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## SUMMARY

| Inspection | |
|---|---|
| **Operation ID and Name** | 243701: FY23 CFU to Potential Class I Recall-Infant Formula |

**Summary Data**

This is a comprehensive report.

**Summary**

This directed comprehensive inspection of BlendHouse LLC, a manufacturer of an infant formula base powder, was conducted as a follow up to a Class I Recall # F-0291-2023. This voluntary recall of five batches of ByHeart Whole Nutrition Infant Formula, Milk Based Powder with Iron for 0-12 months in 24 oz containers, was issued on 12/11/2022 due to the potential for final product contamination with *Cronobacter sakazakii*. The formula under voluntary recall was distributed directly to consumers in the US and was identified by the product batch on the bottom of the can. Recalled product batches were 22273 C1, 22276 C1, 22277 C1, 22278 C1, and 22280 C1 printed with use by 01 JAN 24 or 01JUL 24. The inspection covered the infant formula base identified as an ingredient in the recalled product manufactured from (b) (4)

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 243701 and FACTS ID #12271332.

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

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 05/2022-06/2022 was classified NAI with no FORM FDA 483-Inspectional Observations issued. There were several discussion items which included: 1.)The firm did not follow their SOP MAIN-414-SOP Facility Water Leak. On 05/04/2022, the firm had a water leak in the roof and according to their SOP , they were to conduct swabs for (b) (4) days. The firm realized they did not conduct the (b) (4) day swabs when they were asked for the records pertaining to this event. Although the SOP does not state specifically the time frame of these swabs, the time between swabs from day (b) (4) was 13 days, day (b) (4) was 13 days. *The firm continues to have issues conducting the required swabbing activities for presumptive positives.* 2.) The firm does not test for the same pathogens when a water event occurs as they do in their Environmental Monitoring Program, QUAL-510-SOP. During a water event the firm determines which pathogens to test for according to the type and location of the event. The firm's environmental monitoring program instructs to swab for Salmonella spp., Cronobacter spp. and Listeria spp.. *The firm now tests for all three pathogens during a water event.* 3.) Review of the firm's production records revealed the following; the illegibility/incompletion of records. Productions records revealed multiple cross outs of information and corrections by Quality department for incorrect lot codes of ingredients, job number, customer lot number, etc. Also, at times the handwriting was too small to interpret and not completing the entire form for environmental swabbing all the time. *The firm continues to have multiple cross outs of information on production records. There is a noted improvement since the last inspection, but this still continues on an almost* (b) (4) *occurrence with less frequency.* 4.)The (b) (4) Infant Formula Operation, PROD-304-SOP states to allow the dryer to (b) (4) (b) (4) to ensure (b) (4) ; this (b) (4) time was not being recorded by the firm. *The*

## Summary

*firm is now documenting this drying time of* (b) (4) *on "Infant Formula Dryer Processing Report-PROD-306.27-FM"*

As of 08/21/2022 the firm now operates (b) (4). The firm currently employs (b) (4) full time employees, an increase of approximately (b) (4)% since the last FDA inspection of 05/2022. (b) (4) employees oversee the day to day production operations and (b) (4) employees oversee the finished products.

The firm also manufactures (b) (4) dried organic (b) (4) whole milk powder, vitamin E powder and (b) (4) (b) (4) powders. These products were not being manufactured during this inspection and were not covered as part of this inspection assignment. These products have not been manufactured since 2021.

At the end of the current inspection, FORM FDA 483- Inspectional Observations was issued To Marcellino E. Valdez, Plant Manager for the following:
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.

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. Sibert 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; 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 needs to be corrected; 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 an SOP called a sampling tool a "vial" but in the Event it was referred to as a "sample cup" and a "plastic cup". Also noted during our review of these records was some forms do not document the time an activity was performed. For example " (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.

The inspection also covered product complaints, events, water events, production records, retained samples, cleaning/sanitation SOP's, environmental monitoring and employee training.

No pest activity was observed during the inspection.

Environmental and retain samples were collected from the firm.

(b) (3) (A)

No refusals were noted.

This was reported was written by Investigator Schafer, Investigator Centi and Investigator Phillips and unless noted the section was written by Investigator Schafer.

**On 08/02/2023, Form FDA 483 Amendment 1 (Attachment #5) was received by the firm. The Amended Form FDA 483 tracked via UPS to ensure delivery (Attachment #6). A cover letter was included to explain the necessary change with the firm (Attachment #7).**

| Program Assignment Codes Covered | |
|---|---|
| **Program Assignment Code** | **Program Assignment Title** |
| 03040 | FOOD CGMP INSPECTIONS |
| 03040L | LIMITED SCOPE PCHF INSPECTIONS |
| 21006 | INFANT FORMULA SURVEY |
| 21005 | DOM & IMP NLEA, NUTR SMPL ANAL & GEN'L LBING PROG |

| Summary of Objectionable Conditions on FDA Form 483 - Current Inspection | | |
|---|---|---|
| **CFR Number** | **Citation Text** | **Correction Status** |
| 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. | 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. | Not Corrected |

**Correction Statuses current at time report was signed.**

| Inspection Recalls | |
|---|---|
| **Recall Number(s)** | F-0291-2023 |

| Inspection Samples | |
|---|---|
| **Sample Number(s)** | 1210278; 1210279; 1210280; 1210281; 1210886; 1210887; 1210888 |

## 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 Drive |
| City / State / ZIP | Reading, PA 19606-3765 |
| Website | www.byheart.com |
| **Inspection Date(s)** | 12/21/2022, 12/22/2022, 12/27/2022, 12/28/2022, 1/3/2023, 1/4/2023, 1/5/2023, 1/6/2023, 1/10/2023, 1/11/2023, 1/17/2023, 2/1/2023, 2/2/2023, 2/3/2023, 2/8/2023, 2/9/2023, 2/10/2023, 2/17/2023 |

| FDA Inspection Participants |
|---|
| **Participant Name and Title** |
| Alan Centi, Investigator |

| |
|---|
| Tammy Phillips, 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; present 12/21-22/2022, 01/04-06, 10-11, 17/ 2023, 02/01-03/2023, 02/08-10/2023 and 02/17/2023.
Investigator Alan Centi; present 12/21-22, 27-28/2022, 01/03-06, 10/2023
Investigator Tammy M. Phillips; present 12/21-22, 27-28/2022, 01/03-06/2023,02/01-03/2023, 02/08-10/2023 and 02/17/2023.

The firm was closed due to holidays on 12/23- 26, 29- 31/2022 and 01/01-02/2023.

## 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 |
|---|---|
| 12/21/2022 | Marcellino E. Valdez, Plant Manager |
| 12/21/2022 | Marcellino E. Valdez, Plant Manager |

## FDA Credentials Were Displayed to the Following Person(s)

| | |
|---|---|
| Person's Name and Title | Marcellino E. Valdez, 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 | Hilary Sibert, Senior Vice President of Quality; ByHeart Inc. |
| Person's Name and Title | Heather MacNaughton, Senior Director of Regulatory Audit Compliance; ByHeart Inc. |
| Person's Name and Title | Kristen Fallon, Senior Quality Coordinator; ByHeart Inc. |

## FDA Form 483

| Description | Date Issued | Issued To |
|---|---|---|
| Original | Feb 17 2023 10:15AM | Marcellino E. Valdez, Plant Manager |
| **Amendment 1** | **Aug 02 2023, via UPS** | **Marcellino E. Valdez, Plant Manager** |

## FMD 145 Recipient

| | |
|---|---|
| Person's Name and Title | Marcellino E. Valdez, Plant Manager |
| Email Address | (b) (6) |
| Mailing Address | The same as the firm's mailing address. |
| Phone Number | (610)582-2170 Ext. (b) (6) |

## Industry Portal Representative

| | |
|---|---|
| Person's Name and Title | Marcellino Valdez, Plant Manager |
| Email Address | (b) (6) |

## HISTORY

| | |
|---|---|
| **Other Registrations** | The firm is Kosher, Organic, (b) (4) and (b) (4) certified. |

| | |
|---|---|
| **Hours of Operation** | As of 08/21/2022 the firm operates (b) (4). The firm operates (b) (4) (b) (4) (b) (4) (b) (4). The firm currently employs (b) (4) full time employees.<br><br>Office hours of the firm are Monday- Friday, 8:00 am - 5:00 pm. |
| **New or Current Firm Legal Name** | BlendHouse LLC |
| **Legal Status** | |
| **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.<br><br>On 01/05/2023, ByHeart Inc. announced an agreement to acquire Cascadia Nutrition, an (b) (3) (A) blending and canning facility in Portland, OR. Ms. Sibert stated the firm intends to (b) (4).<br><br>On 01/25/2023, ByHeart Inc. (b) (4). |

## INTERSTATE (I.S.) COMMERCE

| | |
|---|---|
| Description of Interstate Commerce | The firm's top ingredients suppliers are (b) (4)<br><br>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. The bulk pre-blend is shipped in bulk totes to (b) (4). The (b) (4) (b) (4) lactoferrin is (b) (4) in the bulk pre-blend and packaged in metal cans labeled as infant formula. The canned product is sent to (b) (4) (b) (4) in a sealed container with a temporary plastic lid on the container. (b) (4) (b) (4) removes the temporary plastic lid from each container and affixes a new metal lid, with the scoop in the underside of the lid, to each container. The cans are case packed and distributed by (b) (4). directly to consumers who purchase the product through the web site www.byheart.com ((b) (4)% Retail). The cans are sold to consumers in a single can, two can, four can or six can units.<br><br>Interstate records were not collected during the current inspection. |

| | |
|---|---|
| **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) (b) (4) (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) (b) (4). All of the bulk pre-blend is shipped in bulk totes to (b) (4) (b) (4) where it is (b) (4) with lactoferrin and packaged in metal cans labeled as infant formula. The canned product is sent to (b) (4) (b) (4) with a temporary plastic lid on the container. (b) (4) removes the temporary plastic lid from each container and affixes a new metal lid, with the scoop in the underside of the lid, to each container. The cans are case packed and distributed by (b) (4) directly consumers who purchase the product through the web site www.byheart.com |

## JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

| | |
|---|---|
| Description of Jurisdiction | BlendHouse operates as a manufacturer of cow's milk based, dried, powdered infant formula bases that are further processed into a finished infant formula product that is distributed under the brand "ByHeart". The infant formula base is (b) (4), limited up to (b) (4) for quality reasons. **See Exhibit #1 for finished infant formula can product label and Exhibit #2 for web site marketing material for the finished infant formula product.** The finished can label was not reviewed during the current inspection. Consumers can purchase the product through the web site www.byheart.com. The infant formula is marketed to customers via the same website. |

## INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

| **Person #1** | |
|---|---|
| Person's Name and Title | Marcellino E. Valdez, Plant Manager |
| Roles and Authorities | Mr. Valdez is responsible for facility operations which includes but is not limited to the day to day operations, production and maintenance. Mr. Valdez has been with the company since September 2021 and reports to Marcus Jordan, VP of Supply Operation-ByHeart. Mr. Valdez identified himself as the most responsible person on site. **See Exhibit #3 for the firm's organizational charts and Exhibit # 4 for the corporate organizational chart.** |
| The following are applicable to this person | FDA Credentials Displayed to This Person, Industry Portal Representative, Interviewed, FMD 145 Recipient, Accompanied During the Inspection |
| Email Address | (b) (6) |
| Mailing Address | The same as the firm's mailing address. |
| Phone Number | (610)582-2170 Ext. (b) (6) |
| **Person #2** | |
| Person's Name and Title | Fangfei Lou, Director of Quality |
| Roles and Authorities | Ms. Lou is responsible for quality systems and compliance. Ms. Lou is also the back up person for bulk micro testing release. Ms. Lou has been with the firm since May 2022 and reports to Hilary Sibert, Senior VP Quality- 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 the quality systems, document control and internal/external audits. Ms. Rhoades is also the firm's main (b) (4) (b) (4). Ms. Rhoades has been with the company since April 2020 and reports to 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), HR Coordinator |
| Roles and Authorities | Ms. (b) (6), (b) (7)(C) is responsible for recruitment and interviewing of new hires, payroll and onboard and continuous training of employees. Ms. (b) (6), (b) (7)(C) was the scribe for the firm during the inspection up until 01/05/2023. Ms. (b) (6), (b) (7)(C) has been with the firm since January 2021 and reports to (b) (6), (b) (7)(C), HR Manager. |
| The following are applicable to this person | Interviewed |
| **Person #5** | |
| Person's Name and Title | Hilary Sibert, Senior Vice President of Quality; ByHeart Inc. |
| Roles and Authorities | Ms. Sibert is responsible for quality systems, regulatory compliance and approval supply chain. Ms. Sibert can also, when needed authorizes the final release of the canned infant formula. Ms. Sibert has been with the firm since December 2017. Ms. Sibert identified herself as the most responsible ByHeart employee present. Ms. Sibert is located at the firm's corporate address of 131 Varick Street New York, NY and reports to Ron Belldegrun, CEO and Co-Founder. |
| The following are applicable to this person | FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection |
| **Person #6** | |
| Person's Name and Title | Heather MacNaughton, Senior Director of Regulatory Audit Compliance; ByHeart Inc. |
| Roles and Authorities | Ms. MacNaughton is responsible for corporate level audits, supply chain contractors, internal audits, complaints, document control and works with the (b) (4) (b) (4). Ms. MacNaughton also authorizes the final release of the canned infant formula. Ms. MacNaughton is also one of the firm's (b) (4) (b) (4). Ms. MacNaughton has been with the firm since April 2020. Ms. MacNaughton primary office is at the corporate address in New York but does spend approximately (b) (4) at the firm. Ms. MacNaughton reports to Hilary Sibert, Senior VP of Quality. |
| The following are applicable to this person | FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection |
| **Person #7** | |
| Person's Name and Title | Kristen Fallon, Senior Quality Coordinator; ByHeart Inc. |
| Roles and Authorities | Ms. Fallon is responsible for quality systems, complaints and events/deviations. Ms. Fallon has been with the firm since January 2022. Ms Fallon authorizes the final release of the canned infant formula and component parts such as lids and cans as needed. Ms. Fallon reports to Heather MacNaughton, Senior Director of Regulatory Audit Compliance. Ms. Fallon's office is at the corporate office in New York but does spend (b) (4) (b) (4) at the firm per (b) (4). |
| The following are applicable to this person | FDA Credentials Displayed to This Person, Interviewed |
| **Person #8** | |
| Person's Name and Title | (b) (6), (b) (7)(C), Executive Assistant |

| | |
|---|---|
| Roles and Authorities | Ms. (b) (6), (b) (7)(C) is the Executive Assistant to Fangfei Lou. Ms. (b) (6), (b) (7)(C) was the scribe for the firm beginning 01/17/23. |
| The following are applicable to this person | |
| **Person #9** | |
| Person's Name and Title | (b) (6), (b) (7)(C), Internal Auditor |
| Roles and Authorities | Mr. (b) (6), (b) (7)(C) was the scribe for the firm on the afternoon of 02/09/2023 and the day of 02/10/2023. Mr. (b) (6), (b) (7)(C) reports to Katherine Rhoades. |
| The following are applicable to this person | |
| **Person #10** | |
| Person's Name and Title | Michele Otte, Quality Operations Manager |
| Roles and Authorities | Ms. Otte is responsible for the bulk micro testing release. Ms. Otte reports to Ms. Lou. |
| The following are applicable to this person | |
| **Person #11** | |
| Person's Name and Title | Devon Kuehn, MD, Chief Medical Officer; ByHeart Inc. |
| Roles and Authorities | Ms. Kuehn was only present via conference call during the closeout. Ms. Kuehn reports to Ron Belldegrun, CEO and Co-founder. |
| The following are applicable to this person | |

## FIRM'S TRAINING PROGRAM

All employees receive specialized training for their specific job, as well as training in areas of safety, GMPs, documentation, adulteration, food defense, recalls, HACCP, allergens, etc. The firm provides (b) (4) refresher training and continuous training on an as needed basis for any situations that may warrant additional training.

I reviewed training of approximately (b) (4) of the new employees hired since the last inspection and noted two employees were missing quizzes for completed training in their employee folder. The firm was able to show the employees did attend the classes via employee sign in sheet. The firm was unable to provide a reason for the missing quizzes other than the possibility of the quizzes being misfiled.

## MANUFACTURING/DESIGN OPERATIONS

### Process Flow, Operations, and Product Coverage

**Manufacturing Design and Operations**

A walk-through inspection of the manufacturing facility, located at 61 Vanguard Drive, Reading PA was initially conducted on 12/21-22/22 during environmental swabbing and again on 02/01/23 by Investigators Schafer and Phillips to verify the firm was not in production. A walk thru of the warehouse facility, located at 51 Vanguard Drive was conducted on 12/27/2022 by Investigators Centi and Phillips and again on 02/01/2023 by Investigators Schafer and Phillips. According to the firm, manufacturing had ceased as of 12/21/2022.

**Warehouse Inspection**

The warehouse is a (b) (4) square foot facility that has been updated since the last inspection to be temperature and humidity controlled. **See Exhibit # 5 Floor plan 51 address, Warehouse**. The temperature and humidity are monitored (b) (4) with the warehouse manager and warehouse supervisor being alerted when the temperature is beyond the parameters of (b) (4)° F and humidity is maintained at less than (b) (4) %. The firm also has a "reach-in" freezer for holding cold products at (b) (4) F° to (b) ° F that is visually monitored (b) (4) .

The warehouse floor has been replaced since the previous inspection. During the week of 11/7/2022- 11/12/2022 the floor was replaced with a new floor which includes an (b) (4) layer.

The warehouse receives non-bulk ingredients through a bay door. At the time of receiving the truck is visually inspected and the product is unloaded. A warehouse employee visually examines the product against the

**Process Flow, Operations, and Product Coverage**

purchase order to determine that the correct product and quantity was received from the correct manufacturer. The list of approved suppliers is managed by ByHeart which is set up in the firm's system. At the time of receiving, all product is physically moved to a designated quarantine area and entered into the firm's computer system in a quarantine status. The system will notify quality control department (QC) for the need for QC testing.

The received ingredient is transported from the 51 Vanguard Drive facility in a firm owned truck to the 61 Vanguard Drive facility. Ingredient for sampling is collected in the "(b) (4) Room" following the firm's written procedures for collecting materials for product testing.

After sampling, the ingredient is transported back to the 51 Vanguard Drive facility and held in quarantine pending the results of testing. After testing is completed, QC will either release the product from quarantine and move the product to the warehouse, or reject the product, in which in this case the product will be identified and held in the warehouse pending disposition by QC. Each released product is identified with a green sticker that contains the following information: part number, firm's lot number, vendor lot number, date received, date of expiration, and storage conditions.

**Manufacturing Facility Inspection**

Manufacturing operations are conducted in a (b) (4) sq foot facility that includes a (b) (4) dryer used by the firm for drying in-process bulk infant formula base. **See Exhibits #6- floor plan for 61 address and traffic flow for 61 address and Exhibit # 7- dryer** (b) (4)

The following is a description of production process for manufacturing of in-process bulk infant formula base. For a complete description of the process flow diagram and process narrative see **Exhibit #8 , pages 6-10 . See also Exhibit #9**, for the firm's process authority letter - "Process for Thermal Treatment using (b) (4) for Infant Formula".

Individual ingredients are weighed in the (b) (4) Room (b) (4) (b) (4) verifying the identity and amount of each ingredient that is weighed. The ingredients are placed in bags and identified with the following information: part number, firm's lot number, vendor lot number, and the weight of each bag. The bags are placed on a pallet, and the pallet is identified with the following information: the job number and batch number.

At the time ingredients are added to (b) (4) verifies the addition and employees document the addition of ingredients to (b) (4) on a master batch record. Other bulk ingredients are added to a (b) (4) hopper. The ingredients are pumped to a mixing tank, (b) (4) water is added and then mixed and pumped to (b) (4) holding tanks. The firm has a (b) (4) process and therefore the liquid blend does not (b) (4). The maximum holding time in these tanks (Tank (b) (4) and Tank (b) (4)) is (b) (4).

The blend is pumped to a (b) (4) and then to a (b) (4) tank (Tank (b) (4)). The firm monitors the temperature of the liquid in the (b) (4) tank (specification is ≥ (b) (4) ºF). The liquid blend is pumped to a (b) (4) (b) (4) and pasteurized at (b) (4) ºF for ≥ (b) (4). The firm records the temperature on a (b) (4) chart and Production visually monitors and records the parameters of the (b) (4) (b) (4) including: (b) (4) (min (b) (4) ºF); (b) (4) (b) (4) (min (b) (4) ºF); (b) (4) status. The firm also monitors (b) (4) tank level, (b) (4) flow rate; (b) (4) inlet and outlet temperature; (b) (4) dryer feed temperature; (b) (4) and (b) (4) thermometer temperature.

The liquid is sent via a (b) (4) to the (b) (4) dryer. Production conducts (b) (4) monitoring of the dryer conditions on the "Infant Formula Dryer Processing Report" where the firm documents the following:

**Process Flow, Operations, and Product Coverage**

conditions of the dryer operations (b) (4) including inlet temperature (operating range (b) (4) ° F); (b) (4) (b) (4) ; (b) (4) line pressure; (b) (4) tank; (b) (4) and others.

The powder exits the dryer to a (b) (4) before passing through a (b) (4) sifter then a metal detector. The firm inspects the sifter (b) (4) located below the sifter for the presence of foreign material (b) (4) (b) (4) . The firm conducts a (b) (4) on the metal detector and then (b) (4) (b) (4) .

The powder is filled into (b) (4) on pallets. The inner lining of the (b) (4) are heat sealed, the (b) (4) is identified with a label and quarantined pending release (or rejection) by Quality Control. After release, the product is shipped in (b) (4) trucks to the firm's third-party canning facility (or an intermediate third-party warehouse).

The firm typically manufactures (b) (4) per day. A production aggregate typically consists of (b) (4) batches (production units). The shelf life of this bulk pre blend is (b) (4) from date of manufacture.

Each batch (production unit) yields approximately (b) (4) of in-process bulk powder, which is approximately (b) (4) (b) (4) . Lactoferrin is (b) (4) by the firm's contract blender and canner, (b) (4) (b) (4) at a rate of (b) (4) .

The firm does not currently use any rework.

**Pasteurized Dried Milk Powder Processing**

The firm manufactures pasteurized dried milk powder from fluid milk. The pasteurized dried milk powder is used as a component to manufacture the firm's in-process bulk infant formula base. The milk pasteurization equipment and controls are inspected (b) (4) by the Commonwealth of Pennsylvania Department of Agriculture Bureau of Food Safety and Laboratory Services Division of Milk Sanitation.

**Cleaning and Sanitation**

The firm has several standard operating procedures (SOP) pertaining to cleaning and sanitation of the equipment and facility. The "Master Sanitation Procedure SAN-800-SOP" details Clean In Place (CIP) cleaning frequency for the milk processing area which states in part, "..cleaned utilizing a (b) (4) (Full CIP) after a (b) (4) ." The infant formula batching and processing equipment are "cleaned utilizing (b) (4) with a maximum of (b) (4) ." The firm utilizes (b) (4) and (b) (4) ( (b) (4) ). **See Exhibit #10** for more detailed information.

(b) (4) cleaning is performed on ingredient (b) (4), tank lids/hatches and small miscellaneous removable parts as per "(b) (4) Cleaning PROD-300.02-WI". This would include Tanks (b) (4) and (b) (4) which are minor ingredient (b) (4). A (b) (4) is used to (b) (4) clean these items with a product contact brush or scrub pad. After the cleaning has been completed, the items are then sanitized with an (b) (4) solution. **See Exhibit #11** for more detailed information.

The packaging area is cleaned by the packagers or other designated employees as per the firm's "Packaging Area Cleaning Procedure PROD-300.05-WI". The packaging area consists of the equipment in the bulk packaging area ((b) (4)) and the transfer equipment in the (b) (4) room. Once all appropriate equipment has been removed, it is cleaned with a general purpose (b) (4) and sanitized with (b) (4) . **See Exhibit #12** for more detailed information.

The firm's CIP SOPs are broken down into three different systems:
1. "(b) (4), Tank (b) (4) and (b) (4) Tank CIP SAN-802-SOP"
2."Sanitation Standard Operating Procedure: CIP (b) (4) - (b) (4) Room CIP SAN-805-SOP"

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3."(b) (4) Dryer Procedure CIP(b) SAN-803-SOP"

The "(b) (4) Tank (b) (4) and (b) (4) Tank CIP SAN-802-SOP", refers to the cleaning and sanitation of the entire (b) (4) system. Tank (b) (4) ((b) (4) tank) and the (b) (4) are identified as CCP(b) by the firm in their Food Safety Plan. The SOP includes the CIP (b) (4) steps. **See Exhibit #13** for more detailed information.

The "Sanitation Standard Operating Procedure CIP (b) (4) - (b) (4) Room CIP SAN-805-SOP", refers to the cleaning and sanitation for the (b) (4) room ((b) (4) processing area). This includes the following equipment: Tanks (b) (4), batch (b) (4) lines and (b) (4) lines. The SOP includes the CIP procedure, allergen washes and sanitizing steps. **See Exhibit #14** for more detailed information.

The "(b) (4) Dryer Procedure CIP(b) SAN-803-SOP", refers to the cleaning and sanitation for the dryer, (b) (4) lines, (b) (4), sifter and other related equipment in the dryer area. The SOP includes the CIP procedure, (b) (4) washes and sanitizing steps. **See Exhibit #15** for more detailed information. After cleaning and sanitizing the dryer, the dryer is dried for (b) (4) at (b) (4)° F.

The "(b) (4)" of production equipment is cleaned (b) (4) and the "(b) (4)" equipment is cleaned (b) (4), or more frequently if (b) (4).

The firm verifies the effectiveness of cleaning on the (b) (4) by conducting a visual inspection and examination of the equipment. In addition, the firm conducts (b) (4) swabbing of food contact equipment and surface allergen testing on multiple pieces of equipment and (b) (4) for soy protein regardless of when soy was last processed.

(b) (4), the firm conducts a final startup verification to verify that (b) (4) activities have been conducted and all (b) (4) sanitation forms/checklists have been completed including: (b) (4) form, Allergen testing form, and (b) (4) sanitation checklist. Additionally, the firm verifies that the dryer is in production mode and the dryer is dry.

(b) (5)

These records were reviewed with the firm upon our return on 02/01/2023.

After startup of the first new batch/production unit, (b) (4). The product is packaged in a (b) (4) and sent to (b) (4)

The firm is currently in the process of (b) (4). Since the firm has not been manufacturing, (b) (4). These new chemicals were not reviewed during our inspection, since they were not currently in use.

**In Process Bulk Testing**

The firm (b) (4) collects (b) (4) samples of in-process bulk during the filling of (b) (4). The (b) (4) samples are designated as "(b) (4)" samples. (b) (4) samples are composited for microbiological samples and (b) (4) is sent to a third-party lab ((b) (4)) for nutrient analysis. The sample sizes and testing method for (b) (4) are as follows:

Cronobacter spp. (b) (4) g (Method: (b) (4))
Salmonella spp. (b) (4) g (Method: (b) (4))
Listeria monocytogenes (b) (4) g (Method: (b) (4)).

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The in-process bulk is also tested but not limited to the following: Staphylococcus aureus (Method: (b) (4) (b) (4)), B. cereus (Method: (b) (4) ), E. coli (Method: (b) (4) ) and Enterobacteriaceae (Method: (b) (4) ).

The firm also tests in-process bulk for (b) (4) 21 CFR 107.100 infant formula nutrients specifications. Additional testing of in-process bulk includes: pH, fat, (b) (4) (b) (4) , moisture, reconstitution, taste, and color.

Ms. Sibert provided a timeline of the 3rd party laboratories used by the firm for bulk testing as follows:

(b) (4)

The firm verified in correspondence dated 01/27/2023 and 01/26/2023 **(See Exhibit#49 and #50)** that no shipment of their base mix product from production date 10/20/2022-present has been sent to (b) (4) (b) (4) . The firm also provided during the closeout of the inspection on 02/17/2023 a copy of all their base mix product presently in inventory and the location/disposition. **See Exhibit # 51**

**Metal Detection**

I reviewed the firm's "Metal Detector Verification Procedure PROD-307-SOP". The firm utilizes the following metal detector (b) (4) . Metal detection checks are conducted (b) (4) (b) (4) . **See Exhibit #16** for more detailed information.

**Finished Product Testing**

Microbial testing is performed on (b) (4) cans of finished product (b) (4) from the batch during (b) (4) (b) (4) . The samples are sent by (b) (4) to the firm's third-party laboratory for testing for Salmonella (Method: (b) (4) ) and Cronobacter (Method: (b) (4) ). The firm also has the product tested for Bacillus cereus, E. coli, Enterobacteriaceae, (b) (4) , yeast and mold, aerobic plate count and coliforms. Nutrient testing is conducted from (b) (4) cans (b) (4) from the batch during (b) (4) . The samples are sent by (b) (4) to the firm's third-party laboratory for nutrient analysis for (b) (4) 21 CFR 107.100 infant formula nutrients specifications.

Ms. Sibert provided as information as follows for the third party laboratory for finished product testing:

(b) (4)

**Product Retains**

BlendHouse collects (b) (4) of in-process bulk material from (b) (4) of product. The product is kept by BlendHouse for (b) (4) from the date of manufacture.

**Environmental Monitoring Program**

*Begin Investigator Centi*

The firm has a formal environmental monitoring program in place which is similar to what was described in the previous establishment inspection report dated 05/23/2022 and as described below.

The firm maintains the following SOPs relating to environmental monitoring which I reviewed during the inspection: "Environmental Monitoring Program QUAL-510-SOP" (**Exhibit #17**), "Environmental Surface Sampling QUAL-510.07-WI" (**Exhibit #18**), "Environmental Monitoring Positive Response Action Plan QUAL- 510.06-WI" (**Exhibit #19**) and "Event Reporting and Investigation Procedure QUAL-509.05-WI" (**Exhibit #20**).

## Process Flow, Operations, and Product Coverage

The firm continues to collect the following swabs (b) (4) : Cronobacter spp. ((b) (4) swabs), Salmonella spp. ((b) (4) swabs), and Listeria spp. ((b) (4) swabs). The firm has approximately (b) (4) swab sites identified which are required to be sampled (b) (4) . Of these locations, (b) (4) are zone (b) (4) are zone (b) (4) and (b) (4) are zone (b) (4) A comprehensive list of swabbing locations is included as **Exhibit #21**.

In the event of a positive sample (presumptive or confirmed), the firm follows the procedures outlined in "Environmental Monitoring Positive Response Action Plan QUAL- 510.06-WI" (**Exhibit #19**) to include initiation of sanitation efforts and (b) (4) vector swabbing around the suspect site. Should a vector swab result in a presumptive or confirmed positive, the process begins again. If a swab has been confirmed positive, the firm follows the procedures outlined in "Event Reporting and Investigation Procedure QUAL-509.05-WI" (**Exhibit #20**) to begin a formal event report and investigation to include corrective and preventive actions as necessary.

Environmental samples were analyzed by (b) (4) until switching to (b) (4) .

(b) (4) testing methods for environmental swabs are as follows: Cronobacter - Method: (b) (4) , Salmonella- Method: (b) (4) and Listeria- Method (b) (4) (b) (4)

*End Investigator Centi*

We reviewed the firm's Events in relation to their environmental program, water events and other events associated during the inspection. The firm's "Event Reporting and Investigation Procedure QUAL-509.05-WI" defines an Event as " All nonconformities or departures from established Standard Operating Procedures (SOP), Manufacturing Instructions (MI), or current Good Manufacturing Practices (CGMP) are documented if the event has the potential to impact (or lead to conditions that could impact) product safety, identity, purity, quality, or nutritive value ((b) (4)). " Events are classified as (b) (4) . The timeline for completion of these Events are as follows: (b) (4) . The following Events were completed in excess of (b) (4): 2290, 2298, 2299, 22106, 22115, 22116, 22107, 22140, and 22146 **See Exhibit #20**

*Begin Investigator Centi*

During the inspection, I reviewed the following event reports related to confirmed positive environmental samples:

**Environmental Monitoring Events Review**

***Event 2268*** with (b) (4) swab dates of 31MAY2022 and 03JUN2022 involving detection of *Cronobacter spp.* in (b) (4) individual swabs from multiple areas ranging from (b) (4) collected 06JUN and 07JUN. All detected swabs were vectors from previous (b) (4) swabs which were noted as suspect/presumptive. All original swabs were later confirmed negative however they triggered vectoring that found numerous confirmed positives for *Cronobacter sakazakii*. Firm response to presumptive/positives includes increased sanitation events which are documented in the event report. This event resulted in the destruction of (b) (4) lots (b) (4) and (b) (4) .

Investigation of this event led to the discovery that Environmental Monitoring Positive Response Action Plan QUAL-510.06-WI **(Exhibit # 19)** was not being following regarding Sanitation performing the cleaning activities prior to vector swabbing. "Upon review of the swab records for detected sites, it was discovered that personnel from other departments (in addition to Sanitation), including QA and Operations, performed cleaning in various locations. Interviews with some of the personnel from QA and Operations revealed that inadequate cleaning activities were performed." All employees were retrained for this SOP as a result. See **Exhibit #22** for event report.

***Event 2283*** with initial swab date 13JUL22 involving detection of *Cronobacter* and confirmation of *Cronobacter sakazakii* on 20JUL2022 in the 51 Warehouse. Investigation of this Event and Event #22115 and #22140 revealed cracks in the flooring which later led to the entire floor of the 51 warehouse being replaced the week of 07NOV2022.

***Event 2287*** with initial swab date of 17JUL2022 involving detection of *Listeria spp.* on the (b) (4) . The

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event resulted in an increase to the cleaning frequency of the equipment.

***Event 2290*** with initial swab date 20JUL2022 involving detection of *Cronobacter spp.* in the (b) (4) processing room after a water event and subsequent construction event (removal of skylight). Confirmation of *Cronobacter sakazakii* on 26JUL2022. **See Observation #1- 3a and Exhibit #23** for further information.

***Event 2297*** with initial swab date of 31JUL2022 involving detection of *Listeria spp.* on the (b) (4) door of 51 Warehouse. The event resulted in an increase to the cleaning/sanitizing frequency of the door from (b) (4). During this event, the laboratory ((b) (4)) provided an email notification of presumptive findings to the wrong distribution list resulting in the firm only receiving the notification of confirmation on 09AUG2022. This laboratory error led the firm to change third party laboratory provider. **See Exhibit** #24

***Event 2298*** with initial swab date 27JUL2022 involving detection of *Cronobacter spp.* on the (b) (4) base leading to the (b) (4) room. Additional vector swabs taken 13AUG2022 and 27AUG2022 were also confirmed positive for *Cronobacter sakazakii*. Vector swabbing was missed on 20AUG2022 resulting in additional vectors being conducted. The firm determined that (b) (4) was not an effective sanitizer for the (b) (4) and has switched to (b) (4) sanitizer on this surface. **See Observation #1- 3b and Exhibit #25**

***Event 22106*** with initial swab date of 22AUG2022 involving detection of *Cronobacter spp.* from multiple vectors in the (b) (4) Room. Confirmation of *Cronobacter sakazakii* was received on 04SEP2022. The firm changed sanitizing agent from (b) (4) to (b) (4) in this area. During the date range of this event, the firm also detected *Cronobacter sakazakii* in infant formula base aggregate for production date 24AUG2022 **(See Event 22107, Exhibit #38)** which was subsequently destroyed. **See Observation #1- 3c See Exhibit #26** for event report.

***Event 22115*** with initial swab date of 06SEP2022 involving detection of *Cronobacter spp.* on the floor and fixtures of 51 Warehouse. Vector swabbing was missed on 23SEP2022 resulting in additional vectors being conducted. Additionally, the laboratory ((b) (4) new laboratory) incubated the 05OCT2022 vector swabs at the wrong temperature resulting in no analyses for that date. **(Exhibit #27, pgs 31-32)** Investigation of this Event and Event #2283 and #22140 revealed cracks in the flooring which later led to the entire floor of the 51 warehouse being replaced the week of 07NOV2022. Furthermore, this investigation led to the further review of the cleaning schedule of the floors at the 51 address which were cleaned (b) (4). Due to the increase traffic with the (b) (4) operation schedule this was determined to inadequate, and the floors are currently cleaned (b) (4) See **Exhibit #27** for event report.

***Event 22116*** with initial swab date of 04SEP2022 involving detection of *Cronobacter spp.* in the (b) (4) room on vector swabs dated 17SEP2022 and 26SEP2022. Vector swabbing was missed on 23SEP2022 as well as 09OCT2022 resulting in additional vector swabs being conducted. The Event investigation determined the floors were only being sanitized and not cleaned. The (b) (4) room is where employees change into their smocks that they are required to wear. The (b) (4) room also has bathroom facilities. **See Observation #1- 3e and Exhibit #28**

***Event 22140*** with initial swab date 17OCT2022 involving detection of *Cronobacter sakazakii* on the floor of 51 Warehouse. Investigation of this Event and Event #2283 and #22115 revealed cracks in the flooring which later led to the entire floor of the 51 warehouse being replaced the week of 07NOV2022.

***Event 22146*** with initial swab date 24OCT2022 involving detection of *Cronobacter spp.* on the (b) (4) in the 51 Warehouse. The vectoring resulted in a secondary positive on 30OCT2022.

***Event 22166*** with initial swab date 14NOV2022 involving detection of *Cronobacter* (b) (4) in the (b) (4) utilized to move ingredients from 51 Warehouse to the production facility. Vector swabbing was missed on 20NOV2022 resulting in additional vectors being conducted. Furthermore, this investigation led to the further review of the cleaning schedule of the (b) (4) which was cleaned (b) (4) The cleaning frequency of the (b) (4) was changed to (b) (4) See **Exhibit #29** for event report.

On 08/30/2022, No Event number was created. The firm collected environmental swabs per QUAL-510-SOP Environmental Monitoring Program for the week of 08/28/2022. Third-party laboratory results (COAs) received on 09/06/2022 showed seven (7) presumptive positive for *Cronobacter spp.*

a.) (b) (4): Zone (b) - (b) (4) Zone - Floor of (b) (4) from (b) (4) ((b) (4)

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(b) (4) area) to (b) (4) room.

b.) (b) (4) : Zone (b) (4) - (b) (4) - Drain of (b) (4) Room #(b) (4)

c.) (b) (4) : Zone (b) (4) - (b) (4) Zone - Parts Cart on Dryer (b) (4) Level (b) (4)

d.) (b) (4) : Zone (b) (4) - (b) (4) - Floor at (b) (4) after (b) (4)

e.) (b) (4) : Zone (b) (4) - (b) (4) Zone - Floor (b) (4) to (b) (4) Room from Warehouse

f.) (b) (4) : Zone (b) (4) - (b) (4) Zone - Floor (b) (4) Room

g.) (b) (4) : Zone (b) (4) - (b) (4) Zone - Floor at (b) (4) Area.

The firm initiated an email to their third-party laboratory on 09/06/2022 @ 11:50 am to confirm if the (b) (4) suspect/presumptive samples were undergoing confirmation testing. The laboratory responded via email 09/06/2022 @ 2:57 pm and stated "samples tested suspect for Enterobacteria and confirmation tested was confirmed as negative for …" (b) (4) . The laboratory's email further stated "...the lab to run confirmation testing on the below samples (b) (4) " The confirmation email did not provide the necessary information for the confirmation testing, such as and not limited to, analytical method and testing date. **Exhibit #30 pgs. 2-3**

At this point the firm considered the initial (b) (4) swabs as closed due to the laboratory stating they were confirmed negative.

The firm proceeded to treat the remaining (b) (4) unconfirmed sites as positives and began (b) (4) of vector swabbing per SOPs. These follow up actions and results were reviewed for these (b) (4) locations with no objections noted.

An email dated 12/27/2022 from (b) (4) (**Exhibit #30 pg. 4)** indicated that an internal review showed confirmation testing had never been conducted on any of the (b) (4) presumptive positives from the 30AUG22 sampling date. This indicates the (b) (4) presumptive positives referenced above were not subject to confirmation testing by the laboratory nor appropriate investigation and vectoring by the firm. The locations of these (b) (4) samples were in (b) (4) areas of the firm. **See Observation #1- 3d and Exhibit #30 and pgs. 95-97 for letter from (b) (4) – Investigation findings**

*End Investigator Centi*

Review of the firm's Events related to their Environmental Monitoring Program revealed instances of cleaning/sanitation frequencies not being sufficient, sanitizers not being effective, areas were only sanitized and not cleaned and sanitized, personnel performing cleaning activities that they were not properly trained to complete and continued issues with their third-party laboratory even after switching to a new laboratory on or about 30AUG2022. **See Event #2297 Exhibit # 24, Event # 22115 Exhibit #27, pgs 31-32, No Event # for 30AUG2022 Exhibit #30, pgs 2-3, 4, and 95-97.** These events document *Cronobacter sakazakii* throughout the manufacturing environment even though it is a (b) (4) % (b) (4) of manufacturing. Furthermore, many of these issues were during the time of the production dates of the recalled product and these events were not reinvestigated after the recall to determine any possible connection.

In relation to the firm's environmental monitoring program, (b) (4) are randomly swabbed each

**Process Flow, Operations, and Product Coverage**

(b) (4) (b) (4) of (b) (4) is swabbed from the following (b) (4) : (b) (4) (does not note if this is the (b) (4) room) allowing for a potential of (b) (4) per (b) (4) and (b) (4) maximum per (b) (4). (b) (4) in the following (b) (4) are not swabbed (b) (4) according to the firm's master swab location list: (b) (4). The same (b) (4) location is used for an (b) (4) for example, the (b) (4) the (b) (4) "in the (b) (4) …specify initial, if empty (b) (4) " **See Exhibit #21**

According to the firm's "Good Manufacturing Practices (GMPs) QUAL-524-SOP" "..shoes are cleaned at the (b) (4) and maintained in a serviceable condition" and if "…shoes become excessively soiled during work the employee… will reclean their shoes." Employees are responsible for cleaning their shoes (b) (4). Ms. Lou explained that employees are responsible for cleaning with ( (b) (4) ) and sanitizing ((b) (4) **See Exhibit #31 pg 5**

Shoe racks and cubbies are included in the (b) (4) Sanitation Schedule for (b) (4) . **See Exhibit #32**

**Water Events**

*Begin Investigator Phillips*

During the inspection, I asked Ms. MacNaughton if the firm had any reported water events between June 2022 and December 2022, and she replied the firm had two reported water events. Ms. MacNaughton directed Ms. Rhoades to provide me with the records for the two reported water events that occurred on 12/15/2022, which was the water leak in the firm's dryer (b) (4) and on 06/23/2022, which was the roof leak in the firm's (b) (4) processing room.

Ms. Rhoades provided me with the quality document titled, "BlendHouse Event Reporting and Investigation Form QUAL-509.05.01-FM Event # 22179", Event Short Description: Leak in the dryer (b) (4) through the (b) (4) and *Cronobacter spp.* was detected from the swabs collected from the leak with date and time 16DEC2022 10:18, **See Observation #1 -4 and Exhibit #33 and #34** Ms. Rhoades also provided me "BlendHouse Event Reporting and Investigation Form QUAL-509.05.01-FM Event # 2270", Event Short Description: Roof leak in (b) (4) Processing Room in front of (b) (4) tank and nonpathogenic *Listeria Innocua* was detected from one the swabs associated with the leak with date and time 23JUN2022 5:00 **See Observation #1-4 and Exhibit #35.**

Ms. Rhoades pointed out that the events document the firm's corrective action to the two water events. She added that the corrective actions were conducted in accordance with the SOP document titled "Facility Water Leak Control and Cleaning MAIN-414-SOP", and with an Effective Date 17AUG2022, **See Exhibit #36**

Review of the two water events found rain and wind contributed to both leaks. Water infiltration that originates from the outside environment/outdoors is of particular importance since avian activity occurs on roofs, and birds defecating on roof surfaces. Water from the roof of the dryer (b) (4) in the case of water event # 22179 and water from the roof of the (b) (4) processing room, in the case of water event # 2270, is a contributing factor to the contamination of the infant formula base processing environment.

During the inspection when I was reviewing the two water events, Ms. Lou stated that the firm does routinely check the roof of their 61 Vanguard Dr. production facility. She provided an email from (b) (4) dated November 14, 2022, and subject: (b) (4) roof inspection that lists that the roof was inspected. **See Exhibit #37**

Note that the email does not list what roof was inspected, the 51 Vanguard Dr. warehouse and office building or the 61 Vanguard Dr. production building. Review of the email determined that this inspection was of the 61 Vanguard Dr. production building because it lists that (b) (4). During the inspection, Ms. MacNaughton stated that the firm was planning to (b) (4) (b) (4) .

As I was reviewing Event # 22179 for the water leak event that occurred on 12-15-22 in the firm's dryer (b) (4) I noted

**Process Flow, Operations, and Product Coverage**

that the lab did not complete analyses for (b) (4) environmental swab samples collected for *Cronobacter spp.* for this event. The firm received a notification letter from (b) (4) on 1-18-23, stating that the lab completed the analyses for the (b) (4) swabs for *Cronobacter spp.*, but did not conduct an isolate identification for them. The letter stated that the lab technicians failed to input the correct confirmation code in their laboratory information system ((b) (4)). The swab samples were collected on 12-15-22. **See Exhibit #34, page 19** for a copy of the notification letter from the firm's lab.

The firm received another notification letter from (b) (4) also on 1-18-23, stating that the lab canceled (b) (4) environmental swab samples collected for *Cronobacter spp.* for this event. The letter stated that the swab samples were enriched with the incorrect media. The swab samples were collected on 12-15-22. **See Exhibit #34, page 20** for a copy of the notification letter from the firm's lab.

With the discovery of the (b) (4) swab samples not assayed for the *Cronobacter spp.* isolate and the (b) (4) swabs not assayed at all for *Cronobacter spp.,* I reviewed records regarding the lot of infant formula base manufactured on 12-15-23, lot # (b) (4). Records included (b) (4) analytical results reports for infant formula base samples collected from the firm's (b) (4) during the production run of lot # (b) (4) for *Cronobacter spp.* and other pathogens. Review of the analytical results records found no concerns. I also reviewed the firm's "(b) (4) Clean Record, SAN-800.21-FM" for cleaning done on 12-16-22 and found no concerns. Additionally, I reviewed (b) (4) analytical results reports for (b) (4) and vector swabs collected and analyzed for the affected areas of the dryer (b) (4) for *Cronobacter spp.* and other pathogens and found no concerns. The firm collected the swabs from 12-15 to 21-22. And, I reviewed the production records for lot # (b) (4) manufactured on 12-15-22 and found no concerns. See **Exhibit #34** for copies of the records and reports I reviewed.

*End Investigator Phillips*

**Other Events Reviewed**

**Event 22107** On 08/24/2022, infant formula base, Lot # (b) (4), was analyzed by the 3rd party laboratory, (b) (4) which tested positive for *Cronobacter sakazakii*. This was the first production lot manufactured after the recalled product lots implicated in Recall # F-0291-2023. The root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones" **(Exhibit # 42)** was not followed during the work completed on back pressure (b) (4). The exposure of a product contact surface to the environment such as a processing line (b) (4) is highly risky, particularly when intervention procedures are not followed, and effective cleaning is not completed afterwards. This scenario poses the potential introduction of Cronobacter to the product (b) (4)." As noted in the investigation, the "entire lot of (b) (4) was rejected and shall be disposed of (b) (4)." **See Observation 1-2 and Exhibit #38.**

**Event 2299** On 07/21/2022, infant formula base, Lot (b) (4), was analyzed by 3rd party laboratory, (b) (4) . The analysis documented Aerobic Plate Count was out of specification with (b) (4) (b) (4). The root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones" **(Exhibit # 42)** was not followed during work on (b) (4) is (b) (4). The firm lacked documentation that sanitation practices were followed during the Event. Lot (b) (4) was later used to manufacture ByHeart finished product Lot (b) (4) **See Observation 1-2 and Exhibit #39.**

**Event 22108** On 09/02/2022 Lot # (b) (4) was manufactured. At 11:54 four plastic pieces were found on the (b) (4) after Tank (b) (4) and (b) (4) during cleaning after the production run. This equipment is located in the (b) (4) room.

Event #22108 was created to determine the source/cause of the plastic pieces. The investigation revealed that the most probable cause was that the (b) (4) Operator dropped a plastic sample cup in Tank (b) (4) on 09/01/2022 between 15:06 and 15:40 while the Operator was conducting a (b) (4) sample test. It was further determined via comparison of plastic sample cups used that an 8 oz plastic sample cup was the type dropped into Tank (b) (4).

The Event record states the 8 oz plastic cup weighs 29.7 grams on average and only 17.5 grams of plastic was recovered. All of the plastic pieces were not accounted for. **See Observation 1-2 and Exhibit #40-41.**

## Process Flow, Operations, and Product Coverage

**Work Orders**

*Begin Investigator Phillips*

During the inspection, I reviewed the work orders generated by the firm between June 1 to December 31, 2022. I found no concerns.

**(b) (4) Replacement**

Starting on 8-26-22, the firm replaced a (b) (4). The (b) (4) pumps the liquid bulk pre-blend for infant formula base from the process room located (b) (4) of the dryer (b) (4) on level (b) (4) (b) (4). The new (b) (4) was in operation on 31AUG2022 and infant formula base Lot # (b) (4) was manufactured. The firm was not in production again until 12 SEP 2022.

I reviewed the following records associated with this (b) (4) replacement:

"BlendHouse Change Control Assessment Form QUAL-518.01-FM (b) (4) " Date 26AUG2022, **See Exhibit #43**

"BlendHouse (b) (4) Installation Change Control Attachment 1, Process (b) (4) System Supplementary Test Document for Change Control 2022-025", dated August 30, 202, **See Exhibit #44**

"BlendHouse Project Risk Assessment Form QUAL-518.03-FM" for (b) (4) Date: 26AUG2022, **See Exhibit #45**

" (b) (4) (b) (4) New (b) (4) Rev 2 August 19, 2022 Proposal to: BlendHouse Proposal # (b) (4) -PROP-2022-03027", **See Exhibit #46**

My review found no concerns.

**Calibration**

During the inspection, I reviewed the calibration records generated by the firm between June 1 to December 31, 2022, for the (b) (4) for (b) (4) machine and the (b) (4) for (b) (4) machine. I found no concerns.

*End Investigator Phillips*

**Review of Production Records**

During the inspection I reviewed batch production records including ingredient and blend specifications, pre-operational verification tests, in-process production records as well as finished product microbiological testing results for the following products:

1). Lot # (b) (4) with date of manufacture (b) (4)

This was the (b) (4) for the recalled production lots as per the document titled "INFORMATION RELATED TO BYHEART RECALL (b) (4) provided by Ms. Sibert. **See Exhibit #47**

(b) (4) of minor ingredients (b) (4) 08:31-10:31. The event was recognized as a product contact intervention and treated accordingly.

2). Lot # (b) (4) with date of manufacture (b) (4)

## Process Flow, Operations, and Product Coverage

Tote (b) was rejected for scorch (Event 22104).

3). Lot # (b) (4) with date of manufacture (b) (4)

This lot number was the subject of the firm's event # 2299, where the firm's third-party laboratory, (b) (4), found Out of Specification (OOS) Aerobic Plate Count (APC) for a tote. **See Observation # 1-2, Exhibit #39**

4). Lot # (b) (4) with date of manufacture (b) (4)

I noted that the firm took (b) (4) ( (b) (4) ) to review/approve the production records.

5). Lot # (b) (4) with date of manufacture (b) (4)

Totes (b) (4) were rejected for metal, OOS fat, scorch respectively.

6). Lot # (b) (4) with date of manufacture (b) (4)

Totes (b) (4) were rejected due to scorch.

7). Lot # (b) (4) with date of manufacture (b) (4)

I found no concerns with this production record.

8). Lot # (b) (4) with date of manufacture (b) (4)

Totes (b) (4) were rejected scorch, foreign material and OOS fat.

9). Lot # (b) (4) with date of manufacture (b) (4)

Totes (b) (4) were rejected for scorch.

10). ). Lot # (b) (4) with date of manufacture (b) (4)

Batches (b) (4) were scrapped.

*Begin Investigator Phillips*

During the inspection I reviewed batch production records including ingredient and blend specifications, pre-operational verification tests, in-process production records, as well as, finished product microbiological testing results for the following products:

1). Lot # (b) (4) with date of manufacture (b) (4)

This lot number was the subject of the firm's event # 2287, where the firm found listeria during a swab collected on 17JUL2022 on a (b) (4). Additionally, Tote # (b) of this lot was rejected for out of specification of fat level.

2). Lot # (b) (4) with date of manufacture (b) (4)

This lot number was the subject of the firm's event #'s 2289 & 22138.

**Process Flow, Operations, and Product Coverage**

Event # 2289- Metal detector alarming

This event was occurring on 22JUL2022, 26JUL2022 and 02AUG2022. On 22AUG2022, the firm determined that there was a loose wire on the metal detector which made the detector alarm.

Event #22138-Recall of finished product for Cronobacter

This event was the subject of the recall for the finished product infant formula by ByHeart. The firm's impacted "bulk aggregate" that was subject to the recall was manufactured from (b) (4), which includes this lot manufactured on (b) (4)

3). Lot # (b) (4) with date of manufacture (b) (4)

I found no concerns with the production records.

4). Lot # (b) (4) with date of manufacture (b) (4)

I found no concerns with the production records.

This was the last day of production for the recalled production lots as per the document titled "INFORMATION RELATED TO BYHEART RECALL #91308" provided by Ms. Sibert. **See Exhibit #47**

*End Investigator Phillips*

*Begin Investigator Centi*

During the inspection I reviewed batch production records including ingredient and blend specifications, pre-operational verification tests, in-process production records as well as finished product microbiological testing results for the following products:

1).Lot # (b) (4), Date of Manufacture: (b) (4) (b) (4)

(b) (4) originally failed the (b) (4) swab test. The equipment was recleaned and passed the secondary (b) (4) swab test. I also noted this run required a product zone intervention due to product buildup in (b) (4) and Hatch (b) ( of the (b) (4) portion of the dryer. The event was recognized as a product contact intervention and treated accordingly.

(b) (4) fat percentage showed multiple out of range results (out of range by less than (b) ( % fat content). The out of specification results were investigated and deemed acceptable. Additional notes indicate production was advised of the results.

The analytical results for the measure of (b) (4) were consistently higher than the specified range of values. Event/CAPA 2284 was initiated to investigate the issue. The findings indicated an issue with an (b) (4). The equipment was re-assembled with correct (b) (4) position and addressed the issue.

2).Lot # (b) (4), Date of Manufacture: (b) (4), (b) (4)

I observed a noted deviation for a leaking nozzle in the dryer at time 21:32 lasting 2 hours and 32 minutes. Product surrounding this event was discarded. I reviewed the discarded product report as well as (b) (4) records documenting product hold times and diversions.

3).Lot # (b) (4), Date of Manufacture: (b) (4) (b) (4)

**Process Flow, Operations, and Product Coverage**

I noted numerous instances of crossed out and re-written data for such items as lot numbers and dates.

*End Investigator Centi*

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. Ms. Sibert and Ms. MacNaughton explained the minor ingredients are often batched ahead of time (as far ahead as (b) (4), as noted for Lot # (b) (4) and labeled. Employees have at times selected the wrong batch number of minor ingredients due to not paying attention and double checking which would result in having to "cross out" and update the information on the production records. Due to the amount of crossed out information that needs to be corrected, 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. It was noted during my review of Lot # (b) (4) with date of manufacture (b) (4) that the firm took (b) (4) ( (b) (4) ) to review/approve the production records.

Also noted during our review of these records was some forms do not document the time an activity was performed. For example " (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.

## 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:

A production aggregate for the infant formula manufactured by the firm on 1/1/23 would have a product code as follows: " (b) (4) ", where (b) (4) ; and the letters "**BR**" refer to the BlendHouse Reading, PA facility where the product was manufactured.

Note: The firm also has (b) (4) .

## COMPLAINTS

**Review of firm's complaint file(s)**

*Begin Investigator Phillips*

During the inspection, Ms. MacNaughton provided a copy of the firm's Excel spreadsheet (not titled) from the firm's " (b) (4) ." Ms. MacNaughton stated that this is the computer program the firm uses to input complaints received for their finished product powdered infant formula. The firm received 44 complaints

**Review of firm's complaint file(s)**

received between July 13, 2022, to September 1, 2022. Breakdown of the 44 complaints, four complaints involved treatment of the complainant in an emergency room and 15 complaints involved treatment of the complainant by a health care provider, e.g., doctor's office or urgent care clinic. 17 complaints did not provide the infant formula lot number, but through shipment records, the firm could determine the lot number for the product. And for 8 complaints, the firm received information that the complainant was fed more than one lot number of the infant formula.

I reviewed the complaints to first look for the following reported symptoms: sepsis, meningitis, seizures, fever, increased crying, reduced energy, and poor feeding. These symptoms are consistent with symptoms of *Cronobacter sakazakii* infection according to the Centers for Disease Control (CDC) . My review did not find any reported symptoms of sepsis, meningitis, or seizures. I then reviewed the complaints to look for the following reported symptoms: fever, increased crying, reduced energy, and poor feeding. I also included vomiting and diarrhea in case these two symptoms were reported first and may have overshadowed other symptoms more consistent with *Cronobacter sakazakii* symptoms. I found and reviewed 27 complaints.

One complaint involved a 3-day hospital stay but the diagnosis was a urinary tract infection. Eight complaints involved fever. Three of the eight complaints also included symptoms of low energy and reduced feeding. Review of the nine complaints found no follow-up or additional information was reported to the firm. The remaining 18 complaints involved vomiting and diarrhea and all found that there was no follow-up or additional information that was reported to the firm.

The firm determines the severity and related health hazard of complaints by using the "Risk Assessment Rating" matrix in their "Infant Formula Powder Food Safety Plan", QUAL-532-HACCP. See **Exhibit # 8, page 11** for the risk assessment rating matrix.

The matrix lists the consequence versus frequency. The consequence points are: fatality, serious illness, product recall, customer complaint, and insignificant. The frequency points are: common occurrence, known to occur, could occur, not expected to occur, and practically impossible. In the consumer complaint point in the matrix, for common occurrence, the firm gives the severity level of (b) (4), which is there (b) (4) food safety risk. For known to occur point, the firm gives the (b) (4) level of a consumer complaint (b) (4) foods safety risk. For the three remaining points for a consumer complaint, the firm gives a (b) (4) food safety risk.

Note- There are no exhibits associated with this EIR section.

Complaints received into the FDA

Complaints received into the FDA are filed under ByHeart Inc., FEI # 3022729623.

*End Investigator Phillips*

## RECALL PROCEDURES

*Begin Investigator Phillips*

Inspection found that the firm has written 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.

During the inspection, I asked Ms. MacNaughton if the firm has had to conduct a recall in addition to the recall initiated by ByHeart on December 11, 2022. Ms. MacNaughton stated that the firm has not conducted a recall of infant formula base. Ms. MacNaughton added that the firm conducts a mock recall (b) (4) .

*End Investigator Phillips*

**Firm Recall**

A voluntary recall of five batches of ByHeart Whole Nutrition Infant Formula, Milk Based Powder with Iron for 0-12 months in 24 oz containers, was issued on 12/11/2022 due to the potential for cross-contamination with Cronobacter sakazakii. The formula under voluntary recall was distributed directly to consumers in the US and was identified by the product batch on the bottom of the can. Recalled product batches were 22273 C1, 22276 C1, 22277 C1, 22278 C1, and 22280 C1 printed with use by 01 JAN 24 or 01JUL 24.

The firm investigated the *Cronobacter sakazakii* positive as documented in the Event 22138 record. The Event documented the following lot/bulk aggregates were associated with the recall: (b) (4) (b) (4) , in the investigation. However, the firm's parent company provided a record during this inspection titled, Information Related to ByHeart Recall #91308. **(See Exhibit # 47, pg.13)** This record identified lots (b) (4) were implicated. The firm failed to review and investigate these lots that were manufactured on (b) (4) , and the sanitation regarding the surrounding time period. The report provided by the firm's parent company also identified (b) (4) additional batches, (b) (4) (b) (4) that were manufactured that are not in the Event record. The firm failed to review lots on production dates (b) (4) (b) (4) .

A report provided by the firm's customer, (b) (4) , **See Exhibit #47, pgs. 14-18** identified (b) (4) totes implicated in the recall. The firm's investigation identified (b) (4) . Therefore, the firm failed to investigate (b) (4) totes of finished products. See table below.

Table Answer_63_1

The root cause investigation concluded that (b) (4) 3rd party contracted laboratory post-production sample handling and compositing was the most probable cause for the positive Cronobacter sakazakii. The corresponding corrective actions involved "additional preventative measures" at the 3rd party laboratory and "until the corrective actions are adequately addressed, ByHeart will be utilizing alternative laboratories for microbiological testing."

On 11/07/2022, (b) (4) , 3rd party contract laboratory provided a "OOS Result Investigational Report for Microbiological Testing" regarding the *Cronobacter sakazakii* findings in finished product

Lot (b) (4) which concluded that "Laboratory error was not found or supported." **See Observation 1-1 and Exhibits #47 and #48**

Further review of the Event showed the firm did not reinvestigate Events during the time frame of the recalled production lots to evaluate any possible connection.

**Tables and Figures**

Table: Answer_63_1

| Production No. | Corresponding Date | (b) (4) Investigation | BlendHouse Investigation | ByHeart Aggregate Lots |
|---|---|---|---|---|
| (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| Total Totes Identified | | | | Not Noted |

## OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

| **Inspection Observations** | |
|---|---|
| **Observation** | **1** |
| Citation Text | 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. |
| Observation Details | Specifically,<br><br>You were notified, on 10/17/2022, by your parent company, ByHeart, that product used in finished product Lot (b) (4) consisting of (b) (4) cases, in which your base product was a component of, tested positive for Cronobacter sakazakii (b) (4) (b) (4) This finished product is a non-exempt milk based infant formula for which you are the supplier of infant formula base. Your infant formula base product manufactured during a (b) (4) (producing Lots (b) (4) ) was ultimately associated with the finished product positive incident. |

**Inspection Observations**

1. In response to this Cronobacter sakazakii positive you conducted a root cause investigation which was documented in your "Event Reporting and Investigation Form" under "Event Number 22138." Your root cause investigation concluded that the 3rd party contracted laboratory post-production sample handling and compositing was the most probable cause for the positive Cronobacter sakazakii. Your corresponding corrective actions involved "additional preventative measures" at the 3rd party laboratory and "until the corrective actions are adequately addressed, ByHeart will be utilizing alternative laboratories for microbiological testing."

On 11/07/2022, the 3rd party contract laboratory provided a "OOS Result Investigational Report for Microbiological Testing" regarding the Cronobacter sakazakii findings in finished product Lot (b) (4) which concluded that "Laboratory error was not found or supported."

2. Additionally, review of your "Event Reporting and Investigation Form" under "Event Number 22107" found that on 08/24/2022, your infant formula base, Lot (b) (4) was analyzed by the 3rd party laboratory which tested positive for Cronobacter sakazakii . Your root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones was not followed during the work completed on back pressure (b) (4) . The exposure of a product contact surface to the environment such as a processing line (b) (4) is highly risky, particularly when intervention procedures are not followed, and effective cleaning is not completed afterwards. This scenario poses the potential introduction of Cronobacter to the product (b) (4) ." As noted in your investigation, the "entire lot of (b) (4) was rejected and shall be disposed of (b) (4) ."

Further, our record review of Event Number 2299 found that on 07/21/2022, your infant formula base, Lot (b) (4) was analyzed by your 3rd party laboratory. The analysis documented Aerobic Plate Count was out of specification with (b) (4) (b) (4) . Your root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones" was not followed during work (b) (4) (b) (4) is (b) (4) . You lacked documentation that sanitation practices were followed during the Event. Lot (b) (4) was later used to manufacture ByHeart finished product Lot (b) (4)

3. Further, between 7/20/2022 and 09/21/2022, our review of your environmental monitoring program, "Environmental Monitoring Positive Response Action Plan QUAL-510.06-WI" and associated implementation records confirmed the presence of Cronobacter spp. in your manufacturing environment. Examples of environmental monitoring findings that were not adequately addressed regarding root cause analysis include:

a. On 07/25/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the floor after removal of a skylight in the ceiling in a low hygienic area. Confirmation of Cronobacter sakazakii was received on 07/26/2022. Event # 2290 was created and determined the area was "briefly exposed to the outside environment for approximately 1 minute… The exposure to the outside highly likely introduced cronobacter." You do not document, reference, or link this in the root cause analysis evaluation of this Event within your "Environmental Monitoring Program (EMP) Review" of Event 22138. The

**Inspection Observations**

evaluation of this finding in Event 22138 reads, "… swabs were in specification < (b) (4) CFU/swab except for (b) (4) room…" Further, this Cronobacter spp. is linked to a water event (see Item 4 of this Observation).

b. On 08/01/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) base ( (b) (4) ) leading to the (b) (4) room. Confirmation of Cronobacter sakazakii was received on 08/05/2022. Also, during this time vector swabs were missed on one day 08/20/2022 and were restarted on 08/21/2022-08/30/2022. Event # 2298 was created, and it was determined the cleaning frequency of (b) (4) was inadequate and was changed to (b) (4) cleaning and also the (b) (4) was determined to not be an effective sanitizer on the door and was changed to (b) (4). Your Event 2298 record states this area is, "… not in foot traffic…". However, we observed that you move pallets of infant formula base at this door. Employees access this area via pallet jacks and/or forklifts. Furthermore, you did not evaluate employee foot traffic within your root cause analysis regarding Event 22138.

c. On 08/27/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) room. Confirmation of Cronobacter sakazakii was received on 09/04/2022. On 08/30/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) cart. Confirmation of Cronobacter sakazakii was received on 09/02/2022. Event #22106 was created, and it determined the cleaning frequency of this room is not effective. The frequency of cleaning was (b) (4) and was updated to "at least (b) (4)." Further noted was "operations conducts (b) (4) cleaning in the area after production; however, the cleaning instruction and documentation for records are also insufficient." Your root cause analysis of Event 22106 did not evaluate possible sources, such as the positive Cronobacter spp. finding in infant formula base on 08/24/2022 (see Item 2 of this Observation). Further, your Event 22138 documents evaluation of your EMP occurred 07/13/2022-08/27/2022. You did not include this finding in your Event 22138 record. Therefore, you did not adequately evaluate root cause analysis of during your EMP review.

d. On 08/30/2022, you collected environmental swabs. Third-party laboratory results received on 09/06/2022 documented (b) (4) presumptive positive for Cronobacter spp. You received these results on 09/06/2022 and you requested confirmation testing of the (b) (4) presumptive positives via email. The laboratory responded indicating (b) (4) of the samples were confirmed negative but provided no COA's or formal analyses data. They also indicated the remaining (b) (4) resumptive positive samples would receive confirmation testing. At this point you considered the initial (b) (4) as closed due to the lab stating they were confirmed negative. You proceeded to treat the remaining (b) (4) nconfirmed sites as positives and began (b) (4) of vector swabbing. An e il dated 12/27/2022 from your 3rd party laboratory documented confirmation testing had never been conducted on any of the (b) (4) presumptive positives. This indicates the (b) (4) presumptive positives referenced above were not subject to confirmation testing by the laboratory nor appropriate investigation and vectoring were done by your firm. The locations of these (b) (4) samples were in (b) (4) areas of your firm. You did not create an Event for this finding in accordance with your "Event Reporting and Investigation Procedure QUAL-509.05-WI." Therefore, no root cause investigation was performed and no corrective action was taken. Furthermore, you did not evaluate these findings in your Event 22138 record.

| **Inspection Observations** | |
|---|---|
| | e. On 09/21/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the floor of the (b) (4) room in a low hygienic area. We observed this area is used for employees to gown before entering the manufacturing environment. We observed employees' garments, such as pants, touch the floor while gowning. This sample was later confirmed to be undetected for Cronobacter spp. but one of the vector swabs collected was confirmed to Cronobacter (b) (4) on 10/07/2022. Event #22116 was created and determined the floors were only being sanitized with (b) (4) and "the use of (b) (4) as a cleaner prior to sanitizing with (b) (4) was not a requirement." Proper cleaning and sanitizing of surfaces include the removal of organic matter so that sanitization can occur to reduce pathogenic microbial growth. You did not include this sample in your EMP Review of Event 22138. Therefore, you did not evaluate the lack of cleaning agent used in a high foot traffic area regarding Event 22138.<br><br>4. Lastly, review of your "Event Reporting and Investigation Form" found that you identified two water events in where water from outside of your facility's building leaked into your manufacturing areas.<br><br>Specifically, on 12/15/2022, you identified a leak through a deteriorated sealant around a (b) (4) installed on level (b) (4) of the dryer (b) (4) of (b) (4) dryer (b) (4) Event #22179 was created and determined a worn sealant around the frame of the (b) (4) and heavy wind and rain all day on 12/15/2022 caused the leak. During swabbing conducted on 12/15/2022, four swabs were detected positive for Cronobacter spp. in four locations of the dryer (b) (4). They were 1). Level (b) dryer (b) (4) (b) (4) next to repainted surface, 2). Level (b) dryer (b) (4) next to repainted surface (a different swab point), 3). Level (b) dryer (b) (4) (b) (4) (b) (4) table, and (b) (4) Level (b) dryer (b) (4) (b) (4) table. At the time of the water event on 12/15/2022, bulk infant formula base powder lot # (b) (4) was being produced.<br><br>Specifically, on 06/23/2022, you identified a leak through a skylight installed on the roof of the (b) (4) processing room. Event #2270 was created and determined heavy rain on 06/23/2022 caused the leak. Cronobacter spp. was discovered by your environmental monitoring program after (see Item 3a of this Observation). At the time of the water event on 06/23/2022, bulk infant formula base powder lot # (b) (4) was being produced. |
| Citation Reference | 21 CFR 106.55(a) |
| Supporting Evidence and Relevance | **See Exhibits #47 for Event 22138 (Observation 1-1),** Event Reporting and Investigation form for Event 22138- **pgs 1-8,** (b) (4) OOS Result Investigation Report for Microbiology Testing- **pgs. 9-10**, Information Related to ByHeart Recall #91308 **pg. 13**, Report of Investigation from (b) (4) **pgs. 14-18**<br>**Exhibit #48 for Event 22139 (Observation 1-1),** (b) (4) COA showing positive *Cronobacter sakazakii* **pg. 4** for Recalled lot (b) (4)<br>**Exhibit #38 for Event # 22107 (Observation 1-2),** Event Reporting and Investigation form for |

| Inspection Observations | |
|---|---|
| | Event 22107- **pgs 1-7,** (b) (4) COA showing positive *Cronobacter sakazakii* in composite sample, **pg. 8**<br>**Exhibit # 39 for Event 2299 (Observation 1-2),** Event Reporting and Investigation form for Event 2299- **pgs 1-6,** (b) (4) COA showing OOS APC- **pg.13**<br>**Exhibit #42 for Event 2299 (Observation 1-2),** Procedure to document cleaning to perform after intervention into product contact areas **pg. 4**<br>**Exhibit # 19 (Observation1-3),** Environmental Monitoring Positive Response Action Plan QUAL 510.06 WI; documents which personnel will perform the cleaning and how many days vector sampling will occur - **pgs 2-3,**<br>**Exhibit # 23 for Event 2290 (Observation 1-3a),** Event Reporting and Investigation form for Event 2290- **pgs 1-6,** (b) (4) COA showing positive *Cronobacter sakazakii* **pgs. 7-26. See also Event # 2270**<br>**Exhibit # 25 for Event 2298 (Observation 1-3b),** Event Reporting and Investigation form for Event 2298- **pgs 1-9,** (b) (4) COA showing positive *Cronobacter sakazakii* **pgs. 10-77**<br>**Exhibit # 6, pg 2 for Event 2298** 61 Address Floor Plan with Traffic Pattern<br>**Exhibit # 26 for Event 22106 (Observation 1-3c),** Event Reporting and Investigation form for Event 22106- **pgs 1-8,** (b) (4) COA showing positive *Cronobacter sakazakii* **pgs. 9-15**<br>**Exhibit # 20 and 30 for 08/30/2022 Presumptive swabs with no Event # listed (Observation 1-3d),** Email from (b) (4) dated 09/06/2022 regarding (b) presumptive swabs- **pgs. 2-3,** Letter from (b) (4) dated 12/27/2022 regarding (b) presumptive never being further tested **pg. 5-76**<br>**Exhibit # 28 for Event 22116 (Observation 1-3e),** Event Reporting and Investigation form for Event 22116- **pgs 1-7,** (b) (4) COA showing positive *Cronobacter spp.* **pgs. 20, 50**<br>**Exhibit # 33 for Event 22179 (Observation 1-4)** Event Reporting and Investigation form for Event 22179- **pgs 1-12,** (b) (4) COA showing positive *Cronobacter spp.* **pgs. 60, 61, 66**<br>**Exhibit #34 for Event 22179 (Observation 1-4)** Letter from (b) (4) dated 01/18/2023 regarding (b) samples enriched in wrong media and were cancelled **pg. 19,** Second letter from (b) (4) dated 01/18/2023 regarding (b) samples that an isolate of the positives were not prepared **pg. 20,**<br>**Exhibit # 35 for Event 2270 (Observation 1-4)** Event Reporting and Investigation form for Event 2270- **pgs 1-10,** Email from (b) (4) for notification of presumptive positive *Cronobacter spp.* **pgs. 12, 86, 100, 118, 120, 130, 136, 141, 145, 151, 153 and 199**.<br><br>**Amendment:**<br>**To clarify ambiguity of dates listed on the FDA 483, the following is added for Observation #1, Supporting Evidence. Exhibit #47, Event Reporting and Investigation Form, Document Control No.: QUAL-509.05.01-FM, Version No.: 04, Event Number 22138 record, Page 1, section "When was the event discovered", the date of 10/17/2022 is the date ByHeart notified BlendHouse that infant formula base product was used in finished product Lot (b) (4), consisting of (b) (4) cases, which tested positive for *Cronobacter* spp.**<br><br>**To clarify ambiguity of dates listed on the FDA 483, the following is added for Observation #1, Supporting Evidence. Exhibit # 57- BlendHouse Email Correspondence, titled "RE: Closeout", dated 02/16/2023, Exhibit # 58 (b) (4), Certificate of Analysis (b) (4), dated 11/02/2022, and Exhibit # 59 (b) (4), Certificate of Analysis (b) (4), dated 10/18/2022, were added to the report. Exhibit # 57 was the initial email provided by the firm containing Exhibits # 58 and 59, which we recollected at the firm. Exhibit #58, Page 1, provides the date of 10/26/2022 as the date for the completion of the genome sequencing conducted by (b) (4), a third-party laboratory contracted by ByHeart which confirmed *Cronobacter sakazakii*. The COA dated 11/02/2022, documents (b) (4) notification to ByHeart of the confirmatory results. Exhibit # 59 documents preliminary results for Cronobacter sakazakii were complete on 10/15/2022. Exhibit # 58** |

| **Inspection Observations** | |
|---|---|
| | **supersedes Exhibit # 59 per the COA document control numbers documented in the upper right-hand corner of each record.**<br><br>**An Amended Form FDA483 was issued to the firm. This captured clarification surrounding the "10/26/2022" date that is documented in the above evidence.**<br><br>*Begin INV Phillips*<br><br>The environmental swabbing events concerning *Cronobacter sakazakii* positive swabs collected in the production environment during the recalled infant formula time frame, should have had additional investigations conducted. Since the recalled infant formula finished product was contaminated with *Cronobacter sakazakii* these events were imperative to further review.<br><br>INV Schafer also stated that she reviewed the events that occurred outside of the time frame (the discovery of some of the events led to practices that were occurring during the time of production of the recalled lots) of the infant formula recall to ensure that the events were fully investigated to protect the infant formula base contamination. These events could be contributing factors to contamination of the infant formula base, not only in the time frame of the recalled infant formula, but in future productions of the infant formula base.<br><br>Regarding the water events: INV Schafer pointed out that preventive maintenance procedures in the form of inspections of the firm's building and equipment installed on the buildings should be routinely conducted to preclude water from entering the production environment. INV Schafer added that water inclusion into the production environment is a causative factor in the contamination of the production environment and possibly the infant formula base with *Cronobacter*. Other pathogens, such as *Listeria*, are also equipped to survive and grow in environmental conditions where powdered infant formula is manufactured from liquid ingredients, such as milk.<br><br>*End INV Phillips* |
| Discussion With Management | *Begin INV Phillips*<br><br>Obs. 1<br><br>-Sub obs. 1 Cronobacter positive product<br><br>Ms. Sibert stated that BlendHouse and (b) (4) conducted a joint investigation, and both agreed that the third-party laboratory's post-production sample handling and compositing was the most probable cause for the positive Cronobacter Sakazakii. Ms. Sibert added that an additional investigation of the third-party laboratory found other information that was not provided to BlendHouse.<br><br>Ms. Sibert said that no Cronobacter Sakazakii was found in the bulk infant formula base that BlendHouse manufactured. She added that the Cronobacter Sakazakii was found in the finished product can, not in the infant formula base.<br><br>Ms. Sibert said that this observation is an unsupportive statement in that the Cronobacter Sakazakii positive was not from BlendHouse, and that this observation is for the wrong firm.<br><br>Ms. Kuehn asked how does this observation support the violation. She then asked why BlendHouse was implicated in the Cronobacter Sakazakii recall.<br><br>-Sub obs. 2a. Back pressure (b) (4) and Cronobacter positive product |

| **Inspection Observations** | |
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| | No comments were made<br><br>-Sub obs. 2b. (b) (4) work and high APC count<br><br>Ms. MacNaughton stated for the (b) (4), when the high APC count was found, BlendHouse rejected (b) (4) totes.<br><br>Ms. Sibert stated that this event happened at the end of the production run. She added that in the observation, all infant formula base was used. She continued to say that the infant formula base went to waste. Ms. Sibert said that the situation that occurred with this event is different than listed in the observation. She added that the FDA should have had more dialog with BlendHouse during the inspection.<br><br>-Sub obs. 3a. Skylight removed and (b) (4) cronobacter positive<br><br>Ms. Sibert said that the room where the skylight was removed is in a room segregated from the rest of the production facility. She added that no infant formula base was being produced during the skylight removal. She continued to say that when the skylight was removed, the area was cleaned and sanitized per BlendHouse SOP's and no longer poses a threat.<br><br>Ms. MacNaughton stated that through the firm's (employee) gowning, there would not be any possibility of a pathogen leaving the room with the skylight to the rest of the production facility.<br><br>-Sub obs. 3b. (b) (4) and (b) (4) cronobacter positive<br><br>Ms. Sibert stated that the cronobacter positive swab was in a (b) (4). She added that she disagrees that employee foot traffic or hand contact occurs in this area. She continued to say that BlendHouse's swabbing program is aggressive and that the swabbing events are well documented.<br><br>-Sub obs. 3c. Back wall of (b) (4) room and on (b) (4) cart and (b) (4) cronobacter positive<br><br>Ms. Sibert disagreed and stated that looping this event with the infant formula finished product recall is not correct, as this event occurred after the timeframe the infant formula base would have been manufactured.<br><br>Ms. Kuehn said she agreed with Ms. Sibert that this event is not within the timeframe of the recalled product.<br><br>Ms. MacNaughton said that BlendHouse cannot go back in time to conduct a root cause analysis. Mr. Valdez said that if these events were contributing factors to the recalled product, then BlendHouse would be able to wrap their heads around the observations. Ms. Sibert stated that she was disappointed with the FDA in that BlendHouse's words listed in their events were used in the observations. She then reiterated that the FDA should have had more dialogue with BlendHouse during the inspection. |

| **Inspection Observations** | |
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| | -Sub obs. 3d. (b)(4) swabs for cronobacter never confirmed as negative<br><br>Ms. Sibert stated that BlendHouse followed their procedures for this observation. She added that BlendHouse also followed up with the laboratory. She continued to say that the laboratory should be cited for this observation.<br><br>Ms. MacNaughton stated that citing CFR regulation, receiving a certificate of analysis from the laboratory is not needed. She added that she thought the concern was resolved during the inspection.<br><br>Ms. Sibert said when conducting the recall with the FDA, BlendHouse was truthful. She added that they were truthful with the records, but the FDA is using the records to cite BlendHouse.<br><br>The environmental swabbing events concerning *Cronobacter sakazakii* positive swabs collected in the production environment during the recalled infant formula time frame, should have had additional investigations conducted. Further review of these Events was imperative given the recalled infant formula finished product was contaminated with *Cronobacter sakazakii*.<br><br>-Sub obs. 3e. Only sanitizing (b) (4) room floor and (b) (4) cronobacter positive<br><br>Ms. Sibert asked whose clothes did we see touching the floor while gowning. INV Schafer said that the FDA does not name an employee on the Form 483. Mr. Valdez said that while he was in the (b) (4) room with INV Centi, saw INV Centi's pants touch the floor and requested that he re-gown. INV Centi's and a male employee's pants both touched the floor and INV Centi asked Mr. Valdez if they should change and retrieve new pants. Mr. Valdez confirmed they should.<br><br>It was explained the review of the events that occurred outside of the time frame (the discovery of some of the events led to practices that were occurring during the time of production of the recalled lots) of the infant formula recall to ensure that the events were fully investigated to protect the infant formula base contamination. These events could be contributing factors to contamination of the infant formula base, not only in the time frame of the recalled infant formula, but in future productions of the infant formula base.<br><br>It was discussed with the firm during in regards to the recall of the finished product infant formula, BlendHouse could have reviewed their events to look for correlations between the events and the recalled infant formula. It was explained that the Events within the time frame of the infant formula base that were produced, and subsequently used, in the production of the recalled infant formula finished product should have been prioritized to be reviewed, and thoroughly documented.<br><br>-Sub obs. 4 Water Events<br><br>Ms. Sibert asked what were the observations and added that product was rejected and is |

| **Inspection Observations** | |
|---|---|
| | quarantined.<br><br>Mr. Valdez said that the two observations are just two statements. He added that these two observations are not linked to the recalled product.<br><br>Ms. Sibert said the roof is inspected (b) (4)<br><br>Ms. MacNaughton said that movement is common due to temperature fluctuations and leaks happen.<br><br>Ms. Lou said that the dryer (b) (4) is inspection (b) (4) She added that the leak was found immediately. She asked if every water event will be an observation.<br><br>Ms. Sibert stated that the FDA483 talks about observations, but BlendHouse's resolutions are not in the FDA483. She added that the FDA choses not to include BlendHouse's corrective actions. Ms. Sibert said the observations are not rooted in visual observations, but rather in records BlendHouse provided to the FDA. Furthermore, she said the FDA found no issues with BlendHouse's environmental sampling.<br><br>Ms. Sibert stated that the observations on the FDA483 are non-truths and false statements. She asked why can't the information on the FDA483 be rescinded and why does it have to be in black and white. She continued to say that the FDA just conducted the inspection in May and June of 2022 and the inspection was okay. She said that this FDA483 looks like a template from (b) (4).<br><br>Ms. MacNaughton stated that she would have liked to have more dialog with the FDA regarding the FDA483 observations during the inspection. Ms. MacNaughton continued by saying that way, BlendHouse would have been able to explain more properly. During communications with FDA Compliance Officer Andrew Howard, Ms. MacNaughton said that she asked him what was the concern and he did not say.<br><br>Ms. MacNaughton said that procedures such as shoe changing procedures, no street clothes allowed in the production facility, high levels of protective clothing and (b) (4) (b) (4) to don the protective clothing should be listed on the FDA483. She continued to say that BlendHouse uses data and they do not have systemic employee events and maintenance events. She added that we said FDA inspections should be from a learning standpoint, but she does not see this on the FDA483.<br><br>Ms. Kuehn asked why is this considered a lack of control for water events. She added that the dates of the water events are outside the timeline for the product recall, and that they were corrected. Mr. Valdez stated that if a tornado were to rip off a (b) (4), would BlendHouse get an FDA483. Ms. Lou said that the firm has a leak control program to address these issues.<br><br>The firm did not provide any voluntary corrections at the closeout meeting.<br><br>*End INV Phillips*<br><br>**The amended Form FDA 483 was discussed with Ms. Kuehn, Mr. Valdez and Ms. (b) (6), (b) (7)(C), Counsel on 08/04/2023. The firm acknowledged the amendment and there were no further questions from the firm.** |

| **Inspection Observations** | |
|---|---|
| Correction Status | Not Corrected |
| **Observation** | **2** |
| Citation Text | 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. |
| Observation Details | Specifically,<br><br>On 09/02/2022 you manufactured Lot # (b) (4) . At 11:54 four plastic pieces were found on the (b) (4) after Tank (b) (4) and (b) (4) during cleaning after the production run. This equipment is located in the (b) (4) room.<br><br>You created Event # 22108 to determine the source/cause of the plastic pieces. Your investigation revealed that the most probable cause was that the (b) (4) Operator dropped a plastic sample cup in Tank (b) (4) on 09/01/2022 between 15:06 and 15:40 while the Operator was conducting a (b) (4) sample test. It was further determined via comparison of plastic sample cups used that an 8 oz plastic sample cup was the type dropped into Tank (b) (4).<br><br>You recovered 17.5 grams of plastic. Your Event record states 8 oz plastic cup weighs 29.7 grams on average.<br><br>You were not able to account for all plastic pieces. |
| Citation Reference | 21 CFR 106.30(a) |
| Supporting Evidence and Relevance | **See Exhibits #40, pgs 1-17**- copy of Event Report and Investigation for 22108 which includes pictures of plastic recovered during various CIPs conducted from 09/03/2022-09/12/2022. **Pgs 98 -114**, document CIPs/Cleaning/Activities performed<br><br>**See Exhibit #41, all pages** document CIPs/Cleaning/Activities performed (continuation from Exhibit #40) |
| Discussion With Management | *Begin INV Phillips*<br><br><u>Obs. 2 Plastic cup event</u><br><br>Ms. Lou stated that BlendHouse did account for the rest of the pieces. Ms. MacNaughton said she agreed that rest of the pieces were accounted for. Ms. Kuehn stated that the corrective actions are not being captured in the FDA483.<br><br>Ms. Sibert stated that this type of event does not continually occur, and that this was due to human error. She added that BlendHouse has (b) (4) and that this event was handled very aggressively. She continued to say that BlendHouse does not want to have a culture of employees not wanting to bring up accidents. She added that BlendHouse has adequate management and conducted training for this event.<br><br>Ms. Sibert stated that the FDA483 only lists this one event and only lists what BlendHouse did not do right. She added that this observation shows that BlendHouse did nothing. Mr. Valdez said that they conducted multiple (b) (4) to the system. Ms. Sibert said that BlendHouse was down for (b) (4) for this event.<br><br>Ms. Kuehn asked if this was an observation and that BlendHouse was trying to understand why. She added that BlendHouse wrote this up as an event, but they are challenged to respond to the FDA483 because of biased wording. INV Schafer said to firm management that they can respond to the FDA483 in writing within 15 days of the FDA483 issuance.<br><br>The firm did not provide any voluntary corrections at the closeout meeting. |

| Inspection Observations | |
|---|---|
| | *End INV Phillips* |
| Correction Status | Not Corrected |

## REFUSALS

| Inspection Refusals |
|---|
| No refusal |

## GENERAL DISCUSSION WITH MANAGEMENT

The following BlendHouse employees were present in person for the closeout and issuance of FORM FDA 483 Inspectional Observations, Marcellino Valdez; Plant Manger (FORM FDA 483 Inspectional Observations issued to Mr. Valdez), Fangfei Lou; Director of Quality, Katherine Rhoades; Regulatory Compliance Manager, (b) (6), (b) (7)(C) (b) (6), (b) (7)(C); Executive Assistant (Scribe). The following ByHeart employees were present in person for the closeout and issuance of FORM FDA 483 Inspectional Observations, Hilary Sibert; SVP of Quality, Heather MacNaughton, Senior Director of Regulatory Audit Compliance. Devon Kuehn MD, a ByHeart employee was present for the closeout and issuance of FORM FDA 483 Inspectional Observations via phone.

*Begin INV Phillips*

INV Schafer discussed with the firm during closeout regarding the recall of the infant formula finished product, BlendHouse could have reviewed their events to look for correlations between the events and the recalled infant formula. She further explained that the events within the time frame of the infant formula base that was produced and subsequently used in the production of the recalled infant formula finished product should have been prioritized to be reviewed first and thoroughly documented.

The environmental swabbing events concerning *Cronobacter sakazakii* positive swabs collected in the production environment during the recalled infant formula time frame, should have had additional investigations conducted. Since the recalled infant formula finished product was contaminated with *Cronobacter sakazakii* these events were imperative to further review.

INV Schafer also stated that she reviewed the events that occurred outside of the time frame (the discovery of some of the events led to practices that were occurring during the time of production of the recalled lots) of the infant formula recall to ensure that the events were fully investigated to protect the infant formula base contamination. These events could be contributing factors to contamination of the infant formula base, not only in the time frame of the recalled infant formula, but in future productions of the infant formula base.

Regarding the water events: INV Schafer pointed out that preventive maintenance procedures in the form of inspections of the firm's building and equipment installed on the buildings should be routinely conducted to preclude water from entering the production environment. INV Schafer added that water inclusion into the production environment is a causative factor in the contamination of the production environment and possibly the infant formula base with *Cronobacter*. Other pathogens, such as *Listeria*, are also equipped to survive and grow in environmental conditions where powdered infant formula is manufactured from liquid ingredients, such as milk.

*End INV Phillips*

Additional items were discussed with firm management throughout the inspection which included the following: 1.)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 needs to be corrected; 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. 2.)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 an SOP called a sampling tool a "vial" but in the Event it was referred to as a "sample cup" and a "plastic cup". 3.) It was noted during our review of these records was some forms do not document the time an activity was performed. For example "(b) (4) Checklist-Special Testing QUAL-510.03.03-FM", does not document the time the activity was performed. 4.)Lastly, it was noted that the firm does not consistently document downtime on the production records.

Firm management acknowledged these items and stated they would be addressed as necessary.

## ADDITIONAL INFORMATION

*Begin Investigator Phillips*

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

*Begin Investigator Phillips*

## SAMPLES COLLECTED

| Sample Number | INV1210278, INV1210279, INV1210280, INV1210281, 1210886, 1210887 and 1210888 |
|---|---|
| Description | *Begin Investigator Phillips*<br><br><u>Environmental swabs collected</u><br><br>On 12/21/22, INV M. Schafer, INV Centi and I collected 92 environmental swabs from the firm's "process room" (aka process room(b) (4) "(b) (4) dryer(b) (4)" (aka (b) (4) room on level(b) (4), and "(b) (4) filler (aka (b) (4) room(b) (4)), all located in the 61 Vanguard Dr. production facility. The 92 swabs were collected in the following manner: Two swabs were collected at the same 46 swabbing locations, but one swab was collected at one swabbing point and the second swab was collected right next to the first swabbing point.<br><br>46 swabs identified with sample # INV 1210278 were analyzed for *Cronobacter spp.*, and all were found negative. 46 swabs identified with sample # INV 1210279 were analyzed for *Salmonella spp.*, and all were found negative.<br><br>On 12/22/22, INV M. Schafer, INV Centi and I collected 90 environmental swabs from the firm's dryer(b) (4) on the following levels: (b) (4) (b) (4). Additionally, the firm's (b) (4) room was also swabbed. All of the swabbed areas are located in the 61 Vanguard Dr. production facility. The 90 swabs were collected in the following manner: Two swabs were collected at the same 45 swabbing |

| | |
|---|---|
| | locations, but one swab was collected at one swabbing point and the second swab was collected right next to the first swabbing point.<br><br>45 swabs identified with sample # INV 1210280 were analyzed for *Cronobacter spp.*, and all were found negative. 45 swabs identified with sample # INV 1210281 were analyzed for *Salmonella spp.*, and all were found negative.<br><br>The officially sealed original copy and unsealed working copy of discs containing the photographs taken during the sample collection are filed with the original collection report packet.<br><br>*End Investigator Phillips*<br><br>*Begin Investigator Centi*<br><br>During the inspection, the following samples were collected:<br><br>**Sample 1210886** – consisting of 14 whirlpac bags (470g-618g size range) of BlendHouse infant formula base retain samples for production lot "(b) (4) (b) (4)" collected as stored at the firm on 12/27/2022. Samples were collected using clean technique and sent to DENL for *Salmonella spp.* and *Cronobacter spp.* analyses.<br><br>**Sample 1210887** – consisting of 20 whirlpac bags (482g-704g size range) of BlendHouse infant formula base retain samples for production lot "(b) (4) (b) (4)" collected as stored at the firm on 12/27/2022. Samples were collected using clean technique and sent to NFFL for *Salmonella spp.* and *Cronobacter spp.* analyses.<br><br>**Sample 1210888 -** consisting of 30 whirlpac bags (290g-652g size range) of BlendHouse infant formula base retain samples for production lot "(b) (4) (b) (4)" collected as stored at the firm on 01/10/2023. Samples were collected using clean technique and sent to SFFL for *Salmonella spp.* and *Cronobacter spp.* analyses.<br><br>The above referenced samples were found to be Lab Class I.<br><br>*End Investigator Centi*<br><br>Completed Collection Reports (C/Rs) for the above referenced sample numbers can be found in FACTS. |

## EXHIBITS COLLECTED

| Exhibits | | |
|---|---|---|
| **Exhibit Number** | **Description** | **Number of Pages** |
| 1 | Finished Can Labeling | 2 |
| 2 | Marketing Material on Website | 18 |
| 3 | BlendHouse Organizational Charts | 3 |
| 4 | BlendHouse Corporate Organizational Chart | 1 |
| 5 | Floor Plan for 51 Vanguard Address Warehouse | 1 |

| Exhibits | | |
|---|---|---|
| **Exhibit Number** | **Description** | **Number of Pages** |
| 6 | Floor Plan 61 Vanguard Address Manufacturing Site includes traffic pattern | 2 |
| 7 | Dryer Floor Plan (b) (4) Levels | 5 |
| 8 | BlendHouse Food Safety Plan | 49 |
| 9 | BlendHouse Process Authority Letter | 3 |
| 10 | Master Sanitation Procedure SAN 800 SOP | 7 |
| 11 | Manual Cleaning PROD 300.02 WI | 4 |
| 12 | Packaging Area Cleaning PROD 300.05 WI | 6 |
| 13 | (b) (4) Tank (b) (4) (b) (4) Tank CIP SAN 802 SOP | 19 |
| 14 | CIP (b) (4) (b) (4) Room CIP SAN 805 SOP | 38 |
| 15 | Dryer Procedure CIP SAN 803 SOP | 21 |
| 16 | Metal Detection Verification PROD 307 SOP | 7 |
| 17 | Environmental Monitoring Program QUAL 510 SOP | 7 |
| 18 | Environmental Surface Sampling QUAL 510.07 SOP | 10 |
| 19 | Environmental Monitoring Positive Response QUAL 510.06 SOP | 7 |
| 20 | Event Reporting and Investigation QUAL 509.05 SOP | 8 |
| 21 | Master Environmental Swab Locations | 3 |
| 22 | Event 2268 Cronobacter Various Locations | 194 |
| 23 | Event 2290 Positive Cronobacter (b) (4) Processsing Room | 31 |
| 24 | Event 2297 Positive Listeria 51 Warehouse | 25 |
| 25 | Event 2298 Cronobacter (b) (4) | 157 |
| 26 | Event 22106 Cronobacter (b) (4) Room | 121 |
| 27 | Event 22115 Cronobacter 51 Warehouse | 132 |
| 28 | Event 22116 Cronobacter (b) (4) Room Oct 2022 | 92 |
| 29 | Event 22166 Cronobacter (b) (4) Nov 2022 | 51 |
| 30 | Aug 2022 Presumptive Swabs No Event Number | 97 |
| 31 | Good Manufacturing Practices QUAL 524 SOP | 32 |
| 32 | (b) (4) Sanitation Schedule | 4 |
| 33 | Event 22179 Water Event Dec 2022 Dryer Part 1 | 188 |
| 34 | Event 22179 Water Event Dec 2022 Dryer Part 2 | 181 |
| 35 | Event 2270 Water Event June 2022 (b) (4) Processing Room | 201 |
| 36 | Facility Water Leak Control and Cleaning MAIN 414 SOP | 6 |
| 37 | Roof Condition Email Nov 14 2022 | 1 |
| 38 | Event 22107 Positive Cronobacter Composite Sample Aug 24 2022 | 102 |
| 39 | Event 2299 APC OOS Jul 21 2022 | 67 |
| 40 | Event 22108 Plastic Pieces Sept 2022 Part 1 | 114 |
| 41 | Event 22108 Plastic Pieces Sept 2022 Part 2 | 101 |
| 42 | Interventions into Product Contact Zones PROD 310 SOP | 5 |
| 43 | (b) (4) Change Control Assessment Aug 2022 | 4 |
| 44 | (b) (4) Installation and Validation Aug 2022 | 17 |
| 45 | (b) (4) Risk Assessment | 4 |
| 46 | (b) (4) Replacement Proposal Aug 2022 | 6 |
| 47 | Event 22138 Recall | 140 |
| 48 | Recall COAs and Investigation COAs | 60 |
| 49 | Email Correspondence 01 27 2023 | 4 |
| 50 | Email Correspondence 01 26 2023 | 2 |

| Exhibits | | |
|---|---|---|
| **Exhibit Number** | **Description** | **Number of Pages** |
| 51 | Inventory as of 02 17 2023 | 17 |
| 52 | Event Tracker 06 01 2022 thru 12 21 2022 | 3 |
| 53 | BlendHouse Email Correspondence 01 19 2023 | 4 |
| 54 | BlendHouse Email Correspondence 01 21 2023 | 2 |
| 55 | BlendHouse Email Correspondence 01 22 2023 | 4 |
| 56 | BlendHouse Email Correspondence 01 24 2023 | 4 |
| **57** | **Blendhouse Email Correspondence 02 16 2023** | **3** |
| **58** | **COA 11 02 2022 Genome Sequence Confirmation** | **2** |
| **59** | **COA 10 18 2022 Cronobacter Sakazakii Confirmation** | **2** |

## ATTACHMENTS

| Attachments | | |
|---|---|---|
| **Attachment Number** | **Description** | **Number of Pages** |
| | Coversheet PDF Document for Inspection= 243701 | |
| | Inspection Narrative Report | 40 |
| | Coversheet PDF Document for Inspection= 243701 | |
| 1 | Issued 483 | 6 |
| 2 | FORM FDA 482 Notice of Inspection 51 Address | 3 |
| 3 | FORM FDA 482 Notice of Inspection 61 Address | 3 |
| 4 | Infant Formula Attachment B | 1 |
| **5** | **Issued 483- Amendment 1** | **6** |
| **6** | **UPS Tracking for Form FDA 483 Amendment 1** | **2** |
| **7** | **Cover Letter for Form FDA 483 Amendment 1** | **1** |

**SIGNATURE**

Melissa M. Schafer -S Digitally signed by Melissa M. Schafer -S Date: 2023.08.08 09:05:57 -04'00'

Melissa M. Schafer, Investigator

Tammy M. Phillips -S Digitally signed by Tammy M. Phillips -S Date: 2023.08.08 09:11:46 -04'00'

Tammy M. Phillips, Investigator

Alan Centi -S Digitally signed by Alan Centi -S Date: 2023.08.08 09:25:37 -04'00'

Alan D. Centi, Investigator