)) for 2022 (b) (4) water testing to ensure the water meets the EPA's Primary Drinking Water Regulations for chemical, radiological and bacteriological contaminants.
- The SOP PROD-304-SOP, "DI1500 Infant Formula Operation" is maintained, which outlines the operation of the (b) (4) dryer including the (b) (4) process after (b) (4). The SOP does not identify all operational parameters, which must be achieved to initiate the (b) (4) process nor conditions that require re-starting the (b) (4) process. These parameters and conditions are defined in the firm's validation study, "(b) (4) Validation Report" dated 4/28/23.
- (b) (4) are used to verify production scales and are calibrated (b) (4); however, the previous calibrations were performed in 2021. In addition, the production record, "Scale Accuracy Verification Record-(b) (4)" is maintained and this record requires the operator to identify the (b) (4) used and their calibration due date yet review of these records indicated no notation that the (b) (4) were overdue for calibration.
- For finished product testing of the base powder, a (b) (4) sample is pulled from (b) (4) composite and analyzed separately for (b) (4); for (b) (4) testing, the (b) (4) and a (b) (4) is pulled for analysis. As such, the implementation of a higher stringency sampling plan for (b) (4) as compared to (b) (4) should include historical data such as finished product testing and environmental sampling results to support this determination.
- In response to an environmental positive sample, (b) (4) is performed. At a minimum, (b) (4) are obtained over a (b) (4) period with approximately, (b) (4). However, the same (b) (4) are (b) (4) over the (b) (4). Also, (b) (4) are taken (b) (4), which does not allow you to determine the extent of how far a pathogen may have spread. Mold samples are not taken as part of your environmental program when there is a water leak. Positive mold samples are also not further speciated.
- The humidity in your Packing Room (b) (4) is not documented, currently it is monitored and will alarm when it reached (b) (4) relative humidity.
- During the review of batch records, it was noted that for some batches during ingredient addition, there were extreme weight fluctuations as also identified on the HMI screen. The fluctuations were too inconsistent to determine the exact cause.
- Review of production records revealed employees not fully understanding their job responsibilities. It was noted on these records that information on required forms was incomplete, procedures were not followed, equipment was not assembled correctly, etc.

  For example, review of records showed incorrect assembly of the (b) (4) not placed on housing correctly, etc. An employee left a tool left on (b) (4) and another employee broke the sight glass on Packing Line (b) (4). Quality/Post production review of records did not note discrepancies of Master Batch Records; such as (b) (4), calculations wrong at step #11 for (b) (4), etc.

This inspection also covered consumer complaints, non-conformance reports, water events, batch records, retain samples, cleaning/sanitation SOP's, environmental monitoring, raw material, in-process and finished product testing, GMP and quality control audits, information technology, recalls, pest control and employee training.

No samples were collected from the firm.

Summary

The firm's registration was current as required per the BT Act of 2022.

No refusals were noted.

This was reported was written by Investigator Schafer, Investigator Mayer, Investigator Pathiraja, Investigator Centi and Investigator Covill and unless noted the section was written by Investigator Schafer.

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03040	FOOD CGMP INSPECTIONS
03040F	FULL SCOPE PCHF INSPECTIONS
21006	INFANT FORMULA SURVEY
21005	DOM & IMP NLEA, NUTR SMPL ANAL & GEN'L LBING PROG

Summary of Past Observations

CFR Number:	Citation Text:
21 CFR 106.55(a)	You did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.
Correction Status:	Not Corrected
21 CFR 106.30(a)	You did not ensure that equipment or a utensil used in the manufacture, processing, packing, or holding of an infant formula were of appropriate design to facilitate their intended function.
Correction Status:	Not Corrected

Summary of Objectionable Conditions on FDA Form 483 - Current Inspection

CFR Number	Citation Text	Correction Status
21 CFR 106.30(b)	You did not ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source.	No Firm Response Submitted
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.	No Firm Response Submitted
21 CFR 117.35(c)	You did not exclude pests from your food plant to protect against contamination of food.	No Firm Response Submitted
21 CFR 106.6(a)	You did not implement a system of production and in-process controls for an infant formula.	No Firm Response Submitted
21 CFR 106.30(e)(5)	You did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration.	No Firm Response Submitted
21 CFR 106.20(d)	You did not minimize the potential for contamination of raw materials through the use of appropriate measures.	No Firm Response Submitted

Summary of Discussion Items Not on FDA Form 483 - Current Inspection

CFR Number	Citation Text	Correction Status
21 CFR 106.50(a)	You did not prepare a written master manufacturing order that establishes controls and procedures for the production of an infant formula.	No Firm Response Submitted
21 CFR 106.50(b)	You did not establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order	No Firm Response Submitted

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
	was examined by one person and checked by a second person or system.	
21 CFR 117.130(a)(1)	You did not conduct and document your hazard analysis.	No Firm Response Submitted

Correction Statuses current at time report was signed.

ADMINISTRATIVE DATA

Administrative Data	
Firm	BlendHouse LLC
Physical Address	
Address Line 1	61 Vanguard Dr
City / State / ZIP	Reading, PA 19606-3765
Phone	1-610-5822170
Fax	1-610-5821482
Mailing Address	
Address Line 1	51 Vanguard Dr
City / State / ZIP	Reading, PA 19606-3765
Website	www.byheart.com
Inspection Date(s)	12/11/2023, 12/12/2023, 12/13/2023, 12/14/2023, 12/15/2023, 12/18/2023, 12/19/2023, 12/20/2023, 1/11/2024, 1/12/2024, 1/19/2024

FDA Inspection Participants
Participant Name and Title
Elizabeth Mayer, National Expert
Kawshalya Pathiraja, Investigator
Alan Centi, Investigator
Kyle Covill, Investigator
Melissa Schafer, Investigator

FDA Team Members Not Present for the Whole Inspection

The following are the dates Investigators were present for the inspection:

Investigator Melissa M. Schafer; 12/11-15/2023, 12/18-20/2023, 01/11-12/2024, 01/19/2024

Investigator Kawshalya Pathiraja; 12/11-15/2023, 12/18-20/2023

Investigator National Expert Elizabeth Mayer; 12/11-15/2023

Investigator Alan Centi; 12/11-13/2023, 01/19/2024

Investigator Kyle Covill; 12/11-13/2023

The firm was closed due to holidays on 12/22/2023- 01/02/2024.

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
12/11/2023	Jonathan A. Fenstermacher, Plant Manager
12/11/2023	Jonathan A. Fenstermacher, Plant Manager

FDA Credentials Were Displayed to the Following Person(s)

Person's Name and Title	Jonathan A. Fenstermacher, Plant Manager
Person's Name and Title	Fangfei Lou, Director of Quality
Person's Name and Title	Katherine Rhoades, Regulatory Compliance Manager
Person's Name and Title	Heather MacNaughton, Senior Director Regulatory Audit Compliance
Person's Name and Title	Katie Whitesell, Senior Director, Food Safety
Person's Name and Title	William (Bill) Thomas, Senior Director of Manufacturing

FDA Form 483

Description	Date Issued	Issued To
Original	Jan 19 2024 01:02PM	Jonathan A. Fenstermacher, Plant Manager

FMD 145 Recipient

Person's Name and Title	Jonathan A. Fenstermacher, Plant Manager
Email Address	jfenstermacher@byheart.com
Mailing Address	The same as the firm's mailing address.
Phone Number	(610) 582-2170

Guidance Documents Given to the Firm

The following links below were provided via email on 01/19/2024 to the following individuals; Heather MacNaughton, Senior Director Regulatory Audit Compliance (ByHeart), Katie Whitesell, Senior Director, Food Safety (ByHeart), Fangfei Lou, Director of Quality (BlendHouse) and Katie Rhoades, Regulatory Compliance Manager (BlendHouse). Also, provided in the same email were the following handouts; FDA Firm Resources handout, Key Fact About Preventative Controls- Human Food, 21CFR117 and Draft Guidance for Industry Hazard Analysis and Risk Based Preventative Controls for Human Food.

- Access to FDA technical guides https://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/default.htm
- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food and other guidance links https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm
- Mitigation Strategies to Protect Food Against Intentional Adulteration Final Rule and additional guidance. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-mitigation-strategies-protect-food-against-intentional-adulteration
- FSPCA Intentional Adulteration training courses: https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration
- The FDA Food Defense Plan Builder:https://www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm349888.htm
- Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/salmonella/ucm295271.htm#discussions

- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm

- Code of Federal Regulations (CFR): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Guidance Documents Given to the Firm
• FDA "FSMA Technical Assistance Network (TAN)"- can send emails to answer your questions https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm • Guidance for Industry: Product Recalls, Including Removals and Corrections https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

HISTORY

Food Firm Registration Status	Current
Other Registrations	The firm is Kosher, Organic, GRAS and Halal certified.
Hours of Operation	Effective 12/03/2023, the firm was switching production from (b) (4); sanitation/maintenance will remain (b) (4). Production shifts will operate (b) (4). Office hours for the firm are Monday thru Friday 8:00am – 4:00 pm. Shipping and receiving hours are the same as the office hours, in addition all receiving and shipping orders are scheduled. Warehouse hours are from (b) (4). The warehouse operates (b) (4).
Legal Status	LLC
Warning Letter Issued On	08/30/2023
Warning Letter Description	During the inspection at your firm from December 21, 2022, through February 17, 2023, FDA Investigators found significant violations of Title 21, Code of Federal Regulations, Part 106 (21 C.F.R. Part 106), Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications ("the Infant Formula Rule"). At the conclusion of the inspection, the FDA Investigators issued a Form FDA-483, Inspectional Observations ("Form FDA-483"), listing the deviations found at the BlendHouse facility. Based on the inspectional findings, FDA determined that your actions have violated the Federal Food, Drug, and Cosmetic Act ("the Act") and the Infant Formula Rule. *See* Sections 402(a)(4), 412(a)(3), and 301(a) of the Act [21 U.S.C. §§ 342(a)(4), 350a(a)(3), and 331(a)].
Additional Information	ByHeart Inc. is the parent company of BlendHouse LLC, and their corporate address is 131 Varick Street, New York, NY 10013. No product is manufactured at the corporate office, this location is offices only. The firm was using (b) (4) in (b) (4) and (b) (4) for finishing and storage of canned product prior to shipping to customers until 12/08/2022. The firm terminated their contract with (b) (4) sites in July 2023 as per Ms. MacNaughton.

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	The firm's top ingredients suppliers are (b) (4). The product manufactured by BlendHouse is referred to by the firm as a "bulk pre-

	blend" because the product does not include all of the ingredients in the final product form that is sold to consumers via internet and retail stores currently at (b) (4) only. The bulk pre-blend is shipped in bulk totes to ByHeart's blending and packaging facility in Portland, OR which was purchased in 01/2023 (BlendHouse Portland FEI# 3013670080). The final ingredient of lactoferrin is (b) (4) in the bulk pre-blend and packaged in metal cans labeled as infant formula. The canned product is sent to a finishing facility in (b) (4) in a sealed container with a temporary plastic lid on the container. The temporary plastic lid from each container is (b) (4) removed and a new metal lid, with the scoop in the underside of the lid, is affixed to each container. The cans are case packed and distributed directly to consumers who purchase the product through the web site www.byheart.com (b) (4) Retail) or at select (b) (4) stores across the country. The cans are sold on the web site to consumers in a single can, two can, four can or six can units.

Product Covered	BlendHouse operates as a manufacturer of cow's milk based, dried, powdered infant formula base that is distributed under the brand "ByHeart".
Incoming	Yes
Received From	The firm's top ingredients suppliers are (b) (4)
Outgoing	Yes
Sent To	The product manufactured by BlendHouse is referred to by the firm as a "bulk pre-blend" because the product does not include all of the ingredients in the final product. The bulk pre-blend is stored in bulk totes at (b) (4) due to the firm's limited warehouse space. The bulk pre-blend is shipped in bulk totes to ByHeart's blending facility in Portland, OR which was purchased in 01/2023 (BlendHouse Portland FEI# 3013670080). The final ingredient of lactoferrin is (b) (4) in the bulk pre-blend and packaged in metal cans labeled as infant formula. The canned product is sent to a finishing facility in (b) (4) in a sealed container with a temporary plastic lid on the container. The temporary plastic lid from each container is manually removed and a new metal lid, with the scoop in the underside of the lid, is affixed to each container. The cans are case packed and distributed directly to consumers who purchase the product through the web site www.byheart.com ((b) (4) Retail) or at select (b) (4) stores across the country. The cans are sold on the web site to consumers in a single can, two can, four can or six can units.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	BlendHouse operates as a manufacturer of cow's milk based, dried, powdered infant formula base that is further processed into a finished infant formula product that is distributed under the brand "ByHeart". The infant formula base is shelf stable and has a shelf-life of 90 days. **See Exhibit #1** for finished infant formula can product label. Consumers can purchase the product through the web site www.byheart.com. or at select (b) (4) stores across the country. The infant formula is marketed to customers via the same website.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Jonathan A. Fenstermacher, Plant Manager
Roles and Authorities	Mr. Fenstermacher is responsible for facility operations which includes but is not limited to the day- to-day operations, production and maintenance. Mr. Fenstermacher answered questions regarding (b) (4) procedures and CIP parameters. Mr. Fenstermacher has been with the firm for six months and has 7 years of experience in the industry. Mr. Fenstermacher reports to Mr. Bill Thomas, Senior Director of Manufacturing- ByHeart. Mr. Fenstermacher identified himself as the most responsible person on site. **See Exhibits #2** for the firm's organizational charts and **Exhibit # 3** for the corporate organizational chart.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, FMD 145 Recipient, Accompanied During the Inspection
Email Address	jfenstermacher@byheart.com
Mailing Address	The same as the firm's mailing address.
Phone Number	(610) 582-2170
Person #2	
Person's Name and Title	Fangfei Lou, Director of Quality
Roles and Authorities	Ms. Lou is responsible for product safety, quality and compliance program. Ms. Lou answered questions regarding the firm's Environmental Monitoring Program, water leaks, investigations, interventions and other quality related topics. Ms. Lou has been with the firm for 1.5 years and 9 years in the industry. Ms. Lou reports to Ms. Katherine (Katie) Whitesell, Director Food Safety- ByHeart.
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	Katherine Rhoades, Regulatory Compliance Manager
Roles and Authorities	Ms. Rhoades is responsible for regulatory compliance at the firm, 3rd party audits and state inspections. Ms. Rhoades answered questions and provided documentation related to equipment within the facility, batch records, events, water leaks, employee training, and pest control. Ms. Rhoades has been with the firm for 3.5 years and has 7 years of experience in the industry. Ms. Rhoades reports to Ms. Fangfei Lou, Director of Quality.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #4	
Person's Name and Title	(b) (6), (b) (7)(C), Internal Auditor
Roles and Authorities	(b) (6), (b) (7)(C) is responsible for completing QMS and GMP audits, managing supplier approval and assisting with 3rd party audits and state inspections. (b) (6), (b) (7)(C) answered questions regarding audits and ingredients suppliers. (b) (6), (b) (7)(C) was the firm's scribe for various days during the inspection. (b) (6), (b) (7)(C) has been with the firm for 3.5 years and 4.5 years in the industry. (b) (6), (b) (7)(C) reports to Ms. Katherine (Katie) Rhoades, Regulatory Compliance Manager.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #5	
Person's Name and Title	Alicia Dickenson, Release Services Associate Manager
Roles and Authorities	Ms. Dickenson is responsible for overseeing the release of raw materials and base powder for the firm. Ms. Dickenson answered questions related to base powder external laboratory testing and raw material release process. Ms. Dickenson has been with the firm for 21 months and in the industry for 4 yrs. Ms. Dickenson reports to Ms. Fangfei Lou, Director of Quality.
The following are applicable to	Interviewed

this person	
Person #6	
Person's Name and Title	Michele Otte, Quality Operations Manager
Roles and Authorities	Ms. Otte is responsible for the day-to-day operations of the lab and is the quality liaison with production. Ms. Otte answered questions regarding the firm's environmental monitoring of the air and water, lab equipment and lab testing. Ms. Otte has been with the firm for 2.8 years and in the industry for 2.8 years. Ms. Otte reports to Ms. Fangfei Lou, Director of Quality.
The following are applicable to this person	Interviewed
Person #7	
Person's Name and Title	(b) (6), (b) (7)(C), Maintenance Supervisor
Roles and Authorities	(b) (6), (b) (7)(C) is responsible for overseeing maintenance activities for 24/7 coverage for the firm, scheduling vendors for repair/preventative maintenance/calibration work, maintaining the CMMS/CCMS programs, assign and schedule technicians work and review work orders. (b) (6), answered questions regarding plant water supply/usage, (b) (4), roof repairs, batch room CIP, hygienic zoning air pressure, (b) (4) operation and equipment (b) (4). (b) (6), (b) (7)(C) has been with the firm for 3 years and with industry for 6 years. (b) (6), (b) (7)(C) report to Mr. Michael Honsberger, Senior Director of Maintenance and Engineering -ByHeart.
The following are applicable to this person	Interviewed
Person #8	
Person's Name and Title	Karianne Delgado, Production Manager
Roles and Authorities	Ms. Delgado is responsible for production management, scheduling and capacity management. Ms. Delgado answered questions regarding (b) (4) fluctuations, and (b) (4) fluctuations. Ms. Delgado has been with the firm for over 4 years and in the industry for 11 years. Ms. Delgado reports to Mr. Jonathan Fenstermacher, Plant Manager.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #9	
Person's Name and Title	(b) (6), (b) (7)(C), Batching Operator
Roles and Authorities	(b) (6), (b) (7)(C) is responsible for the cleaning and operation of general production equipment in the facility. (b) (6), (b) (7)(C) answered questions regarding (b) (4) and (b) (4) system. (b) (6), (b) (7)(C) has been with the firm for 1.5 years and with the industry for 7 years. (b) (4), (b) (6), (b) (7)(C) reports to Ms. Delgado, Production Manager.
The following are applicable to this person	Interviewed
Person #10	
Person's Name and Title	(b) (6), (b) (7)(C), Process Coordinator
Roles and Authorities	(b) (6), (b) (7)(C) is responsible for IT related duties such as IT and production-based project management, process reporting and share facility security duties. (b) (6), (b) (7)(C) answered questions related to the firm's IT and software-based systems. (b) (6), (b) (7)(C) has been with the firm for 3.5 years and the industry for 45 years. (b) (6), (b) (7)(C) reports to Nr. Jonathan Fenstermacher, Plant Manager.
The following are applicable to this person	Interviewed
Person #11	
Person's Name and Title	Julie McKechnie, Human Resources Manager
Roles and Authorities	Ms. McKechnie is responsible for employee relations, employee development and other human resources roles. Ms. McKechnie provided the following information employee training, general human resources topics pertaining to active/terminated/position changes for employees. Ms. McKechnie was the firm's scribe for various days during the inspection. Ms. McKechnie has been with the firm and with industry for 2.5 years. Ms. McKechnie reports to Ms. Pam Daub, Facilities HR Director.
The following are applicable to	Interviewed

this person	
Person #12	
Person's Name and Title	Heather MacNaughton, Senior Director Regulatory Audit Compliance
Roles and Authorities	Ms. MacNaughton is responsible for both internal and external audits of the firm, document control and certifications. Ms. MacNaughton answered questions regarding complaints, supplier information, recall, master formula, labeling, Attachment B, shipping requirements and stability information. Ms. MacNaughton was present in person for the entirety of the inspection except for the first day (12/11/2023) in which she was present via conference call. Ms. MacNaughton is a ByHeart corporate employee and has been with the corporate office for over 3.5 years and has over 35 years in the Infant formula industry. Ms. MacNaughton reports to Mr. Ron Belldegrun, Chief Executive Office and Co-Founder.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #13	
Person's Name and Title	Katie Whitesell, Senior Director, Food Safety
Roles and Authorities	Ms. Whitesell is responsible for overseeing the site Quality Assurance and Sanitation teams and is responsible for the enhancement, alignment and overview of the Food Safety Programs. Ms. Whitesell was present in person for the majority of the inspection and was able to provide additional corporate feedback. Ms. Whitesell has been at the corporate office for 6 months and has 15 years of Quality/Regulatory experience. Ms. Whitesell reports to Ms. Devon Kuehn, Chief Medical Officer.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #14	
Person's Name and Title	Devon Kuehn, Chief Medical Officer
Roles and Authorities	Ms. Kuehn is responsible for oversight of Research and Development, Nutrition Science, Clinical Trials, Medical Education, Post Market Safety (Pharmacovigilance), and Regulatory. Ms. Kuehn was present only via conference calls held with the corporate office during the inspection. Ms. Kuehn has been with the corporate office for over 3 years and 5.5 years in industry and 10 years in clinical medicine. Ms. Kuehn reports to Mr. Ron Belldegrun, Chief Executive Officer and Co-Founder.
The following are applicable to this person	
Person #15	
Person's Name and Title	Michael Honsberger, Senior Director Maintenance and Engineering
Roles and Authorities	Mr. Honsberger is responsible for managing the overall building maintenance (for both locations of 51 and 61 Vanguard Drive) and (b) (4) for the firm. Mr. Honsberger answered questions via conference calls regarding roof leaks, building repairs and preventative maintenance. Mr. Honsberger was present only via conference calls held with the corporate office during the inspection. Mr. Honsberger has been with the corporate office for 1 year and 22 years in industry. Mr. Honsberger reports to Mr. Ron Belldegrun, Chief Executive Officer and Co-Founder.
The following are applicable to this person	
Person #16	
Person's Name and Title	(b) (6), (b) (7)(C), Executive Assistant
Roles and Authorities	(b) (6), (b) (7)(C) is responsible for providing support to the Chief Operating Officer and Vice President Manufacturing as well as the corporate operations team. (b) (6), (b) (7)(C) was the scribe for the firm on various days during the inspection. (b) (6), (b) (7)(C) has been with the corporate office for 1.5 years and 25 years as an Executive Assistant. (b) (6), (b) (7)(C) reports to Mr. Elias Aoukar, Chief Operating Officer.
The following are applicable to this person	
Person #17	
Person's Name and Title	Steve Gort, Manager of Reliability and Predictive Maintenance

Roles and Authorities	Mr. Gort is responsible for supporting the Maintenance and Engineering Departments with Best-in-Class predictive Technology for all Byheart sites. Mr. Gort provided information via conference calls related to roof leaks, inspections and infrared technology. Mr. Gort was present only via conference calls held with the corporate office during the inspection. Mr. Gort has been with the corporate office for 3.5 months and with industry for 24 years. Mr. Gort reports to Mr. Mike Honsberger, Senior Director Maintenance and Engineering.
The following are applicable to this person	
Person #18	
Person's Name and Title	Marcus Jordan, Vice President Supply Chain
Roles and Authorities	Mr. Jordan is responsible for supply chain and manufacturing operations. Mr. Jordan was present only via conference calls held with the corporate office during the inspection. Mr. Jordan has been with the corporate office for almost 3 years and with industry for almost 26 years. Mr. Jordan reports to Mr. Elias Aoukar, Chief Operating Officer
The following are applicable to this person	
Person #19	
Person's Name and Title	William (Bill) Thomas, Senior Director of Manufacturing
Roles and Authorities	Mr. Thomas is responsible for the manufacturing processes at all of Byheart's locations and travels frequently to all 3 locations. Mr. Thomas was present in person during the first week of the inspection and was present via conference calls held with the corporate office after the first week of the inspection. Mr. Thomas has been with the corporate office for 5 months and industry for 10 years. Mr. Thomas reports to Mr. Marcus Jordan, Vice-President Supply Operations.
The following are applicable to this person	FDA Credentials Displayed to This Person
Person #20	
Person's Name and Title	Elias Aoukar, Chief Operations Officer
Roles and Authorities	Mr. Aoukar is responsible for overseeing manufacturing, procurement and maintenance/engineering. Mr. Aoukar was present only via conference calls held with the corporate office during the inspection. Mr. Aoukar has been with the corporate office for approximately 1 year and with industry for 20 years. Mr. Aoukar reports to Mr. Ron Belldegrun, Chief Executive Officer and Co-Founder.
The following are applicable to this person	
Person #21	
Person's Name and Title	[redacted], Chief Quality Officer
Roles and Authorities	[redacted] recently started with ByHeart has been with the corporate office for a month. [redacted] was only present during the closeout meeting with the firm via conference call.
The following are applicable to this person	
Person #22	
Person's Name and Title	[redacted], Senior Technical Data Analyst
Roles and Authorities	[redacted] is responsible for reviewing information pertaining to the stability of the ingredients/product and trending data. [redacted] answered questions regarding expiration extension data, formulation., and ingredient specifications. [redacted] also evaluates raw material/ingredient that does not meet the established specifications to determine the final disposition. [redacted] also controls master manufacturing/batch records, and translate any formulation changes into the records. During the inspection, [redacted] provided information pertaining to heavy metals related to raw ingredients. [redacted] reports to Ms. Heather MacNaughton, Senior Director of Regulatory Audit Compliance.
The following are applicable to this person	Interviewed
Person #23	
Person's Name and Title	Dhru Patel, Director of Pharmacovigillance

Roles and Authorities	Mr. Patel spoke over the phone on 12/20/2023, and provided information pertaining to the complaint management policy and program. He said he coordinates with the ByHeart Customer Service Department to ensure all complaints are captured. He is responsible for overseeing and investigating any health related complaints. Mr. Patel is a licensed nurse in the State of Pennsylvania. Mr. Patel reports to Ms. Kuehn.
The following are applicable to this person	Interviewed

FIRM'S TRAINING PROGRAM

All employees receive specialized training for their specific job, as well as training in areas of safety, GMPs, good documentation, adulteration, food defense, recalls, HACCP, allergens, CCPs, root cause analysis, intervention into product contact, etc. The firm provides annual refresher training and continuous training on an as needed basis for any situations that may warrant additional training.

I reviewed training of approximately 10 employees and noted no discrepancies.

See **General Discussion with Management #9** for further information.

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

MANUFACTURING/DESIGN OPERATIONS
Production
Facilities (EPM)
This site consists of two main buildings, Building (b) (4) and Building (b) (4). Building (b) (4) and (b) (4). Building (b) (4 (b) (4); the (b) (4) receiving bay and the (b) (4) are no longer used for production, but employees do enter the (b) (4) to access the CIP flow panel when the (b) (4) system is running. The (b) (4) is sealed off from the rest of the facility and is only accessible (b) (4). The (b) (4) and the raw milk receiving bay are cleaned (b) (4), respectively. Building (b) (4 is divided (b) (4) areas and a facility map, which details the zoning into each respective hygiene type was provided **(Exhibit #4)**. In Building (b) (4) Packing Room (b) (4 is equipped with (b) (4) air filters, which filter (b) (4) of particulates; the remainder of the facility uses (b) (4). (b) (4) areas including Packing Room (b) (4 and (b) (4) (b) (4) areas including the (b) (4) dryer tower are maintained under positive pressure. However, in the (b) (4) Room referred to as "(b) (4), the air pressure is not monitored to ensure it is under positive pressure to prevent the introduction of potential air contaminants from the adjacent warehouse, which is a (b) (4). **Please See FDA 483 Observation #6**.

The electronic (b) (4) system, (b) (4) is used for ingredient receipt, production and finished product distribution; however, the firm has not implemented the use of (b) (4) and the scanning of barcodes. The firm relies heavily upon the use of (b) (4) records.

The firm manufactures (b) (4) base powder, which is used in the manufacture of the product, ByHeart Whole Nutrition Infant Formula milk-based powder with iron (24 oz. composite can). (b) (4). Major ingredients of the base powder include lactose, dried whole milk, whey protein concentrate, whey protein hydrolysate, oil blends and vitamins and minerals; the shelf-life of the base (b) (4). Operations at this facility include ingredient weighing and staging, (b) (4), (b) (4) drying and bulk filling. The base powder is packaged in (b) (4) totes and transported to BlendHouse Portland, LLC (Portland, Oregon) for the addition of lactoferrin via (b) (4) followed by packaging in the retail can. From there, the finished product cans are shipped to (b) (4) where the outer collar, scoop and over-cap is added to each can; after which, the product is distributed to customers.

During this inspection, the facility was shut-down and had been since 9/30/23; several projects were completed during this time and

Process Flow, Operations, and Product Coverage

a list was provided **(Exhibit #5)**. The firm was previously in production from 6/24-9/29/23 and product was released. The process flow for the base powder was covered. A flow diagram was provided **(Exhibit #6)**. Each production aggregate is typically (b) (4) and consists of (b) (4) batches; each batch consists of (b) (4) filled totes.

<u>Raw Material Receiving (EPM)</u>
In Building (b) (4), in the warehouse, ingredients arrive (b) (4) deliveries are scheduled. Both (b) (4) loads are received. Upon arrival, a trailer and ingredient inspection is performed, and all associated documents are reviewed. The pallets are labeled with a (b) (4) tag, which identifies the product name, internal part number, vendor lot number, (b) (4) lot number, net weight, received date, expiration date, storage conditions, allergen status and IP status (dairy, Kosher and Halal). Ingredients are tracked via the (b) (4) lot number.

All raw materials are electronically placed on-hold pending sampling results; quality personnel are responsible for releasing ingredients. Testing plans are (b) (4) and all ingredients undergo some level of analysis including identity testing. Certificates of analysis are also received.

Ingredients including DHA and ARA are stored in the reach-in cooler, which is maintained at (b) (4); the temperature is verified (b) (4) and (b) (4) documented. The temperature sensor is replaced (b) (4).

No ingredients are received bulk.

<u>Ingredient Weighing (EPM)</u>
In Building (b) (4), in the (b) (4) Room or (b) (4), minor ingredients including vitamins, minerals and premixes are weighed; partial containers of major ingredients are also weighed. The amount of ingredient to be weighed is identified on the Dispensing Sheet, which is part of the Master Batch Record (MBR). The Dispensing Sheet identifies the following: ingredient, required amount, ingredient lot number and expiration date, scale used, amount dispensed, weighed/verified by and date. (b) (4) operators are responsible for weighing ingredients to allow for the (b) (4). Exact weights are required; there is no tolerance in place.

During this inspection, batch records were reviewed, and it was noted that the usage rate for (b) (4) was adjusted from (b) (4) to (b) (4) due to high vitamin D verification results. However, this change was not implemented for all batches. **Please See Additional Observation #1**.

At the time of weighing, one ingredient is weighed for several batches. There are two scales, an (b) (4) floor scale and an (b) (4) scale, which are calibrated every (b) (4) by (b) (4) and were previously done on 11/27/23. (b) (4) are also used to verify the scale weights. The (b) (4) are calibrated per (b) (4) schedule by (b) (4) but all were previously done on 8/13/21 except for the (b) (4), which was conducted on 4/27/22. In addition, the production record QUAL-511.07.03-FM, “Scale Accuracy Verification Record- (b) (4)” is maintained, which requires the operator to identify the (b) (4) used and their calibration due date; however, during this inspection, review of this record indicated no notation by the operator that the (b) (4) were overdue for calibration. **Please See Discussion with Management Item #4**. Ingredients are weighed utilizing (b) (4) and added to (b) (4), which are sanitized with (b) (4) prior to use; after which, a label is printed and adhered to the (b) (4), which is closed with a twist-tie. The original ingredient container is stored in the (b) (4) room or returned to storage in Warehouse (b) (4).

In Warehouse (b) (4), major and minor ingredients are staged or “kitted” on pallets pending production. At the time of use, ingredient weights are verified by production personnel as they are added to the (b) (4); the lot number, amount added, checked by and date are recorded on the Master Batch Record. However, review of the Master Batch Record for production aggregate (b) (4) indicated that for (b) (4), the amount added was not documented, only the amount required per the recipe was indicated. **Please See Additional Observation #2**. Major and minor ingredient usage is (b) (4) inputted in (b) (4), which also tracks ingredient usage.

<u>Liquid Processing (EPM)</u>
In Building (b) (4), in the (b) (4), (b) (4). (b) (4) The temperature sensor is calibrated (b) (4) and was previously performed on 12/6/23; the (b) (4) is calibrated by (b) (4) every (b) (4) and was previously done on 11/27/23. A portion of the (b) (4) is

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(b) (4).

The (b) (4) and is referred to as the blend tank (b) (4) and is maintained at a minimum of (b) (4). The temperature sensor is calibrated (b) (4) and was previously done on 12/6/23. The (b) (4) is calibrated every (b) (4) by (b) (4) and was previously conducted on 11/27/23. In (b) (4). The (b) (4) is calibrated every (b) (4) by (b) (4) and was previously done on 11/27/23.

From (b) (4). The (b) (4) on (b) (4) is calibrated by (b) (4) every (b) (4) and was previously performed on 11/27/23. The (b) (4); if this occurs, the product is (b) (4).

(b) (4). The temperature sensor is calibrated (b) (4) and was previously performed on 12/6/23. The (b) (4) is calibrated (b) (4) and was previously conducted on 2/21/23. (b) (4).

(b) (4) <u>System (EPM)</u>
In the Process Room, the firm uses a (b) (4) system, which consists of (b) (4) and is the (b) (4) for the product. (b) (4).

The process flow through the (b) (4) system to the (b) (4) is as follows:

(b) (4)

(b) (4)

(b) (4)

Process Flow, Operations, and Product Coverage

(b) (4) [redacted] The (b) (4) [redacted] is calibrated every (b) (4) [redacted] by (b) (4) [redacted] and was previously conducted on 7/21/23. The (b) (4) [redacted] is calibrated (b) (4) [redacted] and was previously performed on 11/27/23. During production, the (b) (4) [redacted] is captured via (b) (4) [redacted] and displayed on the HMI screen.

(b) (4) [redacted] was conducted by IEH Laboratories and Consulting Group and is dated 2/22/21 **(Exhibit #9)**. (b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted] Dryer (EPM)

(b) (4) [redacted]

The (b) (4) [redacted] dryer (b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

Process Flow, Operations, and Product Coverage

(b) (4).

There are (b) (4). The (b) (4) collects (b) (4), which are re-introduced into the (b) (4); the (b) (4) collects (b) (4) and the (b) (4) and also (b) (4). Management stated that the (b) (4) do plug during the summer months. The (b) (4) are inspected (b) (4) and were previously done on 11/29/23; the inspection also included covers, bolts, components, gear box, motor and rotor shaft, bearing and air gland seals and no deficiencies were noted. The (b) (4).

Operational parameters for the (b) (4) dryer system are (b) (4) documented (b) (4) on the record, PROD-306.27-FM, "Infant Formula Dryer Processing Report"; during these checks, the operator also verifies that no water is present in the (b) (4) dryer tower.

(b) (4) <u>Dryer Crack Inspections (EPM)</u>
(b) (4), the firm conducts an internal and external inspection of the (b) (4) dryer including the main chamber, (b) (4) and (b) (4). The firm contracts with (b) (4) to conduct the inspections using (b) (4) to detect cracks, porosities, incomplete welds, corrosion, sugaring, and other defects. The firm contracts with (b) (4) to complete weld repairs of the defects, which are then verified by (b) (4). Internal defects and repairs are documented in the inspection reports with photographs. A SOP for (b) (4) dryer crack inspections is not maintained.

The previous inspection was conducted in December 2023; a summary from Michael Honsberger, Senior Director Maintenance and Engineering was provided along with the inspection reports **(Exhibit #10, #11, #12, #13, and #14)**. The main chamber and (b) (4) had internal and external defects, which were repaired; internal repairs were also verified. The (b) (4) had external and internal defects, which were repaired; the internal repairs were also verified. The (b) (4) had internal defects, which were repaired and verified; there were no external defects.

In February 2023, an inspection was also performed, and the reports were provided **(Exhibits #15, #16, #17 and #18)**. The main chamber had internal and external defects, which were repaired and verified; the (b) (4) did not have any internal or external defects. The (b) (4) had one external defect and one internal defect, which were both repaired and verified; the (b) (4) had internal defects only, which were repaired and verified.

The (b) (4) dryers are CIP'd prior to the inspection. Contractors are trained regarding the firm's safety procedures, and they wear the required PPE and site dedicated footwear; all tools are provided by the contractor and sanitized prior to use. After the inspection is completed and repairs are made, the (b) (4) dryer is (b) (4); the tank is equipped with a (b) (4), which is inspected and cleared by the quality assurance laboratory. After which, the system is CIP'd and (b) (4), which is marked for waste.

<u>Process Interventions (EPM)</u>
The (b) (4) dryer is not routinely entered during production; the firm maintains the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces", which provides specific instructions on required procedures that must be strictly followed when interventions into product contact zones are necessary **(Exhibit #19)**. The SOP states that for interventions after the (b) (4) system, "a minimum of (b) (4) must be discarded upon restarting". Interventions are documented on the form PROD-310.01-FM, "Verification of Product Contact Zone Intervention Procedures". The (b) (4) size was chosen by the firm's Engineering Group who determined that it takes (b) (4) to clear the line from the (b) (4) dryer nozzles to the vacuum receiver on packing line (b) (4); it takes (b) (4) to clear that same line with a (b) (4). Therefore, the (b) (4) ensures that the line is clear with a (b) (4) buffer.

Approximately, 24 interventions were performed from 6/24-9/29/23 and review of form PROD-310.01-FM indicated that on 7/11/23, 8/5/23, 9/8/23 and 9/18/23, post-(b) (4) interventions were performed yet a minimum (b) (4) was not conducted as required by the firm's SOP. In addition, the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces" states that "Notify QA of an intervention, as QA will observe and document the intervention activities". On 6/26/23, an intervention was performed but a quality assurance technician was not present as required by the SOP. **Please See FDA 483 Observation #4.**

<u>Packing Room (b) (4) (EPM)</u>

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In Packing Room [redacted], the powder is filled into single use totes, which have a [redacted] and a [redacted] and expand during filling. Totes are filled at [redacted]. In this room, the relative humidity is maintained at [redacted] and is monitored; however, values are not documented. **Please See Discussion with Management Item #7**.

[redacted]

[redacted].

The powder is filled in the tote. The [redacted] associated with the bulk filling machine are calibrated by [redacted] and were previously done 11/27/23. Once filled, the tote is sealed via a [redacted]; the specific sealing temperature and time were not known. No integrity checks are performed but when the totes arrive at BlendHouse Portland, they are [redacted] inspected for leakage. The totes are labeled and placed on black pallets, which have a more stringent cleaning schedule and are maintained on-site; the totes are also shrink-wrapped prior to transport to the third-party warehouse pending distribution. Label checks are conducted [redacted]. The totes leave Packing Room [redacted] doors.

<u>Bulk Tote Shipment (KDC/EPM)</u>
A positive release program is in place and product is electronically held in [redacted] pending testing results, which typically takes seven business days. BlendHouse employees are responsible for releasing product. During this time, bulk totes are loaded onto refrigerated trailers and transported to the third-party warehouse, [redacted]; a small number are shipped directly to [redacted]. The firm leases space at both warehouses, which are temperature and humidity controlled; Ms. MacNaughton receives and reviews a monthly report summarizing the storage conditions. The firm also conducts an annual inspection of [redacted].

The product must be shipped between [redacted] and maintained at [redacted]. According to Ms. MacNaughton, the firm does not document the temperature at loading at this facility, at the [redacted] warehouse, nor at receiving in [redacted]; she further stated that the firm relies upon the trucking companies to notify firm management of any temperature deviations. Products are shipped from this facility and are received the same day at [redacted]; items shipped to [redacted] take approximately [redacted] to arrive.

Products are shipped via two, third-party carriers, which are dedicated to transporting food products. During this inspection, Ms. MacNaughton contacted one of the carriers, [redacted] who provided a letter explaining the trailers are affixed with a temperature monitoring system, which will alert the driver in the event of a temperature deviation **(Exhibit #20)**. Ms. MacNaughton also provided a letter from the other carrier, [redacted] which explained that the company complies with the Sanitary Transportation of Human and Animal Food Rule **(Exhibit #21)**. If the temperature and humidity specifications are exceeded per the firm's specifications, Ms. MacNaughton stated that the corporate office is currently working on a procedural document, which addresses this situation and the appropriate corrective actions. Employees document trailer and product inspections on the forms WHSE-201.07.FM and WHSE-201.08, "[redacted] Shipping/Receiving Log" and "[redacted] Shipping/Receiving Log", respectively; these forms document the general sanitation of the trailer including spills and pests and the condition of the products/ingredients.

Major and Non-Major (Before First Processing) Changes (EPM)
During this inspection, major (90-day) and non-major (Before First Processing) submissions, which were submitted to the Infant Formula and Medical Foods Staff (IFMFS) at CFSAN and in "completed" status were reviewed as identified in the Plant Report **(Attachment)**. [redacted]

Microbiological, Nutrient and Stability Testing (EPM)
Microbiological and nutrient testing is done on the base powder; the document QUAL-2521.21-PMS, "Infant Formula Base Powder

Process Flow, Operations, and Product Coverage

Release Specification-(b) (4) was provided, which summarizes the analyses performed and specifications **(Exhibit #22)**. Nutrient testing is done (b) (4) and by (b) (4); microbiological analyses are performed by (b) (4).

In Packing Room (b) (4), there is an (b) (4), which (b) (4); a summary of the samples pulled was provided **(Exhibit #23)**.

Certificates of analysis dated 6/24-9/29/23 were reviewed for all released lots of base powder; no deficiencies were noted. The firm has not had any pathogen positive product.

Retain samples of base powder are not maintained.

<u>Microbiological Testing</u>
Per the document QUAL-2521.21-PMS, "Infant Formula Base Powder Release Specification (b) (4) microbiological testing of the finished powder is performed for (b) (4). (b) (4) are tested at a minimum (b) (4) on all products produced between bracketing sanitation breaks; in 2023, this testing was only done one time due to the extended shutdown.

In Packing Room (b) (4), microbiological samples are taken throughout the tote to create a representative composite. The document QUAL-517.06.02, "ByHeart Customer Guideline" was provided to (b) (4) for guidance regarding the analysis of samples **(Exhibit #24)**. Per the guidance, individual tote composites are composited by (b) (4) into one, representative sample and analyzed for (b) (4); for (b) (4), individual tote composites are analyzed separately and not composited into one sample. As such, the sampling plan for (b) (4) is more stringent than that for (b) (4). **Please See Discussion with Management Item #5**.

<u>Nutrient Testing</u>
All nutrients required by 21 CFR Part 107.100 are either tested in the base powder or at the finished product stage. The FDA Form, "Infant Formula Nutrient Information Reporting Form" (Attachment B) was provided for the base powder and finished powder **(Attachment #4)**.

In Packing Room (b) (4), the (b) (4); at (b) (4), the individual samples are separately analyzed and as a composite. On the document QUAL-2521.21-PMS, "Infant Formula Base Powder Release Specification-(b) (4) there are specific testing components for "composite" samples and individual samples, which are referred to as "content uniformity". For the base powder, routine release testing includes (b) (4); additional testing is performed for the (b) (4) commercial lots of a new formula or revised formula. Samples are also analyzed (b) (4) for (b) (4).

Nutrients are either added individually or via a premix. There are (b) (4) premixes used in the manufacture of the base powder, which are provided by (b) (4). Upon arrival, certificates of analysis are received, and testing is also done by (b) (4) to ensure that all nutrients are present in each premix. The premixes include:

(b) (4)

Indicator nutrients are tested either in the base powder or finished powder.

Individually added nutrients include (b) (4).

<u>Stability Testing</u>

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The firm performed a stability study for the base powder, which is captured in the document DEV-28.03-FM, "Review of Stability Data- Bulk Blendhouse Base Powder Tote Stability Report", initial effective date 10/1/21 **(Exhibit #25)**; however, the stability study was initiated on 2/15/23 and was performed on (b) (4) lots. The objective of this study was to establish current tote stability on unopened totes to determine (b) (4) in addition to physical and nutrient parameters. The overall goal was to establish the shelf-life on the totes, which can be filled into the final retail container and still achieve end of shelf-life claims.

Totes from the (b) (4) lots were stored at ambient temperature at (b) (4) ; the totes were (b) (4) . Samples were collected at different timepoints ranging from (b) (4) in (b) (4) with different lots beginning at different time points. At each collection point, (b) (4) unopened totes from the lot were sampled at (b) (4) different sample locations within the tote for testing. The (b) (4) locations included: (b) (4) . Samples were analyzed for (b) (4) .

In summary, all nutrient and organoleptic data generated was within release specification for ByHeart infant base powder and within typical ranges observed with base powder produced at BlendHouse; throughout the (b) (4) storage of the base powder within bulk totes, there was no detrimental change in nutrient content or quality of the formula.

Batch Record Review (MMS/EPM)

Infant formula records are primarily paper based; manual entries of critical and operational parameters are documented. Electronic systems are also used to capture critical and operational parameters; they are printed, reviewed and included with the batch records.

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 cover many areas including ingredient, in-process and finished product testing, environmental sampling, allergen control and sanitation. In addition, a Master Manufacturing Order (MMO) referred to by the firm as a Master Batch Record (MBR) is maintained for each batch.

The firm provided a copy of their released production lots for 2023 and a list of their production dates with disposition date including rejection reason for 2023, see **Exhibits #26 and #27.**

The following productions lots were reviewed:

(b) (4)

Review of the firm's production records revealed the following discrepancies:

- The "(b) (4) CCP Check Form", effective date 11/13/23 is utilized to (b) (4) document critical parameters every (b) (4) for the (b) (4) system, which is the final "kill step" for the product. The minimum processing temperature is (b) (4) and the maximum flow rate is (b) (4) ; operating parameters are (b) (4) or higher at (b) (4) . To ensure that the minimum temperature is achieved, there is a temperature indicating device (TID) and a temperature recording device (TRD) at the hold tube outlet. The (b) (4) CCP Check Form states, "Notify your Supervisor immediately if the chart recorder is reading higher than the indicating thermometer or if it has a greater than (b) (4) difference". During this inspection, batch records were reviewed for ByHeart milk- based powdered infant formula with iron. For Lot (b) (4) (production date (b) (4)), review of (b) (4) CCP Check Form identified 13 instances of the TRD reading higher than the TID and 24 instances that the two devices read more than (b) (4) apart. For Lot (b) (4) (production date (b) (4)), review of (b) (4) CCP Check Form identified 12 instances of the TRD reading higher than the TID and 30 instances that the two devices read more than (b) (4) apart. The operator did not notify their supervisor nor was this issue identified during record review by management. Both lots were released. **See FDA 483 Observation # 5, Exhibits #7 and #8.**
- Additionally, the temperature of the TRD is obtained from the HMI screen and not from the TRD unit itself, which does provide a digital readout. The TRD is located on the same control panel as the TID. **See FDA 483 Observation #5, Exhibit # 28.**

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- The "Master Batch Record", effective date 05/11/2023 is utilized to record the addition of ingredients and time/ temperature for batches for the infant bulk pre-blend. The Master Batch Record breaks this down into a (b) (4) process where various information regarding the batching is recorded. It was noted at Step 2 the calculated weight for (b) (4) after addition of (b) (4) the weight should be (b) (4). The form does not account for any weight variances/acceptable ranges to be off from the (b) (4). Lot (b) (4) all (b) (4) batches were off from this target weight for Step 2. **See Exhibit #29,** The differences ranged from a shortage of (b) (4) to an overage of (b) (4). Lot (b) (4), batch (b) (4) and batch (b) (4). **See Exhibit #30.** Lot (b) (4), all (b) (4) batches showed overages; (b) (4). **See Exhibit #31.** These differences were not noted by the Batch Operator or the Quality Reviewer. Additionally, at Step 11 a calculation is performed in order to determine how much (b) (4) at the end of the batching. The calculated or target weight for (b) (4) is (b) (4). The form instructs the Batch Operator to calculate the (b) (4). The difference (if there is one) at this point would indicate to the Batch Operator to (b) (4). Lot (b) (4), batch (b) (4) calculation was to (b) (4) but (b) (4), batch (b) (4) - calculation shows (b) (4) but should have (b) (4). **See Exhibit #29.** These differences were not noted by the Batch Operator or the Quality Reviewer. The firm was asked what could be causing these fluctuations in weights and at first Mr. Fenstermacher stated it was due to the (b) (4) in (b) (4) I discussed with Mr. Fenstermacher if it was (b) (4), it would cause every batch to have fluctuations and that was not the case. Mr. Fenstermacher later stated it could be due to improper installation of the (b) (4) for (b) (4). Mr. Fenstermacher later provided a video of the HMI screen showing fluctuations of weight for (b) (4). The firm contacted the company that installed the equipment and will be replacing all the wiring and adding a protective covering to cut down on electric "noise" which the firm feels is the root cause of the fluctuations in the weight.
- Ingredients are premeasured and "kitted" for batches. It was noted in some production lots these ingredients were premeasured as far ahead as (b) (4) before the ingredients were used in a production batch. **See Exhibit #32** Lot 179 , **Exhibit #33,** Lot 242 Dispensal Records. The kitted ingredients are stored on pallets located near the maintenance roll up door. The maintenance area was identified as an area of heavy pest activity. **Please See FDA 483 Observation #3 Exhibit # 34** photo of area where kits are stored.
- Temperature and pH are not recorded in the same consistent manner, for example at times they are documented to one decimal point and other times two decimal points.
- Employees were not completing all required information on the forms. For example, employees did not write their initials or the date when an activity was completed, not writing the complete expiration date of an ingredient. These omissions were not noted during the quality review of the records.

Internal GMP and Quality Control Audits (EPM)

Internal audits covering GMPs, and quality control procedures are conducted; no set schedule is maintained as audits are conducted as a result of current concerns. However, the document QUAL-504.03-FM, "Appendix A: BlendHouse- Reading Audit Plan Requirements" is also maintained and identifies the completion date of an audit objective **(Exhibit #35- pages 10-13)**. Ms. Whitesell and (b) (6), (b) (7)(C) are the internal auditors and have no responsibility for the areas that they audit; they have received both internal and external training and are SQF, HACCP and PCQI certified. The SOP QUAL-504-SOP, "Audit Program" is maintained, which addresses both internal and external audits **(Exhibit #35)**.

GMP audits are conducted (b) (4) with a more in-depth audit done (b) (4); (b) (4) audits are documented on the form QUAL-504.19-FM, "GMP Room Check" and (b) (4) audits are documented on the form QUAL-504.02-FM, "(b) (4) Plant Inspection Checklist" **(Exhibits #36 and #37 respectively)**. The form QUAL-504.20-FM, "Internal Audit Checklist and Summary" is used to document quality control audits; areas covered include the applicable requirements of 21 CFR Parts 106, 107 and 117. **(Exhibit #38)**

Deviations are classified as non-major, major and critical as defined by SQF; corrective actions must be completed within (b) (4). All findings are reviewed with the responsible departments. A non-conformance report is opened for critical deviations and are immediately addressed by senior management. Deviations are tracked in the electronic systems, (b) (4) (action plans) or (b) (4) (work orders).

An external audit was performed by FDAQRC dated 8/16-8/18/23 in response to the firm's previous FDA 483 Observations and Warning Letter; we were not provided the report to review. We were also not allowed to review internal audit results.

Sanitation (EPM)

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(b) (4) [redacted]

[redacted]

[redacted]

[redacted]

[redacted].

The SOP PROD-SOP-304, "D1500 Infant Formula Operation" is maintained, which provides instructions for the (b) (4) [redacted] step of the (b) (4) [redacted] dryer **(Exhibit #42)**. However, during this inspection, review of this document indicated that the required operational parameters to begin the (b) (4) [redacted] step and the conditions requiring re-initiation of the (b) (4) [redacted] step were not all identified as outlined in the validation study. As such, the document was updated with an effective date of 12/18/23 to include these parameters **(Exhibit #43)**. However, review of the updated SOP noted that not all conditions, which result in the re-initiation of the (b) (4) [redacted] were included. In addition, the validation document states that (b) (4) [redacted]; this instruction was not included in the updated SOP. **Please See Discussion with Management Item #3**.

<u>Process and Batch Rooms CIP (MMS)</u>
The Master Sanitation Procedure, SAN-800-SOP **(Exhibit #44)** outlines the cleaning frequency for the equipment used in the batching and processing of the infant formula base. A (b) (4) [redacted]

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(b) (4) .

The firm changed their chemical cleaning supply company from (b) (4) to (b) (4) since the last inspection. A list of the new chemicals and their safety data sheets were forwarded to FDA subject matter experts at the Center for Food Safety and Nutrition (CFSAN) and no discrepancies were noted.

The firm provided a comparison list of the previous chemical used to the new chemicals currently used (**Exhibit #45)** and their full approved sanitation chemical list **(Exhibit #46).**

(b) (4) and (b) (4) CIP, SAN-802-SOP (**Exhibit #47**) outlines the cleaning for the entire (b) (4) system which includes (b) (4) within the system in the processing room. The cleaning includes CIP and (b) (4) cleaning.

Sanitation Standard Operation Procedure: (b) (4) System- Batch Room (b) (4) -SOP (**Exhibit #48**) outlines the cleaning for (b) (4) , lines and any other equipment in the batching room. The cleaning includes CIP and (b) (4) cleaning.

<u>Quality Assurance/Control</u>
Environmental Monitoring Program: (KP)
The firm has a written environmental monitoring program, refer to **Exhibits #49 and #50** ("Environmental Monitoring Program", and "Environmental Surface Sampling") for a copy of the SOPs. The environmental monitoring program encompasses the firm's water sampling program, air sampling program, and surfaces sampling program within the facility.

<u>Environmental Surface Sampling Program</u> **(KP/EMP)**
General procedures for the firm's Environmental Surface Sampling include testing zones (b) (4) for pathogens ((b) (4)) on (b) (4) basis. As part of the (b) (4) , the firm collects at minimum (b) (4) .

Firm stated they uses the (b) (4) to randomize the (b) (4) selection of sampling sites from the Master Sampling Locations (for a copy of the sampling sites, both outdated and updated, refer to **Exhibits #51 and #52**). Firm said all sites on the list must be (b) (4) . They also mentioned the (b) (4) site list is continually updated based on the firm's evaluation of the program based on their sample results/findings.

To address pathogen findings (presumptive or confirmed), firm has written procedures, refer to **Exhibit #53** (Environmental Monitoring Positive Response Action Plan) for a copy of the firm's SOP. Firm stated that when notification of pathogen findings is received, the firm will clean and sanitize the identified area. Then (b) (4) will be collected. Investigator Mayer spoke to the firm about collecting the (b) (4) prior to cleaning and sanitizing. Refer to **Discussion with Management Item #6.**

In addition, (b) (4) is repeated for (b) (4) with minimum of (b) (4) taken (b) (4) episode. (b) (4) are collected in (b) (4) . The firm explained that during (b) (4) the same (b) (4) are sampled over (b) (4) to verify that cleaning procedures are effective. In the event pathogens are found during (b) (4) , then from that positive site, (b) (4) will be collected for (b) (4) . Firms stated in the event of a positive (b) (4) finding, the firm would implement new cleaning procedures. Moreover, in the event of confirmed pathogen finding, the firm will conduct a root cause investigation, and the pathogen will be identified using (b) (4) .

Zone (b) (4) is not (b) (4) on routine basis for pathogens or indicator organisms. Firm stated after cleaning and sanitation, prior to preproduction, if the visual inspection passes, then they collect (b) (4) on product contact surfaces (zone (b) (4)) using (b) (4) . Firm's established limit for all surface is (b) (4) . For out of specification (OOS) results, the firm would clean and sanitize, and recollect (b) (4) . For more information on the firm's procedures related (b) (4) sampling, refer to **Exhibit #54**("Use of (b) (4) for Hygiene Monitoring").

The monitoring records ("Pre-Op (b) (4) Checklists-Enhanced Testing") for (b) (4) sampling performed during 6/27/2023-9/29/2023 were reviewed, no discrepancies were found.

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Please note, firm no longer monitors for (b) (4) in zones (b) (4) as of September 2023.

During the inspection, (b) (4) results from 6/24/2023-9/29/2023 were reviewed. Based on this time period the firm provided the following data,

- Number of (b) (4) obtained from 6/24/23-9/29/23 are:

  (b) (4)

- Based off the list of sampling sites for 6/24/23-9/29/23, the number of (b) (4) per sampling zone is as follows:

  (b) (4)

- The (b) (4) positivity rate is (b) (4).

Employee Shoe Cleaning (MMS):
During the inspection, it was noted that employees were responsible for the cleaning and sanitizing of their shoes at the end of their 12-hour shift as per Shoe Cleaning, SAN-806-SOP. A discussion with management revealed there was no documentation of the shoe cleaning and management decided to change this duty to the sanitation department and add this to the Daily Sanitation Schedule**. Exhibit # 55**

Maintenance (b) (4) (MMS):
Review of the firm's environmental (b) (4) locations revealed the firm (b) (4) all the various (b) (4) except for the maintenance (b) (4) Due to the activities performed by the maintenance department and the fact they perform work in all hygiene areas of the firm, I did question why their (b) (4) was not part of the environmental master site list. The firm management stated this was an oversight and immediately added this (b) (4) to the master list. The firm also updated the procedure when a shoe cubby is empty, instead of (b) (4) the empty cubby, the next cubby with shoes would be (b) (4) in order to effectively demonstrate the cleaning and sanitizing of the employee shoes.

Environmental Records (AC/MMS)
Environmental monitoring records were reviewed for the time frame of 06/19/2023-09/25/2023. The firm utilizes (b) (4) to conduct their environmental testing and (b) (4). The (b) (4) data from positive samples collected by the firm is not uploaded to (b) (4).

Environmental positive investigations are documented on the firm's Environmental Positive Investigation Form, QUAL-510.01-FM effective 10APR2023. The following were reviewed during the inspection:

EMP23011 was created in response to water event LN23018 from 07SEP2023 in the Air Compressor Room at Dryer Tower (b) (4) (level (b) (). The positive swab was collected on day 1 on the floor at the top of the steps, post-clean following water event. After the suspect notification, all (b) (dryer levels were deep cleaned ((b) (4)) using (b) (4) and then (b) (4) as sanitizer. The outside of the dryer was sanitized with (b) (4). The firm collected (b) (4) following presumptive notification. All vectors were negative. The positive swab was identified as (b) (4) with the (b) (4) showing a unique strain- unrelated to any other samples from the firm. According to Fungfai, the incident and correction was discussed multiple times with the suspect employee and the sanitation SOP "MAIN-414-SOP" is in the process of being updated to ensure more in-depth cleaning and to eliminate repeated errors. A revised copy was provided with an effective date of 03JAN2024. **Exhibit #56**

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EMP23012 was created in response to positive (b) (4) found on floor of Packaging Room (b), airlock room ((b) (4)) collected on 08SEP2023. The air lock room is on a daily sanitation schedule. The (b) (4) completed for this sample, showed to be distinct from any other isolates found in the firm. All vector swabs were negative. The firm's investigation determined the likely source was the single use pallets. Prior to this event, the inbound back pallets (received in stacks of 8 to 9 pallets shrink-wrapped together) were not all sanitized. The bottom unit of the stack was the only one sanitized when moved from (b) (4 Vanguard warehouse to the (b) (4 Vanguard manufacturing building. Corrective action is now to use blue pallets between the air lock room and packing room and the pallets will be sanitized before entering the packaging room and cleaned after every product aggregate. **Exhibit #57**

EMP23013 was created in response to positive (b) (4) found on the blue floor scale ((b) (4)) in the packing area collected on 11SEP2023. The scale is used to hold single use black pallets for the filled and sealed totes of bulk powdered prior to shipment. The room and scale are on a (b) (4) sanitation schedule. The (b) (4) completed for this sample, showed to be distinct from any other isolates found in the firm. The firm's investigation determined the likely source was the single use pallets. Prior to this event, the inbound back pallets (received in stacks of 8 to 9 pallets shrink-wrapped together) were not all sanitized. The bottom unit of the stack was the only one sanitized when moved from (b) (4 Vanguard warehouse to the (b) (4 Vanguard manufacturing building. Corrective action is now to include sanitizing each individual pallet. The firm is also working with the supplier of the pallets to determine if the pallets are adequate for their microbiological needs. All vector swabs were negative. Production Lots (b) (4) and (b) (4) were rejected. **Exhibit #58**

<u>Water Supply and Water Sampling Program (KP and EPM)</u>
Water is received from (b) (4) , (b) (4) , who obtains the water from (b) (4) , which is then (b) (4) . (b) (4) also (b) (4) and the (b) (4) . There is one entry point into the facility. The main water line has (b) (4) , which are inspected (b) (4) by (b) (4) and were previously done on 7/16/23; at that time, (b) (4) was replaced as it was leaking.

(b) (4) .

During this inspection on 12/15/23, the firm provided the document, "(b) (4) Inspection Form" and stated that parameters will be (b) (4) documented (b) (4); a Work Order was opened to initiate this process. In addition, (b) (4) review of the (b) (4) parameters will be performed. The (b) (4) unit is CIP'd (b) (4) and was previously done in April 2023. After the (b) (4) .

Firm sample process water ((b) (4)) on (b) (4) basis, for more information about their sampling sites, frequency, analysis, and limits refer to **Exhibit #59, pages 3-5**, "Water Analysis Program" SOP.

Per 21 CFR 106.20 (f), the firm is conducting (b) (4) testing (sampled at (b) (4)) for (b) (4) contaminants. (b) (4) testing is performed by a 3rd party lab ((b) (4)). Per the water report provided by (b) (4) for year 2022, it stated fluoride is not added to the water supply.
During the inspection, the (b) (4) water testing reports (from (b) (4)) were reviewed. (b) (4) water sampling for (b) (4) has not been performed at the time of the inspection. During the review of water testing report Job ID: 810-48143-1 for samples collected on 12/21/2022 (report generated date of 2/4/2023), firms' Quality Operations Manager, Ms. Michele M. Otte, stated these (b) (4) reports are reviewed by corporate office; however, the report was not reviewed, refer to **Discussion with Management Item #2**, for more details.

Also, the firm conducts (b) (4) service of the (b) (4) system. Last report dated to 9/23/20233 was provided for review. This report stated (b) (4) ; however, that recommendation was not followed until April 2023, when firm started to conduct (b) (4) inspections; no records are kept of such inspections. Refer to **Discussion with Management Item #2**, for more details.

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Moreover, firm conducts (b) (4). These tests are performed (b) (4). Firm maintains records.

The (b) (4) water testing records from July 2023-Spetember 2023 were reviewed and no deviations from the established limits (for (b) (4)) were observed. However, firm provided an investigation form (Environmental Positive Investigation Form; EMP Report Number EMP23004) completed for a positive (b) (4) test for water collected from (b) (4) on 6/6/2023. Water was collected from the (b) (4) instead of the (b) (4); during resampling, water was not collected from the (b) (4) for verification of cleaning, refer to **Discussion with Management Item #1**, for more details.

Furthermore, the last four (b) (4) tests ((b) (4)) conducted by the firm for water were reviewed. These tests were conducted by a 3rd party lab ((b) (4)). For the (b) (4) testing, water was tested for (b) (4). Records did not indicate any deviations from the established limits.

<u>Back flow Prevention (EPM)</u>
Hose stations and the boiler make-up water line are equipped with back flow prevention devices, which are inspected (b) (4) by (b) (4) and were previously done on 1/30/23.

<u>Boilers (EPM)</u>
The firm has (b) (4), which utilize (b) (4). The FDA approved additive, (b) (4) is added, which is provided by (b) (4); a letter of continuing guarantee is maintained on-file.

<u>Air Sampling Program(KP)</u>
Firm monitors the microbial load of the ambient air in product manufacturing, packaging, and laboratory areas. Ambient air is passively collected on (b) (4) basis to test for (b) (4), refer to **Exhibit #60** for the firm's SOP ("Ambient Air Monitoring") describing the sampling procedures, sampling sites, and acceptance limits. Firm stated that if the acceptance levels exceeds then a retest will be performed. If the acceptance limits on the retest exceeds then an investigation is performed. For (b) (4), the acceptance limits are (b) (4) in a critical or high zone and (b) (4) minutes exposure for medium zone. For (b) (4), the acceptance limits are (b) (4).

Records from 6/20/2023-9/27/2023, for (b) (4) air monitoring was reviewed (Ambient Air Testing Results), no discrepancies were noted.

During record review, any investigated mold events from January 2022-Decemeber 2023 were reviewed. Firm provided a total of 8 investigation reports. The "Environmental Positive Investigation Form" (EMP Report Number EMP23010) documented mold was found inside the (b) (4) tank. Investigation report suggested mold was introduced from the environment (air in the Batch Room), refer to **FDA 483 Observation #1,** for more information.

<u>Water Events (MMS)</u>
Facility Water Leak Control and Cleaning- MAIN -414-SOP, Effective 13JUL2023 **(Exhibit #61**)was reviewed and all water leaks for 2023. During the walk-through of the firm on 12/11/2023, we observed an active water leak at the Dryer Level (b) (4) roof- below the gas burner. The duct work for this gas burner is located in the ceiling where the water was dripping. **See FDA 483 Observation # 2,** for further information.

The firm has experienced many roof leaks during the year which has intruded into the manufacturing areas in different hygienic areas. The roof to the manufacturing facility is composed of five different sections, the age of which was unable to be determined by the firm or the roofing company. Events are created to document/investigate/determine the risk of an external water leak. Below is a summary of external roof leaks for the year 2023 categorized by hygiene area.

<u>Packing Room (b) (4) – (b) (4) Area</u>
On 09/24/2023, LN23019 was created for a water leak that occurred in packing room (b) (4), from the ceiling near the hatch door handle. **Exhibit #62**

On 10/14/2023, (20 days later) LN23021 was created for a water leak that occurred in packing room (b) (4), from the ceiling at the

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corner of the light near the sack conveyor. **Exhibit #63**

<u>Dryer Tower</u> (b) (4) (b) (4) **<u>Hygiene Area</u>**

On 03/28/2023, LN23004 was created for a water leak that occurred in Dryer Tower- Level (b)(and Level (b)(on a beam and wall opposite the side of the dryer. **Exhibit #64**

On 04/01/2023, 04/15/2023, 04/30/2023 and 06/06/2023; LN23003, LN 23005, LN23007 and LN23008 respectively, were created for a water leak that occurred in Air Compressor ((b) (4)) and Fire Suppression ((b) (4)) rooms. **Exhibit #65, #66, #67, and #68**

On 06/25/2023, LN23010 was created for a water leak that occurred Air Compressor ((b) (4)) and (b) (4) rooms (Dryer Level (b)(). **Exhibit** # 69

On 07/09/2023, LN23012 was created for a water leak that occurred in (b) (4) room. **Exhibit #70**

On 07/24/2023, 08/08/2023 and 09/07/2023; LN 23013, LN23015 and LN 23018 respectively were created for a water leak that occurred in (b) (4) room. **Exhibit #71, #72, and #73**

On 07/25/2023, LN23014 was created for a water leak that occurred in Dryer Tower- (b) (4) at Exit Door (due to door seal being damaged). **Exhibit #74**

On 08/10/2023, LN23016 was created for a water leak that occurred in Dryer Tower-Level (b) (4) (exhaust fan) side down to Level (b)(. **Exhibit #75**

On 08/13/2023, LN23017 was created for a water leak that occurred in Air Compressor and Fire Suppression rooms. **Exhibit #76**

On 12/11/2023, LN23026 was created for a water leak that occurred in Dryer Tower-Level (b)(Dryer (b) (4) duct. **Exhibit #77**

<u>Supply Chain (KP)</u>
Firm has a written and signed food safety plan, refer to **Exhibit #78**. However, the food safety plan did not have a written hazard analysis that documented the evaluation of the raw material/ingredients, for more information refer to **Additional Observation #3**. During the discussion pertaining to supply chain, Ms. Heather MacNaughton, Sr. Director of Regulatory Audit Compliance said the firm does not rely on their supplier to control for hazards pertaining to any of their ingredients because, they test all ingredients. Firm was reminded the hazards they are verifying that their supplier is controlling ((b) (4)) are part of the supply chain program. Moreover, ingredient testing is a verification activity conducted under supply chain program (refer to **Additional Observation #3).**

Firm has a written supplier approval program, refer to documents, number QUAL-507-SOP, "Supply Chain Management" (**Exhibit #79),** and QUAL-507.04-WI**,** "Supplier, Ingredient and Material Approval" (**Exhibit #80)** for a copy of BlendHouse procedures. Also refer to document number QUAL-2505-SOP, "Supplier Quality Management", **Exhibit #81,** for a copy of the ByHeart procedures related supply chain program. Ms. MacNaughton stated suppliers are assessed and approved by the corporate team.

Firm appeared to be purchasing from approved suppliers, and they maintain a list of approved suppliers in (b) (4), a software used for supplier management program at BlendHouse. For a copy of the approved supplier list, refer to **Exhibit #82**. On 12/18/2023, (b) (6), (b) (7)(C), Internal Auditor, highlighted (in purple) some of the vendors on the list to show vendors that are not active, meaning currently, the firm is not purchasing from these vendors. Moreover, Ms. MacNaughton provided for review, their "Supplier/Material Approval Form" for their suppliers, (b) (4) These forms are part of the supplier approval documentation.

Ms. Alicia Dickenson, Release Service Associate Manager, stated she reviews all receiving paperwork (including COAs) of raw ingredients and raw material against the established specifications, prior to approving them for release into production (refer to **Exhibit #83**, for a copy of the SOP Document number QUAL-517-SOP, "Review and Release of Materials and Products"). She mentioned for any ingredient or material that failed to meet specifications/review, these will be investigated. For any rejected item,

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these will be quarantined (identified as quarantined) and will be dispositioned accordingly. Firm also have written procedures to account for change controls (refer to **Exhibit #84**, "Change Control Procedure") and procedures to handle any temporary changes (refer to **Exhibit #85,** "Temporary Change Notification Procedure").

During the inspection, receiving paperwork for all ingredients included in aggregate (b) (4) were reviewed. During this review, heavy metal test results from the raw ingredients (b) (4) and mineral premixes (b) (4) added to aggregate (b) (4) were submitted to CFSAN for feedback on (b) (4) limits on raw ingredients. There were no issues found on the COAs submitted; however, Investigator Pathiraja, during the close-out meeting, shared with the firm that currently, (b) (4), referencing the food chemical codex (III) has no specifications for (b) (4), and U.S. FDA has no specifications for heavy metals associated with the mineral pre-mixes. Moreover, Investigator Pathiraja stated that under the Closer to Zero initiative U.S.FDA is examining infant formula to better understand levels of toxic elements in ingredients. Additionally, it was recommended, per Closer to Zero initiative, even with action levels for heavy metals, industry should strive to get as closer to zero as possible.

Furthermore, during the review of the receiving paperwork, for the mycotoxin hazard identified for (b) (4), firm could not provide documentation to indicate they verify their supplier controls for such hazard, refer to **Additional Observation #3.**

IT Programs (KP)
Firm maintains a document (MAIN-402.04-FM) with all the software/hardware/IT systems, refer to **Exhibit #86** Firm also identified (b) (6), (b) (7)(C) as the main point of contact related to IT questions. During the discussion related to mechanical and electronic equipment, (b) (6), (b) (7)(C) pointed out the authorized personal is also knowledgeable regarding each software/hardware/system they oversee.

Firm uses the (b) (4) (Enterprise Resource Planning (ERP)) software system to run the business, from receiving to distribution. (b) (6), (b) (7)(C) stated system was validated upon installation. Both (b) (6), (b) (7)(C) and Ms. Karianne Delgado, Production Manager (who is authorized to oversee the software) stated they are unsure of the IT security installed into the system (i.e., firewall); however, they both responded that only authorized personnel have access to the system. (b) (6), (b) (7)(C) stated (b) (4) is a cloud based program that is backed up on daily basis.

To streamline maintenance operations and management, firm uses the (b) (4). (b) (6), (b) (7)(C) stated this was installed two years ago and it was validated upon installation. The authorized person to oversee the software is (b) (6), (b) (7)(C), Maintenance Supervisor. (b) (6), (b) (7)(C) stated access is limited to only authorized individuals based on their role.

(b) (6), (b) (7)(C) explained the firm uses the (b) (4) monitoring tablets to monitor all production activity and utilities remotely. (b) (6) stated all production operators and managers uses this. (b) (6) also said access is credential based and data is backed up (b) (4) to a dropbox.

Firm also uses the (b) (4) for all plant operations. (b) (4) and (b) (4) is an integrated system that help run the plant (machinery and manufacturing) by controlling and monitoring manufacturing processes/equipment. (b) (6), (b) (7)(C) stated this system was validated upon installation. General upkeep is needed for periodic control changes and equipment changes. This system is overseen by plant manager. System is used by production employees, engineers and maintenance crew. The system is backed up regularly.
For document control and retention firm uses (b) (4). It is a cloud based system that is backed up (b) (4). Ms. Katherine Rhoades, Regulatory Compliance Manager has authority to oversee the system.

The lab also utilized various equipment/ software systems for performing lab activities. Ms. Michele Otte Quality Operations Manager who is authorized to oversee these equipment and software stated the firm no longer uses the (b) (4) for (b) (4) testing in raw milk. She said they continue to use the (b) (4) to test (b) (4) levels on the (b) (4 base powder, (b) (4) for (b) (4 analysis, and (b) (4) for conducting (b) (4) analysis on the (b) (4 base powder. Calibration records for the lab equipment, (b) (4) were reviewed, firm appeared to calibrate equipment in routine basis; no discrepancies were noted.

Firm also uses a (b) (4), a web based interface that allows control of the HVAC system in the (b) (4). (b) (6), (b) (7)(C) stated (b) (6 oversee the system and the HVAC system is not in a schedule for routine maintenance; however, if there is an issue it will be addressed. He also added the (b) (4) in the production area are changed (b) (4).

Process Flow, Operations, and Product Coverage

Pest Control (KDC/MMS)

During the walk-through inspection of the firm, we observed at the Dryer Level (b) (several flies actively flying around the ceiling and a dead fly on the ledge. The Dryer is a (b) (4) Area. Also, a fly land on the arm of your plant manager just outside the door leading to the (b) (4) for Packing room (b) (4. Packing Room (b) (4 is a critical hygiene area. **See FDA 483 Observation # 3**

Pest control services for both buildings are provided by (b) (4) located in (b) (4). Interior traps and inspections are conducted (b) (4). Light traps for night flying insects are checked on an irregular basis for a total of (b) (4). Night flying insects are any flying insect caught by the light trap and includes over a thousand of individual species. (b) (4) does not speciate the insects found in the traps. The sanitation supervisor is responsible for speaking with the (b) (4) representative at the completion of every service to review findings. According to Ms. Rhodes, the previous sanitation supervisor retired on August 19, 2023. A new supervisor was not appointed until 10/02/2023. The firm's quality operations manager was responsible for the sanitation supervisor duties in the interim.

Pest control records for the entirety of 2023 for both facilities including individual reports and trending (b) (4) data were reviewed. **See Exhibits #87 and #88** The following was noted for Building (b) (4)

- On 06/29/2023, (b) (4) noted a gap in the ceiling leading from the warehouse to the outside located centrally along the south end of the building. On 08/30/2023, a work request was created. On 09/21/2023, the work request was marked complete.
- An increase in the trending data for night flying insects was noted April through June 2023 with a total of (b) (4) .

The following was noted for Building (b) (4:

- On 06/08/2023, a gap was noted by (b) (4) in the bottom right side of the delivery door. On 08/03/2023, a work request was created. On 08/10/2023, the work request was marked completed.
- On 11/30/2023, a gap in the ceiling leading from the drying tower to the outside was noted by (b) (4).

Investigator Covill asked Ms. Rhodes to explain why there were large time gaps in between the deficiencies being found and work requests being created. She stated she could not explain the gaps because the previous sanitation supervisor has retired. She stated that when the quality operations manager was assigned to review the pest control records in August 2023, the work requests were submitted. Ms. Rhodes explained the following pest control activities have been ordered or completed during the ongoing construction:

- The (b) (4) waste line fitting, which leads to the outside, was installed on 12/02/2023.
- The wall behind the waste tank is to be sealed. The sealant was delivered on 12/11/2023.
- A 10-mesh metal screen covering the exhaust vent stack (b) (4 was installed on 11/16/2023.
- A 10-mesh metal screen covering the exhaust vent stack (b) (4 was installed on 11/27/2023.

On 12/13/2023, Ms. Rhodes stated they will be implementing a routine audit of the pest control records. (b) (6), (b) (7)(C), internal auditor, will be responsible for reviewing the pest control records on a routine basis. She explained they spoke with (b) (4) and will be adding more ILTs in the facility concentrating on the maintenance shop.
(b) (4) also performed on 11/28/2023, a comprehensive inspection of the firm's manufacturing building (61 Vanguard Drive) where the Dryer Tower was identified as "…the hub of insect activity…" **See FDA 483 Observation # 3 and Exhibit #89**

MANUFACTURING CODES

The firm assigns a production aggregate number to each bulk tote of in-process product. The following is an example of the firm's product coding system for a production aggregate:

(b) (4) [redacted]

COMPLAINTS

Review of firm's complaint file(s)

(KP)
Firm only manufactures one Infant Formula Powder base, there were no new or reformulated products since the last inspection. During the current inspection, complaints were reviewed since the last inspection, from January 2023-December 2023. On the complaint report, there were 295 reported complaints. Out of the 295, 150 complaints were reported as health related (this count includes some that are listed as both health related and quality related), and 145 were reported as quality related complaints. Firm stated none of the health related complaints involved a potential health hazard. Moreover, no complaints were received by the firm for mold during this time.

For a copy of the complaint report provided, refer to **Exhibit #90**. Also, for copies of the SOPs pertaining to the firm's complaint management program (QUAL-514-SOP) and policy (QUAL-2503-POL), refer to **Exhibits #91** and **#92**, respectively.

Firm uses the (b) (4) [redacted] for complaint management and the (b) (4) [redacted], medical dictionary for coding. According to Ms. MacNaughton the corporate team (b) (4) [redacted] filters through complaints to separate them as quality related or health related or both. Information pertaining to each complaint is captured in "Individual Case Report" in (b) (4) [redacted]. Mr. Dhru Patel, Director of Pharmacovigillance reviews each health related complaint within 24 hours. If additional information is needed, he will follow-up with the complainant within 3-5 days. On 12/20/2023, Mr. Patel stated all health related complaints are evaluated for potential health hazards. For complaints related to potential health hazard, the Chief Medical Officer will be notified for further investigation.

During the inspection, all associated "Individual Case Reports" for batch codes (b) (4) [redacted] were reviewed. For these batches, firm reiterated no potential health hazards were identified related to the product.

Additionally, no other complaints were found in the U.S. FDA database since the last inspection, as such, there were no previously known complaints to FDA that is covered during this inspection.

RECALL PROCEDURES

Review of the firm's recall procedures found that they contain the four elements required to be in a recall plan per 21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls. The four elements are: directly notifying the direct consignees of the food being recalled, notify the public about any hazard presented by the food, conduct recall effectiveness checks, and appropriately dispose of recalled product.

Additionally, review of the firm's written recall procedures found that they contain the five elements required to be in a recall plan per 21 CFR 107, Infant Formula. The five elements are: evaluate in writing the hazard to human health associated with the use of the infant formula, devise a written recall strategy suited to the individual circumstances of the particular recall, promptly notify each of its direct accounts about the recall, the firm request point of sale establishments to post a notice of the recall, and furnish to the FDA district office specific information listed in the infant formula recall section of 21 CFR 107.

The firm has not had a recall since 12/11/2022 which was initiated by their parent company, ByHeart.

Ms. MacNaughton provided an update to the firm's recalled product being held at the (b) (4) locations (**Exhibit #93**), the product is scheduled to be destroyed in 01/2024.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Inspection Observations	
Observation	**1**
Citation Text	You did not ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source.
Observation Details	Specifically, on 9/7/2023, during a routine post-CIP inspection, your batching operators found an unidentifiable "red stain" on the inside of the batch tank (b) (4), which prompted the operators to inspect the (b) (4) tank. During this inspection of the (b) (4) tank, your employees found mold above the water line. The (b) (4) system circuits the batch room tanks, and the dryer feed lines. The (b) (4) tank holds clean water for (b) (4) the (b) (4) system during cleaning. Upon the discovery of the mold in the (b) (4) tank, on 9/7/2023, prior to cleaning and sanitizing, you collected swabs for yeast and mold confirmation testing. These swabs were collected from the interior of the (b) (4) tank where you found growth. The lab report for these swabs collected said "many confluent colonies" of mold growth were seen in the (b) (4) plates (the report EMP23010, referred to these findings as "TNTC" -too numerous to count). In your "Environmental Positive Investigation Form report" number EMP23010, under "INVESTIGATION SUMMARY AND RCA", it stated "Mold present in the air was likely introduced to the interior surface of the tank". Review of your "Event Reporting and Investigation Form/ Environmental Positive Investigation Form" from January of 2022 through December of 2023 for mold events indicated that there were two prior mold findings (Event Number 2240 and EMP Report Number EMP23002) in the same hygienic area (Batch Room). Event number 2240 (Event dated 4/13/2022) documented an out of specification results of yeast and mold in ambient air in the batching room as likely the result of "build-up" (off white and black in color) found underneath the exterior surface of the homogenizer and the (b) (4) tank. EMP Report Number EMP 23002 (Event dated 3/13/2023) documented finding of mold on the water pipe on north/west corner of rear batching room. Yet you stated that prior to mold finding in 9/7/2023, your firm did not clean the interior of the (b) (4) tank, because the tank is used only for holding clean water. Furthermore, your batching employee stated he inspects the water level and the interior of the (b) (4) tank prior to each CIP cycle, but you do not maintain any record of such inspections. As such, cannot determine when mold was first introduced into the tank.
Citation Reference	21 CFR 106.30(b)
Supporting Evidence and Relevance	**(KP)** Visible mold growth should not be found in clean environment like an infant formula manufacturing site, specifically, the (b) (4) tank that circuits the batch tanks in the batch room (b) (4) area) and the dryer feedline. For more information on the (b) (4) tank mold event, the firm's actions/corrective actions and other mold events, see below: 1. <u>EMP Report number EMP 23010</u>: Refer to "Environmental Positive Investigative Form", EMP Report number EMP 23010 to review information and findings pertaining to the mold found in the (b) (4) tank above the water level (**Exhibit #94**). **Page 1** of the report shows a photo taken by the firm of the mold found inside the (b) (4) tank.

Inspection Observations

On this report (**Page 6**), under "Manufacturing", it stated during the (b) (4) inspection of the batch tank (b) (4), the batch operators found a "red stain" inside of the tank. Firm could not identify the "red stain". During the inspection, after reviewing raw ingredient specifications and CIP chemicals, only thing the firm uses that appeared to be red is their (b) (4) , Refer to **Exhibit #95, page 1**).

On 12/14/2023, Investigator Pathiraja asked the batch operator (b) (6), (b) (7)(C) to describe the red stain, and (b) (6 said, the stain was smaller than dime ("small dot") that is a reddish orange in color. The batch operator nor the firm could provide any more information. There was no documentation (photo) of the "red stain" nor was it sampled for identification (i.e., mold). As such, cannot determine whether the "red stain" is food/chemical debris left behind after CIP cycle or mold.

After the finding of the "red stain" in batch tank (b) (4), some of the actions taken by the firm includes:

- The batching operators conducted a visual inspection of the (b) (4) system, including the (b) (4) tanks in (b) (4) and (b) (4) During this inspection, no other "red stains" and mold were found.

  In the report, the firm did not mention evaluation of the CIP system for (b) (4) circuit. Firm said that is because the (b) (4) circuit only has a wash tank, no (b) (4) tank. The (b) (4) uses (b) (4) , refer to **Exhibit #96**, (b) (4) Schematics.

- Firm does not routinely swab surfaces for mold. On the EMP Report number EMP 23010, **page 3**, under "III" documented the "CIP (b) (4) tank interior surface is not routinely (b) (4) ".

  On 09/07/2023, for the mold event in the (b) (4) tank, firm collected samples from the interior surface of the (b) (4) tank for mold identification prior to cleaning the (b) (4) tank. These tests were performed in-house. Fangfei Lou, Director of Quality stated they did not speciate the mold or conducted any further testing to assess for mycotoxins. Michele Otte, Quality Operations Manager, mentioned that their in-house lab does not have the capabilities to speciate mold or test for mycotoxins.

  The lab report for the swabs collected on 9/7/2023, said "many confluent colonies" of mold growth were seen in the (b) (4) plates, refer to Lab Report-Pre clean (**Exhibit #97**). The report EMP 23010 (**Page 8**), under "Product Risk Assessment" referred to these findings as "TNTC (too numerous to count").

  For the lab SOP for "Yeast and Mold Count (b) (4) " which explains firm's procedures for testing yeast and mold, refer to **Exhibit #98**, labeled Yeast and Mold Count (b) (4) .

- The firm did not test water in the (b) (4) tank upon discovery of mold prior to any cleaning or sanitizing of the tank on 9/7/2023. However, on 9/11/2023, water samples from the (b) (4) tank were collected for yeast and mold before and after the application of (b) (4) and (b) (4) treatments for mold (refer to **Pages 3 & 4** of the report EMP23010). The results were 15 CFU/mL before using (b) (4) and 0 CFU/mL after (the report said this was for an average of 10 samples).

  The firm conducts (b) (4) of their (b) (4) at the batch tanks, including tank T2200. However, the (b) (4) tank is not a scheduled location for routine (b) (4) water testing performed for yeast & mold (refer to **Exhibit #59**, SOP Water Analysis Program, **pages 3-5** for the locations, the frequency, and limits).

  For the results of the yeast and mold testing performed on (b) (4) tank on 9/11/2023, refer to (**Exhibit #99**, **Pages 13-14**, Portable Water Microbial Monitoring Results).

Inspection Observations

- Based on the report EMP23010, the following bulk infant formula base powder ((b) (4) base powder) lots were manufactured prior to the mold finding (manufactured between 9/1/2023-9/5/2023):

(b) (4)

Report documented that after running CIP on 9/7/2023, and (b) (4) cleaning and sanitizing (b) (4) tank, additional (b) (4) swabs for mold testing were collected from inside the (b) (4) tank to test for mold. The results ranged from 2 CFU-16 CFU, refer to Lab Report-Post Clean (**Exhibit #100)** and **page 4** of the EMP Report number EMP 23010 (**Exhibit #94**). Also, in the report EMP 23010, on **page 4** it stated, there are no [established] limits for yeast and mold on (b) (4) tank/equipment surfaces. However, based on the report it appeared the firm had manufactured additional (b) (4) base powder lots following the cleaning on 9/7/2023.

After 9/7/2023, the following lots were manufactured:

(b) (4)

Additionally, in the report EMP23010, it stated that as part of the investigation, lots (b) (4) were tested for yeast and mold. But the firm did not further evaluate infant formula base for potential mycotoxin contaminations. For (b) (4) powder base testing analytical reports refer to **Exhibit #101**, Product Testing for Mold.

Furthermore, out of the 5 (b) (4) base powder lots manufactured between 9/1/2023-9/9/2023, only three were tested for yeast and mold after the discovery of mold in (b) (4) tank. During the close-out, firm was unable to answer why only three lots were evaluated for yeast & mold, when firm cannot affirm when mold was first introduced inside the (b) (4) tank. During the discussion, Investigator Pathiraja shared with the firm that although mold may grow within 24-48 hours it may not become visible sometimes until weeks (possibly18 days or more) later.

2. (b) (4):

(b) (4) system circuits the batch room tanks, and the dryer feed lines, see the schematic provided (**Exhibit #102**, (b) (4) Schematic).

- Firm's current practice is to conduct CIP no more than (b) (4) prior to use/before manufacturing (for the (b) (4)). CIP was performed in (b) (4) circuit on 9/6/2023 and on 9/7/2023. On 9/7/2023 CIP was performed twice, once before the findings of the mold and once after, refer to **Exhibit #103**, (b) (4) System Graphs.

As stated on the EMP Report number EMP 23010, the chemical and the sanitizer used in (b) (4) system bypasses the (b) (4) tank, the (b) (4) tank does not get cleaned during CIP or on routine basis (not a scheduled site for cleaning).

Only clean water ((b) (4)) (b) (4) is supplied to the (b) (4) tank for circulation through the CIP circuit for use during (b) (4) steps. The (b) (4) is fed to the (b) (4) tank from the top of the tank (valve system that dumps water from the top), as seen on the schematic provided. Even though the mold was found above the water line, it is possible these mold spores can fall into (b) (4) water.

Inspection Observations

- Earlier in the inspection, there was a conversation related to potential mold/mold spores being transferred to other surfaces on the (b) (4) circuit from the (b) (4) water. Ms. Lou stated if mold were to be introduced into the batch tanks or food contact surfaces pertaining to the circuit, the sanitizer should be effective against mold/mold growth.

Firm uses (b) (4) . However, the sanitizer label stated that for the chemical to be used as an effective fungicide, it has to be applied as directed under the disinfectant directions (refer to **Exhibit #104**, (b) (4)). Differences noted when used as a sanitizer or a disinfectant are, the instructions provided for the dilution concentrations, and the requirement for a (b) (4) . Although, when used as a sanitizer, the label instructed no (b) (4), when used as a disinfectant, the instructions say, "(b) (4) ".

During the close-out meeting, the firm was reminded, if chemicals are not used according to the instructions provided by the chemical manufacturer, then the chemical may not be effective.

For SSOP pertaining to (b) (4) system, refer to **Exhibit #48 (SAN 805 SOP (b) (4))**.

3. <u>Other Mold Events</u>:

During the inspection, firm's mold events from January 2022- December 2023 were reviewed. The firm provided all the reports for mold events that they have performed an investigation. See the summary of the events on the table below:

Event #/ Event Date	**Surface**	**Air**	**Description/Location**
2240- 4/13/2022		x	Batching Room air retest results was (b) (4) , on 4/19/2022. Report indicated possible cause as finding "build-up" under exterior surface of homogenizer and (b) (4) tank. Same hygienic zone as event EMP 23002 and EMP23010
EMP 23001- 3/2/2023	x		Vacuum filter bag in packaging room #1. Vacuum used for cleaning floor. Also, during the firm's investigation, they observed mold in vacuum cleaner bags in dryer room (on (b) (4)).
EMP 23002- 3/13/2023	x		Mold growth on water pipe in back of the batch room (supplies water to vacuum pump-not a food contact surface). Same hygienic zone as event 2240 and EMP23010. During firm's investigation, they found a leak on the pipe.
EMP 23005- 6/7/2023		x	Air sampled at the dryer (b) (4) . Report noted on 6/6/2023 there was a discovery of an external leak in the air compressor room on the (b) (4) . Report concluded it was unlikely the leak contributed to the out of specification air tests.

Inspection Observations

EMP 23006-6/15/2023		x	QA lab under fume hood. Last two out of specification air samples from QA lab are from 10/27/2022 and 11/2/2022. During the investigation, debris was found in air vents.
EMP 23008-8/1/2023		x	QA lab, sample was collected from a table located at the center of the room. QA lab is located on the second floor mezzanine of 61 Vanguard. During investigation found debris in air vents.
EMP 23009-8/1/2023		x	(b) (4)-(b) (4) room- sample collected from the top surface of the yellow chemical storage cabinet. Investigation found debris in the air vents.
EMP 23010-9/7/2023	x		Found mold growth above water line in the (b) (4) tank in the batch room. Same hygienic zone as event 2210 and EMP 23002.

Reviews of these reports indicated that Event Number 2240 and EMP Report Number EMP23002 were in the same hygienic area (Batch Room). This suggests, mold could have been introduced into the (b) (4) tank from the environment in the batch room.

For more information on the firm's air sampling program, refer to EIR section under **"Quality Assurance/ Control"**.

The batch room has two sections, and it is located next to the processing room. It is considered a (b) (4) area. Refer to **Exhibit #105**, Batch Room Maps. **Page 2 of Exhibit #105** (of the Batch Room Maps) shows where mold was found (in yellow highlights). This map was drawn out by the firm; however, the yellow highlights are added by Investigator Pathiraja. On the map, where it says "Water Supply to Vacuum pump" shows the location where mold was found in event EMP 23002. Also on the map, "(b) (4)" and "homogenizer" shows where (b) (4) tank and the homogenizer are located in the batch room (per event EMP 23010 and event 2240).

For copies of the other mold investigation reports refer to **Exhibit #113**, for Event 2240 (**Exhibit #106**), and EMP23002 (**Exhibit #107**).

For the root cause analysis conducted for Event 2240 (event date 4/13/2022), firm inferred the likely cause of OOS results for the weekly air testing in the batch room was likely due to the "build-up" on the exterior surfaces of the homogenizer and the (b) (4) tank. This is because when the air was sampled prior to cleaning the "build-up" and after cleaning the "build-up", there was a reduction in yeast and mold counts after cleaning (refer to **Exhibit #106, page 3**, for Event 2240). For photos of the "build-up" refer to **Exhibit #106**, **page 4.** During the close-out meeting, I was able to confirm that for this event, the firm only sampled the air for yeast and mold, no surfaces were swabbed for mold confirmation.

For the EMP Report Number, EMP23002 (event date 3/13/2023), growth found on the pipe in the batch tank was samples for mold confirmation. Report indicated presence of mold, (refer to **Exhibit #107, page 2**). Firm inferred the mold growth was likely due to a leaking pipe and lack of routine cleaning and sanitation of the pipes (refer to **Exhibit #107, page 5**).

During the close-out, Investigator Pathiraja emphasized that although it may be normal to have certain amount of mold spores in the air, it becomes a concern when mold spores are provided with the right conditions to grow. She reminded the firm that all it may take is one mold spore to grow when given the right conditions regardless of the set

Inspection Observations	
	acceptance limits for air sampling (b) (4) .
Discussion With Management	During the close-out meeting, firm did not say anything other than the promise to respond to U.S. FDA in writing within 15 business days. Below are some items discussed throughout the inspection. Investigator Pathiraja encouraged the firm to document findings with photography, for instance documenting the “red stain” with photography. Earlier in the inspection, Ms. Lu commented that events EMP23010, Event Number 2240 and EMP Report Number EMP23002 were isolated/unrelated. She also said that the firm will not swab the apparent mold in the event they have another mold event. Investigator Pathiraja explained to her that it is a good practice to identify/sample the growth on the surface so that the firm can identify the problem and take/implement appropriate corrections/corrective actions. (b) (4) tank was not in the cleaning schedule and was not routinely cleaned prior to this mold event on 9/7/2023. Ms. Lou stated since the mold finding, firm has included all CIP (b) (4) tanks into the cleaning schedule. She also stated the visual inspection prior to CIP will be documented going forward. During the close-out, the firm stated Yeast & Mold Testing during sanitation breaks was added due to this event. On their updated “Batch Room Cleaning Record”, it instructed operators, for “(b) (4) ”, “perform (b) (4) tank cleaning and sanitize if necessary”. During the close-out Investigator Pathiraja reminded the firm since mold may not be visible for days or weeks, just cleaning and sanitizing when surface is insanitary (only when mold is visible) may not be adequate corrective action.
Correction Status	No Firm Response Submitted
Observation	**2**
Citation Text	You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.
Observation Details	Specifically, on 12/11/2023, during the walk thru inspection of your facility, we observed an active water leak at the Dryer Level (b) (4 roof- below the gas burner. The duct work for this gas burner is located in the ceiling where the water was dripping. Your facility has experienced many roof leaks during the year which has intruded into the manufacturing areas in different hygienic areas. The roof to the manufacturing facility is composed of five different sections, the age of which was unable to be determined by you or the roofing company. Events are created by your firm to document/investigate/determine the risk of an external water leak. Below is a summary of external roof leaks for the year 2023 categorized by hygiene area. **<u>Packing Room (b) (4 – Critical Hygiene Area</u>** On 09/24/2023, LN23019 was created for a water leak that occurred in packing room (b) (4, from the ceiling near the hatch door handle. There was a similar leak in this area according to your records previously on 05/04/2022. Lot (b) (4) was in production during this time. On 10/14/2023, (20 days later) LN23021 was created for a water leak that occurred in packing room (b) (4, from the ceiling at the corner of the light near the sack conveyor. No product was being manufactured at the time. **<u>Dryer Tower (b) (4) (b) (4) Hygiene Area</u>** On 03/28/2023, LN23004 was created for a water leak that occurred in Dryer Tower- Level (b) (and Level (b) (on a beam and wall opposite the side of the dryer. No product was being manufactured at

Inspection Observations	
	the time. On 04/01/2023, 04/15/2023, 04/30/2023 and 06/06/2023; LN23003, LN 23005, LN23007 and LN23008 respectively, were created for a water leak that occurred in Air Compressor ((b) (4)) and Fire Suppression ((b) (4)) rooms. No product was being manufactured at the time. On 06/25/2023, LN23010 was created for a water leak that occurred Air Compressor ((b) (4)) and Electrical rooms (Dryer Level (b) ( ). No product was being manufactured at the time. On 07/09/2023, LN23012 was created for a water leak that occurred in Air Compressor room. Lot (b) (4) was in production during this time. On 07/24/2023, 08/08/2023 and 09/07/2023; LN 23013, LN23015 and LN 23018 respectively were created for a water leak that occurred in Air Compressor room. No product was being manufactured at the time. On 07/25/2023, LN23014 was created for a water leak that occurred in Dryer Tower- (b) (4) at Exit Door (due to door seal being damaged). Lot (b) (4) was in production during this time. On 08/10/2023, LN23016 was created for a water leak that occurred in Dryer Tower-Level (b) ((exhaust fan) side down to Level (b) (. Leak was discovered at the end of production for Lot (b) (4) . On 08/13/2023, LN23017 was created for a water leak that occurred in Air Compressor and Fire Suppression rooms Lot (b) (4) was in production during this time. On 12/11/2023, LN23026 was created for a water leak that occurred in Dryer Tower-Level (b) (Dryer (b) (4) duct. No product was being manufactured at the time.
Citation Reference	21 CFR 106.20(a)
Supporting Evidence and Relevance	**(MMS)** See Exhibit #62 for LN 23019- Water leak Packing Room (b) (4 09/24/2023 See Exhibit #63 for LN 23021- Water leak Packing Room (b) (4 10/14/2023 See Exhibit #64 for LN 23004- Water leak Dryer Tower Level (b) (4) 03/28/2023 See Exhibit #65 for LN 23003- Water leak Dryer Tower; Air Compressor and Fire Suppression Rooms 04/01/2023 See Exhibit #66 for LN 23005- Water leak Dryer Tower; Air Compressor and Fire Suppression Rooms 04/15/2023 See Exhibit #67 for LN 23007- Water leak Dryer Tower; Air Compressor and Fire Suppression Rooms 04/30/2023 See Exhibit #68 for LN 23008- Water leak Dryer Tower; Air Compressor and Fire Suppression Rooms 06/06/2023 See Exhibit #69 for LN 23010- Water leak Dryer Tower; Air Compressor and Electrical Rooms 06/25/2023 See Exhibit #70 for LN 23012- Water leak Dryer Tower; Air Compressor Room 07/09/2023 See Exhibit #71 for LN 23013- Water leak Dryer Tower; Air Compressor Room 07/24/2023 See Exhibit #72 for LN 23015- Water leak Dryer Tower; Air Compressor Room 08/08/2023 See Exhibit #73 for LN 23018- Water leak Dryer Tower; Air Compressor Room 09/07/2023 See Exhibit #74 for LN 23014- Water leak Dryer Tower; (b) (4) at Exit Door 07/25/2023 See Exhibit #75 for LN 23016- Water leak Dryer Tower; Level (b) (4) exhaust fan 08/10/2023 See Exhibit #76 for LN 23017- Water leak Dryer Tower; Air Compressor and Fire Suppression Rooms 08/13/2023 See Exhibit #77 for LN 23026- Water leak Dryer Tower; Level (b) (Dryer (b) (4) duct 12/11/2023 See Exhibit #108 Infrared Inspection Report conducted 08/2023 See Exhibit #109 Copy of Picture of Roof

Inspection Observations	
	See Exhibit #110 2023 Work order for Dryer Tower, Air Compressor Room and Packing Room 2
Discussion With Management	During the close-out meeting, the firm stated that corrections will be implemented and that they will respond to the agency in writing within 15 business days.
Correction Status	No Firm Response Submitted
Observation	**3**
Citation Text	You did not exclude pests from your food plant to protect against contamination of food.
Observation Details	Specifically, on 12/11/2023, during the walk thru inspection of your facility, we observed at the Dryer Level (b) (4) several flies actively flying around the ceiling and a dead fly on the ledge. The Dryer is a (b) (4) Area. Furthermore, on our walk thru inspection of your facility, an investigator observed a fly land on the arm of your plant manager just outside the door leading to the (b) (4) for Packing room (b) (4). Packing room (b) (4) is a Critical Hygiene area. On 11/28/2023, (b) (4) (Pest Control Company) performed a comprehensive inspection of your manufacturing building located at 61 Vanguard Drive. The Drying tower was identified as "the hub of insect activity lately", entry points were noted (exterior and interior), and the area of the chemical storage cage. The 8 page report included pictures of areas with gaps on the Drying tower, chemical storage cage, tank farm, employee main door entrance, maintenance door entrance, batching room ceiling, etc. Reviewing your pest control records from 01/01/2023 thru 12/31/23, revealed your firm had varied miscellaneous flying pests activity during the (b) (4) quarters of 2023. Areas of concern noted are: ***Please note for the chart the following: ILT= Insect Light Trap, the number for each* (b) (4) *represents the total number of flying pests for all ILTs in that area.*

Area	ILT #s	(b) (4)		
Dryer- All Levels (b) (4))	7,8,9,10,14	399	1,760	608
(b) (4) Staging Area (b) (4)	1	1,090	675	60
Maintenance (Limited Access)	2,12,15,16	4,175	9,720	835

Citation Reference	21 CFR 117.35(c)
Supporting Evidence and	(MMS)

Inspection Observations	
Relevance	See Exhibit #87 (b) (4) Reports and Firm's Work Orders See Exhibit #88 (b) (4) ILT Information See Exhibit #89 (b) (4) Full Inspection Report of Facility 11 2023 See Exhibit #34 Copy of Photo of Kit Staging Area in Relationship to Maintenance Area See Exhibit #111 Photo of flies in dryer ceiling See Exhibit #112 Photo of dead fly on ledge
Discussion With Management	During the close-out meeting, the firm stated that corrections will be implemented and that they will respond to the agency in writing within 15 business days.
Correction Status	No Firm Response Submitted
Observation	**4**
Citation Text	You did not implement a system of production and in-process controls for an infant formula.
Observation Details	Specifically, the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces" is maintained, which provides specific instructions on required procedures that must be strictly followed when interventions into product contact zones are necessary. The SOP states that for interventions after the (b) (4) system, "a minimum of (b) (4) of (b) (4) must be discarded upon restarting". Interventions are documented on the form PROD-310.01-FM, "Verification of Product Contact Zone Intervention Procedures". Approximately, 24 interventions were performed from 6/24-9/29/23 and review of form PROD-310.01-FM indicated that on 7/11/23, 9/8/23 and 9/18/23, post-(b) (4) interventions were performed yet a minimum (b) (4) was not conducted as required by the firm's SOP. For the interventions on 7/11/23 and 8/5/23, the (b) (4) dryer (b) (4) were removed or changed, and no (b) (4) was performed; for the intervention on 9/8/23, the autosampler in Packaging Room (b) (4) was repaired and only a (b) (4) was performed and finally, for the intervention on 9/18/23, the (b) (4) on the (b) (4) dryer was jammed, and no (b) (4) was conducted. In addition, the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces" states that "Notify QA of an intervention, as QA will observe and document the intervention activities". On 6/26/23, an intervention was performed but a quality assurance technician was not present as required by the SOP.
Citation Reference	21 CFR 106.6(a)
Supporting Evidence and Relevance	**(EPM)** The SOP PROD-310-SOP states that for interventions after the (b) (4) system, "a minimum of (b) (4) must be discarded upon restarting" **(Exhibit #19)**. Approximately, 24 interventions were performed from 6/24-9/29/23, which were documented on the form PROD-310.01-FM; review of these records indicated that on 7/11/23, 8/5/23, 9/8/23 and 9/18/23, post-(b) (4) interventions were performed yet a minimum (b) (4) was not conducted as required by the firm's SOP **(Exhibit #114)**. For the intervention on 9/8/23, form PROD-310.01-FM identified that a (b) (4) was done but it was noted that the scale was not accurate; however, there was no indication on the form that corrective actions were implemented including recalibration of the scale. For the intervention on 9/18/23, the (b) (4) was jammed, and as identified on form PROD-310.01-FM, the operator did not deem that a (b) (4) was applicable after the repair yet on 9/19/23 and 9/28/23, the operator did conduct a (b) (4) after the (b) (4) jammed **(Exhibit #114)**. In addition, the SOP states that "Notify QA of an intervention, as QA will observe and document the intervention activities". On 6/26/23, an intervention was performed but as stated on form PROD-310.01-FM, a quality assurance technician was not present as required by the SOP **(Exhibit #114)**.

Inspection Observations	
Discussion With Management	During the close-out meeting, the firm stated that corrections will be implemented and that they will respond to the agency in writing within 15 business days.
Correction Status	No Firm Response Submitted
Observation	**5**
Citation Text	You did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration.
Observation Details	Specifically, the document, "(b) (4) CCP Check Form", effective date 11/13/23 is utilized to (b) (4) document critical parameters every (b) (4) for the (b) (4) system, which is the final "kill step" for the product. The minimum processing temperature is (b) (4) and the maximum flow rate is (b) (4); operating parameters are (b) (4) or higher at (b) (4). To ensure that the minimum temperature is achieved, there is a temperature indicating device (TID) and a temperature recording device (TRD) at the hold tube outlet. The (b) (4) CCP Check Form states, "Notify your Supervisor immediately if the chart recorder is reading higher than the indicating thermometer or if it has a greater than (b) (4) difference". During this inspection, batch records were reviewed for ByHeart milk-based powdered infant formula with iron. For Lot (b) (4) (production date (b) (4)), review of (b) (4) CCP Check Form identified 13 instances of the TRD reading higher than the TID and 24 instances that the two devices read more than (b) (4) apart. For Lot (b) (4) (production date (b) (4)), review of (b) (4) CCP Check Form identified 12 instances of the TRD reading higher than the TID and 30 instances that the two devices read more than (b) (4) apart. The operator did not notify their supervisor nor was this issue identified during record review by management. Both lots were released. In addition, the temperature of the TRD is obtained from the HMI screen and not from the TRD unit itself, which does provide a digital readout. The TRD is located on the same control panel as the TID.
Citation Reference	21 CFR 106.30(e)(5)
Supporting Evidence and Relevance	**(EPM)** The (b) (4) CCP Check Form states, "Notify your Supervisor immediately if the chart recorder is reading higher than the indicating thermometer or if it has a greater than (b) (4) difference". During this inspection, review of the (b) (4) CCP Check Form for Lots (b) (4) and (b) (4) identified the following: for Lot (b) (4), there were 13 instances of the TRD reading higher than the TID and 24 instances that the two devices read more than (b) (4) apart; for Lot (b) (4), there were 12 instances of the TRD reading higher than the TID and 30 instances that the two devices read more than (b) (4) apart **(Exhibits #7 and #8, respectively)**. The operator did not follow the instructions identified on the form nor did management identify this issue during record review and both lots were released. For the (b) (4) system, a TID and a TRD are required at the hold tube outlet; this ensures that the process temperature is achieved per the Master Batch Record and provides a "check and balance" system. The TID is the "official" thermometer and is not adjusted between calibrations and the TRD provides a continuous record of temperature and controls the flow diversion valve. The TID is compared to the TRD to ensure that the TRD does not read higher than the TID and that the readings are within a few degrees of each other. If so, adjustments to the TRD are made as it is not the "official" thermometer. In addition, the operator obtained the TRD readings from the HMI screen in the Control Room rather than from the TRD itself, which has a digital display for temperature. The TID and TRD are located adjacent to one another on the same control panel and therefore, readings should be obtained simultaneously to ensure the most accurate information. Currently, it takes the operator (b) (4) to walk the (b) (4) from the Control Room to the control panel where the TRD and

Inspection Observations	
	TID are located **(Exhibit #28)**. During this inspection, the updated (b) (4) CCP Check Form, effective date 1/10/24 was provided **(Exhibit #115)**.
Discussion With Management	During the close-out meeting, the firm stated that corrections will be implemented and that they will respond to the agency in writing within 15 business days.
Correction Status	No Firm Response Submitted
Observation	**6**
Citation Text	You did not minimize the potential for contamination of raw materials through the use of appropriate measures.
Observation Details	Specifically, in Building 61, in the (b) (4) Room referred to as (b) (4) minor ingredients including vitamin and mineral premixes are weighed into smaller containers; partial containers of major ingredients are also weighed. During the weighing process, ingredients are exposed to the environment. The (b) (4) room is a (b) (4) area and is adjacent to the warehouse, which is a (b) (4) area; the (b) (4) room doors open directly into the warehouse. In the (b) (4) room, the air pressure is not monitored to ensure that it is under positive pressure to prevent the introduction of potential air contaminants from the warehouse; the air pressure in the warehouse is also not monitored. In addition, ambient air sampling is performed in production areas including the (b) (4) room; records were reviewed from January 2022-December 2023. In the (b) (4) room, mold was identified in air samples on two occasions, 8/6/22 and 1/20/23. The root cause investigations determined the most likely source as the room's air vents.
Citation Reference	21 CFR 106.20(d)
Supporting Evidence and Relevance	**(EPM)** **On the FDA 483, the date was incorrectly noted as 8/6/22 instead of 8/6/23 for the mold event in the (b) (4) Room**. In the (b) (4) Room, minor ingredients including vitamin and mineral premixes are weighed into smaller containers; partial containers of major ingredients are also weighed. As expected in a (b) (4) (b) (4) area, the room must be maintained under positive pressure to ensure that ingredients are not potentially contaminated during the weighing process. Ambient air sampling is performed in production areas including the (b) (4) Room; an example of the testing log dated 6/20/23-9/27/23 was provided **(Exhibit #116)**. In the (b) (4) Room, there were two events on 8/6/23 and 1/20/23 where mold was identified. On 8/1/23, an air sample was collected the (b) (4) Room as part of the firm's (b) (4) air monitoring; the sample was collected from the top surface of the yellow chemical storage cabinet. On 8/6/23, the results indicated that the mold level was 20 colony forming units (CFU); the firm's limit is (b) (4) **(Exhibit #117)**. A second sample was collected on 8/6/23; the results dated 8/11/23 identified 8 CFU. Prior to this event, the last out of specification result for mold in the (b) (4) Room was on 1/20/23; form QUAL-510.01-FM, "Environmental Positive Investigation Form" was not opened in response as there was only one OOS result and not two, which warrants an investigation. The root cause investigations for both events determined the most likely source as the room's air vents **(Exhibit #117- page 2)**. At the time of these events, the air vents were not on the routine cleaning schedule; a corrective action included adding the air vents to the master sanitation schedule for (b) (4) cleaning. During this inspection, management stated that magnehelic gauges were ordered to monitor the air pressure in the (b) (4) room **(Exhibit #118)**.
Discussion With Management	During the close-out meeting, the firm stated that corrections will be implemented and that they

Inspection Observations	
	will respond to the agency in writing within 15 business days.
Correction Status	No Firm Response Submitted

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	You did not prepare a written master manufacturing order that establishes controls and procedures for the production of an infant formula.
Observation Details	Specifically, on May 15, 2023, you have adjusted your usage rate for the (b) (4) from (b) (4) due to Vitamin D verification results being high as mentioned in your Temporary Change Notification Report, TCN23-0007. Your TCN23-0010 rev.2 (dated 7/28/2023) documented maintaining the usage rate at (b) (4) Blend Batch Record /Dispensing Sheets. For any revisions of these batch records, your Senior Technical Data Analyst captures document revisions, and provide Blendhouse with the updated and approved (signed/dated) batch records. During the review of the Master Fat Blend Batch Record /Dispensing Sheets for lot (b) (4) and for lot (b) (4) indicated that you have adjusted usage rate (b) (4) on the batch record for your (b) (4) batches but did not adjust the changes on the batch record for your (b) (4) batches. The batch record for the (b) (4) batches has a last modification/approval date of 5/4/2023, which is prior to the change implementation date, which is 5/15/2023.
Citation Reference	21 CFR 106.50(a)
Supporting Evidence and Relevance	**(KP)** It is Important to have a system in place to ensure any changes to batch records are implemented across all batch records (that captures all different batch amounts). • Refer to **Exhibit #119, pages 1-3**, for the Temporary Change Notification Report-TCN23-0007 (dated 5/12/2023) completed by the firm due to higher purity of Vitamin D in the premix lot (b) (4) with an expiration date of 7/7/2023. This change was to be in place until the lot is exhausted. This report documented the changes made to usage rate of the premix (refer to **page 1**), adjusted from (b) (4) . For a (b) (4) . For an updated master fat blend batch record (used with lot premix lot (b) (4)) by the firm during the manufacturing of master fat blend lot (b) (4) refer to **Exhibit #119, pages 11-12**. **Page 11** contains (b) (6), (b) (7)(C) signature for when the records were last updated/approved by him for use by BlendHouse during manufacturing. The signature indicated it was signed on 5/16/2023. • Refer to **Exhibit #119, page 10**, for a copy of the document revision history provided by the firm to show the changes made to the master fat blend batch record and dispensal sheet. This documents per TCN23-0007, usage rate was adjusted in the batch record and the dispensal sheet on 5/16/2023. Document revision history does not indicate any changes made to batch records or dispensing sheets that are allocated for less than 10 batches.

Observations Not Listed on FDA Form 483	
	• TCN23-0010 (dated 7/7/2023) was created to document the testing of premix lot 9400045232 for a shelf life extension (refer to **Exhibit #119, pages 4-6**). Since the test results showed no degradation, the firm continued to use the premix lot (b) (4) until 7/31/2023, and to maintain the usage rate at (b) (4). The report documented the base powder test results for the vitamins in the premix were within the firm's specifications. • The premix lot (b) (4) was retested for a shelf life extension. Because the test results showed no degradation, the firm continued to use the premix lot (b) (4) until 8/31/2023, and to maintain the usage rate at (b) (4). For more information refer **Exhibit #119**, **pages 7-9,** for a copy of the TCN23-0010 rev.2 (dated 7/28/2023). • Master fat blend batch record/dispensal sheets for (b) (4)-batches for master fat blend lot (b) (4) showed the firm continued to use the batch record/dispensal sheets updated on 5/16/2023, refer to **Exhibit #119, pages 13-15**. The production date for the master fat blend lot (b) (4) is documented as 9/16/2023. This indicated that firm maintained the premix usage rate of (b) (4) even after exhausting the premix lot (b) (4). The (b) (4) vitamin premix with the adjusted usage rate of (b) (4) requires (b) (4). This amounts includes/accounts for the additional (b) (4). On 12/20/2023, Ms. Dickenson stated the premix recipe includes (b) (4) to account for any loss during manufacturing. • Master fat blend batch record/dispensal sheets for (b) (4) batches for master fat blend lot (b) (4) showed the firm has not adjusted the usage rate, refer to **Exhibit #119, pages 16-18**. The production date for the master fat blend lot (b) (4) is documented as 9/29/2023. The required amount of (b) (4) is calculated with (b) (4). (b) (6), (b) (7)(C) signature indicated (**page 16**), the record was last approved for use on 5/4/2023.
Discussion With Management	Firm did not have any additional comments or discussions related to the observation during the close-out meeting. They promised to make correction in a timely manner.
Correction Status	No Firm Response Submitted
Observation	**2**
Citation Text	You did not establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order was examined by one person and checked by a second person or system.
Observation Details	Specifically, review of your master batch record for aggregate (b) (4) showed that for (b) (4), the record only indicated the amount needed to be added per recipe. The master batch record does not show how much is actually added.

Observations Not Listed on FDA Form 483	
Citation Reference	21 CFR 106.50(b)
Supporting Evidence and Relevance	**(KP)** • Refer to the **Exhibit #120, pages 1-5**, for the firm's most up-to-date master batch record that was last approved for use by (b) (6), (b) (7)(C) on 12/14/2023. **Page 2** shows the calculated weight of GOS required per recipe ((b) (4)); however, no space to include the actual weight. • Refer to **Exhibit #120, pages 6-13** for the batch record and dispensing sheets for aggregate (b) (4) . This version of the batch record was approved for use by (b) (6), on 5/11/2023. Again, this record indicated the calculated weight for GOS with employees signing off on weight verifications and whether or not ingredient was added to the batch; however, actual weight is not recorded. • Firm said the employees uses (b) (4) for weighing GOS (refer to **Exhibit #120, page 14**, for a photo provided by the firm of the pails used). Each of these pails may have a weight variation; so, it is important to properly weigh ingredients using these pails to ensure the master recipe is followed without deviations. This is to ensure all label claims are met and the consistency, the quality, and the safety of the product is met each time the product is made. • Firm said the batch operators are trained upon hiring to tare the scale and their competency is assessed at new hire and at annual assessment (refer to **Exhibit #120, pages 15-18**, for a copy of the master record titled, "Batching Operator New Hire & Annual Assessment". Page 16 under "Week 2 Plan", it stated (b) (4) ". Additionally, firm also maintains a record for such assessment, refer to **Exhibit #120, pages 20-24**.
Discussion With Management	At the close-out meeting, firm could not provide a reason as to why the actual weight of GOS is not recorded. Ms. Heather MacNaughton agreed the actual weight of GOS should be captured on the batch record. Firm promised to make corrections in a timely manner.
Correction Status	No Firm Response Submitted
Observation	**3**
Citation Text	You did not conduct and document your hazard analysis.
Observation Details	Specifically, your firm manufactures one Infant Formula powder base for your finished product, ByHeart Whole Nutrition Infant Formula. Your SOP, "Supplier, Ingredient and Material Approval" Document Control No. QUAL-507.04-WI (effective date 4/10/2023) stated the "Quality shall conduct a documented hazard analysis of incoming materials before use in manufacturing". However, review of your Food Safety Plan, "BlendHouse Infant Formula Powder Food Safety Plan" (effective date 10/2/2023) indicated that you did not conduct and document a hazard analysis for the ingredients used in your Infant Formula powder base. Additionally, your Infant Formula powder base contains ingredients such as (b) (4) which contains (b) (4) that are associated with the hazard mycotoxins/natural toxins. Your Food Safety Plan did not identify mycotoxins/natural toxins as food safety hazards and did not mention controls implemented for controlling mycotoxins/natural toxins in ingredients such as your (b) (4) . Moreover, your ingredient specifications included under your "Raw Material Testing" (effective date 6/8/2021) does not include mycotoxins under (b) (4) . Furthermore, review of your receiving records for the raw ingredients included in your aggregate (b) (4) indicated, you have added (b) (4) into manufacturing your aggregate (b) (4) . The certificates of analysis (CoA) for the abovementioned vendor lots were reviewed, and none indicated testing for mycotoxins. During the inspection, you provided your "Purchased Material Specification" for (b) (4)

Observations Not Listed on FDA Form 483	
	(b) (4) , which is signed by your vendor and your firm in March of 2022. Which said "(b) (4) . You also provided a document from your vendor dated to 12/18/2023 indicating most recent mycotoxins monitoring results for the oils used in (b) (4) . However, you did not provide documentation to show that you are verifying that your vendor is conducting such testing on (b) (4) basis.
Citation Reference	21 CFR 117.130(a)(1)
Supporting Evidence and Relevance	**(KP)** • At the close-out meeting, the following regulations were shared with the firm, 21 CFR 117.130 (a) (2) (iii), a written hazard analysis is required. Per 21 CFR 117.130 (c) (2), for the hazard evaluation, the firm must consider the effect of raw material and other ingredients, on the safety of the finished food for the intended consumer. Per 21 CFR 117.415 (a) (2)- the firm needs to document supplier verification activities and Per 21 CFR 117.475 (c) (9), firm must document review of the supplier's relevant food safety records. • Refer to **Exhibit #80** for SOP, "Supplier, Ingredient and Material Approval" Document Control No. QUAL-507.04-WI (effective date 4/10/2023). Refer to **page 4** under "Procedure-Ingredient Hazard Analysis", letter C, to locate where the firm stated that they will conduct a documented hazard analysis. • Refer to **Exhibit #78** for a copy of the firm's Food Safety Plan (FSP), "Blendhouse Infant Formula Powder Food Safety plan". See **page 12** of FSP for hazards identified at the firm's "INGREDIENTS AND PACKAGING, RECEIVING AND STORAGE" step. Ingredient receiving step does not capture whether the firm has identified mycotoxins as a potential hazard. On **pages 24 and 39** of FSP for hazards identified at processing step, (b) (4) . This step has been identified as CCP 1 for controlling pathogens, not mycotoxins/natural toxins. This shows the firm does not have controls in place to address mycotoxins/natural toxins at their facility. As such, requires supply chain controls. At an earlier conversation during the inspection pertaining to supply chain, Ms. Heather MacNaughton, Sr. Director of Regulatory Audit Compliance said the firm does not rely on their supplier to control for hazards pertaining to any of their ingredients because the firm test all ingredients. At the close-out meeting, firm was reminded that sampling is a verification activity that can be conducted under supply chain program. Also emphasized, whatever hazards that the firm is verifying that their supplier is controlling are part of the supply chain program. Investigator Pathiraja also emphasized, if the HA identifies a hazard that requires a preventive control and the firm will rely on the supplier to control the hazard, then the firm must have and implement a written supply chain program. Also shared that verification activities are done to ensure the controls implemented are effective in minimizing hazards. • Refer to **Exhibit #121** for a copy of the "Purchased Material Specification" signed by the firm and their supplier of (b) (4) , located at (b) (4) . This document includes information related to the ingredient composition, refer to **page 1** under "Material Composition". Fat blend consists of (b) (4) . Additionally, this signed document, on **page 4**, documented that the firm will test for "(b) (4) as a quality indicator. • Refer to **Exhibit #122** for a copy of the "Raw Material testing" specifications provided by the firm. Firm stated this document indicate the specifications for raw ingredients. Ms. Alicia Dickenson, Release Service Associate Manager stated, at receiving, these listed specifications need to be met for ingredient to be approved to be released for use in production. Ms. Dickenson mentioned the "Raw Material testing" specification provided were outdated, as such she provided the most current ingredient specification document, refer to **Exhibit #123**, for the "ByHeart Ingredient Confirmation Testing Specification" with an effective date of 11/27/2023. This document also does not mention mycotoxins

Observations Not Listed on FDA Form 483	
	under (b) (4) (refer to **page 2**) as well. • Ms. MacNaughton provided the firm's new "(b) (4) Product Material Specification" with an effective date of 12/8/2023. She explained this form has not been completed, need to be reviewed and signed by the supplier and the firm (Refer to **Exhibit #124**). On **page 4** (under section 5.2 Contaminants and Residue) she said the firm mentioned mycotoxins as a potential hazard; however, it does not indicate who is responsible for controlling mycotoxins, identify verification activities, nor their frequencies. • Ms. Dickenson said two (b) (4) were added into manufacturing the aggregate (b) (4). For copies of the receiving documents and the approval for release of these lots, refer to **Exhibit #125**, receiving documents-(b) (4). Ms. Dickenson stated, she reviews the vendor COAs (refer to **pages 3-4** for lot 173461 and **pages 9-10** for lot 173296) and COAs (refer to pages 13-15 for lot 173296 and pages 16-18 for lot 173461) for tests perform by (b) (4) lab for ingredient specifications mentioned on their "Raw Material testing" and "ByHeart Ingredient Confirmation Testing Specification". These COAs do not indicate the firm test for mycotoxins. • When asked about how the firm address the chemical hazard mycotoxins associated with their fat blend, Ms. MacNaughton provided a letterhead dated to 12/18/2023 from their vendor, (b) (4), documenting how often mycotoxins are tested at the vendor and the test results for the most recent oils used in a fat blend. This document does not show these results were reviewed by the firm and that review was documented. For a copy refer to **Exhibit #126**, (b) (4) Mycotoxin Monitoring Results. Firm has not given any other documents to show that they conduct these verification activities on (b) (4) basis. • On 1/12/2023, firm provided Investigator Schafer, a letter from their Supplier, (b) (4), for their justification as to why they do (b) (4) Mycotoxin testing, refer to **Exhibit #127** ((b) (4) justification) for a copy.
Discussion With Management	Key Facts about Preventive Controls for Human Food was shared along with the FDA weblink to finding more information pertaining to food safety plan, hazard analysis, and supply chain. This information along with other information was provided electronically to the firm, see report section "Guidance Documents Given to the Firm" for further information. Additionally, Ms. MacNaughton stated, Ms. Dickenson is responsible for conducting supplier verification activities at BlendHouse. Activities such as review of COAs for COAs received per each lot or other activities set periodically (i.e., review mycotoxins result from vendor on annual basis). Also, she informed us the firm will finalize all their raw material specifications into their new format "Product Material Specification" by the end of the first quarter of the current fiscal year. I, Investigator Pathiraja, reminded the firm that in this "Product Material Specification", specifically under "contaminates and residue" section, the firm needs to indicate who is implementing the controls for a hazard (firm or supplier), type of verification, frequency of these verification activities, and acceptable limits/specifications. During the close-out meeting, firm did not have additional comments or discussions related to the observation. However, on 12/15/2023, as a result of the supply chain discussions, firm stated they are in the process of completing an ingredient risk assessment/hazard analysis.
Correction Status	No Firm Response Submitted

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

(KP, EPM, MMS)

1. 21 CFR 106.20 (d) You did not minimize the potential for contamination of in-process materials through the use of appropriate measures.

On 6/6/2023, during your routine (b) (4) water testing at batch tank (b) (4), the water sample tested positive for (b) (4). You stated in your "Environmental Positive Investigation Form" report number, EMP23004, batching operator collected the water sample at the (b) (4), but not at the (b) (4). The report stated a retest sample was collected from the (b) (4) following standard procedures and the results was negative for (b) (4). However, you did not retest the water collected from the (b) (4) in batch tank (b) (4) after performing CIP on 6/7/2023 to ensure that there is no potential contamination of the water/ingredient from the batch tank.

Refer to **Exhibit #128 (pages 1-5)** for a copy of the "Environmental Positive Investigation Form" EMP report number EMP23004 to learn more about the positive coliform water sample collected from batch tank (b) (4). The report indicated no production (b) (4) (refer to **page 2**). Firm also stated they did (b) (4) swabbing of the batch tank (b) (4), including the sample port, after cleaning and sanitizing (CIP) prior to the production of the next product lot (refer to **page 6**). No deviations were noted for (b) (4) results.

At the close-out meeting, firm was reminded it is a good practice to resample the water from the (b) (4) just to ensure cleaning and sanitation was effective in eliminating the source of coliform.

2. You did not review your annual (b) (4) Analytical Report (Job ID:810-48143-1) for 2022 annual (b) (4) water testing to ensure the water meets the EPA's Primary Drinking Water Regulations for chemical, radiological and bacteriological contaminants.

Additionally, for (b) (4), you said you do an (b) (4) service of the system. Last report in 9/23/2022 recommended replacing (b) (4); however, according to your Maintenance Supervisor, weekly inspections of the (b) (4) system were started in April 2023, these inspections are not documented. For the (b) (4), operational parameters including differential pressures, conductivity and flow rate are visually confirmed weekly via the HMI but are not manually recorded.

During the inspection, Investigator Pathiraja requested to review the 2022 annual water quality report from (b) (4), no discrepancies were noted. For the annual (b) (4) for 2022 (b) (4) water testing, for any result that were listed out of specification to reporting limits/requested limits were compared to EPA's limits for contaminants; all were within EPA's specifications. During the close-out meeting, I, Investigator Pathiraja reminded the firm to review and then document the review of the water testing.

For annual customer service reports (refer to **Exhibit #131, page 1** for "Engineer's Remarks"), I also reminded the firm that it is a good practice to follow-up on any recommendations from the service engineer (for instance, replacing (b) (4)) and if warranted, implement corrections, and sign off on those items as completed. Moreover, I added, it is a good practice to document (b) (4) inspections conducted by the firm and those findings.

For the (b) (4), operational parameters including differential pressures, conductivity and flow rate are visually confirmed (b) (4) via the HMI but are not manually recorded. It was discussed with management that these parameters be documented to ensure that (b) (4) checks are performed and also, as a permanent record if there is a future issue with the system.

Additionally, Investigator Pathiraja, discussed the following two other items with the firm during the inspection as well as the close-out meeting:

During the review of the "Portable Water Microbial Monitoring Results" from 7/12/2023-7/13/2023 (refer to **Exhibit #132**) for the (b) (4) water testing, the record did not include sampling site HPP 1500 (this site is part of the scheduled sites). Ms. Michele Otte, Quality Operations Manager said currently, there is no record to capture information related to sites that are scheduled to be tested but not tested. As such, firm was encouraged to include space on the record to capture that information.

Firm was reminded to update SOP, document number QUAL-508-SOP ("Water Analysis Program", refer to **Exhibit #59**) to include E. coli under "Analysis Required" for (b) (4) testing and to Indicate the microbiological specifications for E. coli.

Firm promised to make corrections in a timely manner.

3. The SOP PROD-304-SOP, "DI1500 Infant Formula Operation" is maintained, which provides instructions for the (b) (4) step of the (b) (4) dryer (**Exhibit #42**). The SOP does not identify all operational parameters, which must be achieved to initiate the (b) (4) process nor conditions that require re-initiation of the (b) (4) process. These parameters and conditions are defined in the firm's validation study, "(b) (4) Dryer System (b) (4) Validation Report" dated 4/28/23.

   During this inspection, the SOP was updated with an effective date of 12/18/23 to include these parameters (**Exhibit #43**). However, review of the updated document noted that not all conditions, which result in the re-initiation of the (b) (4) were included. In addition, the validation study states that an additional (b) (4) will be added to the (b) (4) if there are signs of moisture in the system after the (b) (4) is completed; this instruction was not included in the updated SOP.

4. (b) (4) are used to verify production scales and are calibrated (b) (4); however, the previous calibrations were performed in August 2021 and April 2022. In addition, the production record, QUAL-511.07.03, "Scale Accuracy Verification Record- (b) (4)" is maintained and this record requires the operator to identify the (b) (4) used and their calibration due date yet review of these records indicated no notation that the (b) (4) were overdue for calibration. **Exhibit #129**

   During this inspection, Ms. MacNaughton stated that there was a miscommunication between operations and quality personnel regarding who oversaw the calibration of the check weights. The (b) (4) were sent out for calibration and new ones were also purchased. In addition, the form, "Scale Accuracy Verification Record- (b) (4)" was updated with an effective date of 12/17/23 and it now states, "Report Out of Calibration (b) (4) immediately to the Maintenance Manager or Maintenance Supervisor AND Quality Operations Manager." (**Exhibit #130**). The calibration of the (b) (4) is now identified as an (b) (4) preventive maintenance task in (b) (4).

5. For finished product testing of the base powder, a (b) (4). As such, the implementation of a higher stringency sampling plan for (b) (4) as compared to (b) (4) should include historical data such as finished product testing and environmental sampling results to support this determination.

6. In response to an environmental positive sample, vector swabbing is performed. At a minimum, (b) (4) vector swabs are obtained over a (b) (4) with approximately, (b) (4) locations (b) (4). However, the same (b) (4) locations are swabbed over the (b) (4).

Also, swabs are taken (b) (4), which does not allow you to determine the extent of how far a pathogen could have spread.

Mold samples are not taken as part of your environmental program when there is a water leak. Positive mold samples are also not further speciated.

The firm acknowledged using the same vector locations and cleaning before taking the initial swab does not allow them to accurately determine the extent of the spread of a pathogen. The firm also acknowledged the benefit of adding mold testing as part of the environmental program when there is a water leak. The firm stated these would all be taken under advisement and updates would be made as necessary.

7. The humidity in your Packing Room (b) (4) is not documented, currently it is monitored and will alarm when it reached (b) (4) relative humidity.

The firm is currently working on a written procedure to document the humidity monitoring and the process when the humidity exceeds the set upper limit.

8. During the review of batch records, it was noted that for some batches during ingredient addition, there were extreme weight fluctuations as also identified on the HMI screen. The fluctuations were too inconsistent to determine the exact cause.

The firm became aware of the fluctuations during our record review and even provided a video to show the fluctuation. The firm is working with the company that installed the equipment to replace wiring and shield all wiring in the batching room to help reduce electrical "noise" which is what the firm believes to be causing the weight fluctuations. **Exhibit #55**

9. Review of production records revealed employees not fully understanding their job responsibilities. It was noted on these records that information on required forms was incomplete, procedures were not followed, equipment was not assembled correctly, etc.

For example, review of records showed incorrect assembly of the (b) (4) not placed on housing correctly, etc. An employee left a tool left on (b) (4) and another employee broke the sight glass on Packing Line (b) (4). Quality/Post production review of records did not note discrepancies of Master Batch Records; such as weights off after (b) (4), calculations wrong at step #11 for (b) (4), etc.

The firm is looking into further evaluation of their current training program to possibly include train the trainer sessions, further specialize in house training and outside training options.

ADDITIONAL INFORMATION

Note: On the FDA 483, the date was incorrectly noted as 8/6/23 instead of 08/06/23 for the mold event in the (b) (4) Room.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Finished Can Labeling	1
2	BlendHouse Organizational Chart	4
3	Corporate Organizational Chart- ByHeart	1
4	Manufacturing Hygiene Zone Map	1
5	Fall 2023 Projects	1
6	Process Flow Diagram	1
7	Lot 179 (b) (4) CCP Check Form	3
8	Lot 192 (b) (4) CCP Check Form	4
9	IEH Validation Study Thermal Treatment using (b) (4) 22FEB2021	2
10	Dryer Inspection Summary Memo Dec 2023	1
11	Main Chamber Dryer Inspection Dec 2023	59
12	(b) (4) Dryer Inspection Dec 2023	7
13	(b) (4) Dryer Inspection Dec 2023	16
14	(b) (4) Dryer Inspection Dec 2023	9
15	Main Chamber Dryer Inspection Feb 2023	19
16	(b) (4) Dryer Inspection Feb 2023	3
17	(b) (4) Dryer Inspection Feb 2023	4
18	(b) (4) Dryer Inspection Feb 2023	6
19	PROD 310 SOP EFF28MAR2023 Interventions into Product Contact Zones	6
20	(b) (4) Transportation Requirements	1
21	(b) (4) Letter Regarding Transportation Requirements	1
22	QUAL 2521.21 PMS Infant Formula Base Powder Release Specs	3
23	(b) (4) Packing Room 2	1
24	QUAL 517.06.02 ByHeart Customer Guideline	4
25	DEV 28.03 FM Review of Stability Data Bulk	14
26	2023 Released Lots	1
27	2023 Production Status as of Jan 12 2024	8
28	Map and Time for Temperature Recordings HMI	1
29	(b) (4) Master Batch Record Batchs 1 thru 10	50
30	(b) (4) Master Batch Record Batches 3 and 9	10
31	(b) (4) Master Batch Record All Batches	20
32	(b) (4) Dispensal Sheet all batches	20
33	(b) (4) Dispensal Records	37
34	Firm Photo of Kit Staging Area in Relation to Maintenance Area	2
35	QUAL 504 SOP Audit Program	13
36	Qual 504.19 FM GMP Room Check	2
37	QUAL 504.02 FM (b) (4) plant Inspection	35
38	QUAL 504.20 FM Internal Audit Checklist Summary	3
39	CIP Cycles (b) (4) 2023 thru (b) (4) 2023	1
40	SAN 803 SOP Dryer Lines (b) (4) and Dryer (b) (4)	20
41	(b) (4) Dryer System (b) (4) Validation Report 04 23 2023	96
42	PROD 304 SOP D1500 Infant Formula Operation 03JUL2023	8

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
43	PROD 304 SOP D1500 Infant Formula Operation 18DEC2023	8
44	SAN 800 SOP Master Sanitation Procedure	6
45	Comparison of (b) (4)	2
46	Sanitation Chemicals Approved	2
47	SAN 802 SOP (b) (4) and (b) (4) CIP EFF 02MAY2023	18
48	SAN 805 SOP Sanitation Standard Operating Procedure (b) (4) System Batch Room CIP EFF 02May2023	38
49	QUAL 510 SOP Environmental Monitoring Program 8 pgs EFF 13NOV2023	8
50	QUAL 510.07 WI Environmental Surface Sampling EFF 09MAR2023	10
51	Master Swab Location List During Production Months JUN thru SEP 2023	5
52	Master Swab Location List Effective 15DEC2023	5
53	QUAL 510.06 WI Environmental Positive Response Action Plan EFF 14APR2023	7
54	QUAL 510.03 WI Use of (b) (4) for Hygiene Monitoring	7
55	CD Video of (b) (4) Weight Fluctations provided by firm	1
56	EMP23011 08SEP2023 (b) (4) top of step (b) (4)	78
57	EMP23012 08SEP2023 (b) (4) Floor airlock room packing line (b) (	50
58	EMP 23013 (b) (4) 11SEP2023 Blue floor scale	61
59	QUAL508 SOP Water Analysis Program EFF28JUL2023	8
60	QUAL510.12 WI Ambient Air Monitoring EFF19APR2023	7
61	MAIN 414 SOP Facility Water Leak Control and Cleaning	10
62	LN23019 24SEP2023 Packaging Room 2 Ceiling Hatch Door	72
63	LN23021 14OCT2023 Packaging Room 2 Corner of Light Above Sack Conveyor	64
64	LN23004 28MAR2023 Dryer Tower Level (b) (4)	42
65	LN23003 01APR2023 Air Compressor Fire Compressor Rooms	72
66	LN23005 15APR2023 Dryer Tower (b) (4) and Fire Suppression Room	44
67	LN23007 30APR2023 Air Compressor and Fire Suppression Rooms	72
68	LN23008 06JUN2023 Air Compressor and Fire Suppression Rooms	130
69	LN23010 25JUN2023 Air Compressor and Electrical Room	74
70	LN23012 09JUL2023 Air Compressor Room	125
71	Exhibit 71 LN23013 24JUL2023 Air Compressor Room 53 pgs.pdf	53
72	LN23015 08AUG2023 Air Compressor Room	64
73	LN23018 07SEP2023 Air Compressor Room Fluid next to Bed Level of Dryer	116
74	LN23014 25JUL2023 Dryer Tower Exit Door (b) (4)	53
75	LN23016 10AUG2023 Dryer Tower Level (b) (4) Side to Level (b) (Scrubber	57
76	LN23017 12AUG2023 Air Compressor and Fire Suppression Rooms	74

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
77	LN23026 11DEC2023 Dryer Tower Level (b)	30
78	BlendHouse Food Safety Plan	48
79	QUAL 507 SOP Supply Chain Management EFF24MAR2023	6
80	QUAL 507.04 WI Supplier Ingredient and Material Approval EFF10APR2023	8
81	QUAL 2505 SOP Supplier Quality Management EFF27APR2023	6
82	Supply Chain Approved Suppliers	2
83	QUAL 517 SOP Review and Release of Materials and Products EFF17SEP2023	6
84	QUAL 518 SOP Change Control Procedure EFF10APR2023	9
85	QUAL 518.06 WI Temporary Change Notification Procedure EFF30OCT2023	5
86	MAIN 402.04 FM Mechanical Electronic Equipment Used	5
87	(b) (4) Map Reports and Firm Work Orders	50
88	Pest Control Report (b) (4) Building	8
89	(b) (4) Full Inspection of BlendHouse 11 2023	11
90	Complaints.Report-2023	4
91	QUAL 514 SOP Complaint Management Program EFF16AUG2023	6
92	QUAL 2503 POL Complaint Management Policy EFF22NOV2022	13
93	2023 Recalled Inventory at (b) (4) Locations in (b) (4)	4
94	EMP23010	10
95	CIP cleaner (b) (4)	12
96	(b) (4) Schematics	1
97	Lab Report-(b) (4) Swabs	1
98	QUAL 510.11 WI Yeast and Mold Count (b) (4) EFF 09APR2023	7
99	Potable Water Results 27JUN2023 thru 28Sep2023	19
100	Lab Report -Post Initial Clean Swabs	1
101	(b) (4) Product Testing mold	6
102	(b) (4) (b) (4) processing Schematics	1
103	(b) (4) System Graphs	3
104	(b) (4) Sanitizer	17
105	Batch Room Maps	2
106	Event 2240 26APR2022 Yeast and Mold Air OOS	6
107	EMP23002 13MAR2023 Mold on Water Pipe in Batch Room	7
108	Infrared Roof Inspection Report AUG 2023	18
109	Roof Pictures Sections Identified	2
110	All 2023 WO for Dryer Tower_Air Compressor Room_Packing Room 2	36
111	Blendhouse Flys FY24 Dryer Ceiling	1
112	Photo of Dead Fly Dryer Ledge	1
113	Other Mold Events	36
114	Interventions 06 24 2023 09 29 2023	48
115	(b) (4) CCP Check Form EFF 10JAN2024	2
116	Ambient Air Sampling 06 20 2023 09 27 2023	9

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
117	EMP23009	7
118	WO 000673 (b) (4) Air Pressure Gauges	1
119	(b) (4)	18
120	Batch Records LOT (b) (4)	24
121	Purchased Material Specifications	5
122	Raw Material Testing	2
123	ByHeart Ing Confirmation Testing Specs	6
124	(b) (4) -Product Material Specification	7
125	Receiving documents-(b) (4)	16
126	(b) (4) Mycotoxins Monitoring Results	2
127	(b) (4) justification	1
128	(b) (6), (b) (7)(C) 06JUN2023 (b) (4)	6
129	Scale Accuracy Verification	1
130	Revised Scale Accuarcy Verification	1
131	(b) (4) Customer Service Report	2
132	(b) (4) Water Results 27JUN2023 thru 28Sep2023	2

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FORM FDA 482 Notice of Inspection	6
2	FORM FDA 482 Notice of Inspection	6
3	Issued 483	6
4	ByHeart Attachment B	2

SIGNATURE

Melissa M Schafer
Investigator
Signed By: Melissa M. Schafer -S
Date Signed: 02-17-2024 15:26:08

Kawshalya Pathiraja
Investigator
Signed By: Kawshalya Pathiraja -S
Date Signed: 02-17-2024 13:07:05

Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer -S
Date Signed: 02-17-2024 20:41:40

Alan D Centi
Investigator
Signed By: 2001860402
Date Signed: 02-18-2024 09:52:06

Kyle D Covill
Investigator
Signed By: 2001656079
Date Signed: 02-18-2024 15:01:04