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SUMMARY

Inspection	
Operation ID and Name	224192:

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This comprehensive inspection of a manufacturer of infant formula was conducted in accordance with assignment FY22 Schedule of Inspections/Sample Collections for Infant Formula (7321.006) and Medical Foods (7321.002) Programs, DFPG #22-12, FACTS # 12167786. Coverage for this inspection was afforded under PAC 21006 Infant Formula Survey, PAC 03040 Food cGMP Inspection as a full scope PCHF inspection, PAC 03040F, and PAC 21005 Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Program and eNSpect Op ID 224192.

The production facility for this firm is located 61 Vanguard Drive, Reading, PA and is owned by the parent company, ByHeart. The production facility is approximately (b) (4) square feet. The dryer 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. See **Exhibit # 1, page 4 Facility Map of 61 Vanguard**

The firm currently operates (b) (4) . The hours (b) (4)

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

This was the firm's initial inspection. At the end of the current inspection, no FORM FDA 483- Inspectional Observations was issued but there were a few discussion items. These items included, 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. Also, 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, cronobacter and listeria. Review of the firm's production records revealed the following; the illegibility/incompletion of records. Productions records reviewed for the following days of April 30, 2022, and May 2, 4, 5, 9, 11, 12, 2022 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. Finally the specs were not always listed on QA testing forms. The (b) (4) Infant Formula Operation, (b) (4) -SOP states to allow the dryer to (b) (4) to ensure (b) (4) ; this (b) (4) time was not being recorded by the firm.

The inspection also covered product complaints, stability testing, equipment calibration, retained samples, sanitation SOP's, environmental monitoring, audits, water quality, employee training.

No pest activity was observed during the inspection and no samples were collected.

(b) (3) (A)

No refusals were noted.

This was reported was written by both Investigator Schafer and Investigator DiFiore and unless noted the section was written by Investigator Schafer.

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
03040	FOOD CGMP INSPECTIONS

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

ADMINISTRATIVE DATA

Administrative Data	
Firm	BlendHouse
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
Inspection Date(s)	5/23/2022, 5/25/2022, 5/31/2022, 6/1/2022, 6/7/2022, 6/8/2022, 6/9/2022

FDA Inspection Participants
Participant Name and Title
Gerard Difiore, Investigator
Melissa Schafer, Investigator

FDA Team Members Not Present for the Whole Inspection
CSO Gerard DiFiore was only present at the firm on the following days; June 7- 9, 2022.

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**
5/23/2022	Marcellino Valdez, Plant Manager
6/7/2022	Heather MacNaughton, Senior Director of Regulatory Audit Compliance
6/7/2022	Heather MacNaughton, Senior Director of Regulatory Audit Compliance
5/23/2022	Marcellino 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	Katherine Rhoades, Regulatory Compliance Manager
Person's Name and Title	Fangfei Lou, Director of Quality
Person's Name and Title	(b) (6), HR Coordinator
Person's Name and Title	Hilary Sibert, Senior VP Quality
Person's Name and Title	Heather MacNaughton, Senior Director of Regulatory Audit Compliance
Person's Name and Title	Kristen Fallon, Senior Quality Coordinator

Additional FDA Forms Issued	
Issued to	Marcellino E Valdez, Plant Manager
Additional Information	FORM FDA 482, Notice of Inspection was completed for both addresses of 61 Vanguard Drive and 51 Vanguard Drive Reading, PA 19606 on 05/23/22. See **Attachments # 1 and # 8.** The second FORM FDA 482, Notice of Inspection for the 51 Vanguard Drive address was issued after realizing the firm has the manufacturing process and outgoing product at the 61 Vanguard Drive address and the 51 Vanguard Drive address is for the firm's offices and incoming ingredients warehouse. The inspection including the tour of the facility was conducted at both addresses. On 06/06/2022 when Investigator Gerard DiFiore joined the inspection another set of FORM FDA 482, Notice of Inspection were issued to Heather MacNaughton, Senior Director of Regulatory Audit Compliance for both addresses. See **Attachment #6 and #7.** See **Exhibits #2-4** for the firm's organizational chart and the corporate organizational charts. **Note: Due to system issues under the Attachment list at the end of this report, there are some misnumbering of attachments, there are no attachments 2, 3 or 4.**

FDA Correspondence Recipient	
Person's Name and Title	Marcellino E Valdez, Plant Manager
Email Address	mvaldez@theblendhouse.com
Mailing Address	51 Vanguard Drive Reading, PA 19606
Phone Number	(610) 582-2170 Ext 2150

Guidance Documents Given to the Firm
Marcellino Valdez, Plant Manager and Heather MacNaughton were provided via email the following guidance documents: Firm Resources (QR Codes) and the link to use for FSMA Technical Assistance.

HISTORY

(b) (4)		
	The firm is Kosher, Organic, Grassfed and (b) (4) certified.	
Hours of Operation	The firm currently operates (b) (4) . The firm currently employs approximately (b) (4) full time employees.	
New or Current Firm Legal Name	BlendHouse LLC	
Legal Status	LLC	
State of Incorporation	------	
Additional Information	ByHeart is the parent company of BlendHouse, the corporate office address is 131 Varick Street, New York, NY 10013. No product is manufactured at the corporate office, this location is only offices. ByHeart purchased the 61 Vanguard Drive Reading, Pa facility in September 2019 from Balchem Corporation. BlendHouse began their trial runs of production for the pre-blend infant formula in July 2021 and in September 2021 the commercial runs were started with the product available for the public to purchase via internet from ByHeart in March 2022. Since the purchase of this	

	facility, one of the (b) (4) dryers was removed, all equipment not being used was removed and one wall was erected. ByHeart has (b) (4) has been earmarked to add a (b) (4) and other improvements to the facility. The time line of these changes is still in the development stage. The production facility is approximately (b) (4) square feet. The dryer building is approximately (b) (4) square feet of the (b) (4) total square feet and is (b) (4) high. The warehouse and offices are located next door at 51 Vanguard Drive, Reading, PA and is leased not owned. The warehouse facility is approximately (b) (4) square feet.

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	*Begin Investigator Schafer* The firm's top ingredients suppliers are (b) (4) The product manufactured by BlendHouse is referred to by the firm as a "bulk pre-blend" because the product does not include all of the ingredients in the final product form that is sold to consumers via internet. The bulk pre-blend is shipped in bulk totes to (b) (4) (b) (4) . The (b) (4) (b) (4) the bulk pre blend and packaged in metal cans labeled as infant formula. The canned product is sent to (b) (4) with a temporary plastic lid on the container. (b) (4) removes the temporary plastic lead 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). *End Investigator Schafer*

Product Covered	BlendHouse operates as a manufacturer of cow's milk based, dried, powdered infant formulas that are 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 shipped in bulk totes to (b) (4) ((b) (4)) where it is (b) (4) 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 lead 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)

Begin Investigator DiFiore

BlendHouse operates as a manufacturer of cow's milk based, dried, powdered infant formulas that are distributed under the brand "ByHeart". **See Exhibits # 5, #6 and #7 for product label and marketing material.** ByHeart is the parent company of BlendHouse and is referred to as the "manufacturer of record". 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 shipped in bulk totes to (b) (4) where it is (b) (4) (b) (4) 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 lead 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.

The firm also operates as a manufacturer of vitamin E and (b) (4) powders. These products were not being manufactured during this inspection and were not covered as part of this inspection assignment.

End Investigator DiFiore

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 the operations, production and maintenance. Mr. Valdez has been with the company for approximately 7 months and reports to Marcus Jordan, VP of Supply Operations-ByHeart.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Most Responsible Person Present, FDA Correspondence Recipient, Accompanied During the Inspection
Email Address	mvaldez@theblendhouse.com
Mailing Address	51 Vanguard Drive Reading, PA 19606
Phone Number	(610) 582-2170 Ext 2150
Person #1	
Person's Name and Title	
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Most Responsible Person Present, FDA Correspondence Recipient, Accompanied During the Inspection
Person #2	
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 PCQI person and completed that training in November 2017. Ms. Rhoades has been with the company for 2 years 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 #3	
Person's Name and Title	Fangfei Lou, Director of Quality
Roles and Authorities	Ms. Lou is responsible for quality systems and compliance. Ms. Lou has been with the firm for approximately 2 months. Ms. Lou 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 #4	
Person's Name and Title	(b) (6) HR Coordinator
Roles and Authorities	(b) (6) is responsible for recruitment and interviewing of new hires, payroll and onboard

	and continuous training for all employees. (b) (6) was the scriber for the the firm during the inspection.
The following are applicable to this person	FDA Credentials Displayed to This Person, Accompanied During the Inspection
Person #5	
Person's Name and Title	Hilary Sibert, Senior VP Quality
Roles and Authorities	Ms. Sibert is responsible for quality systems, regulatory compliance and supply chain. Ms. Sibert is located at the firms corporste 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
Person #6	
Person's Name and Title	Heather MacNaughton, Senior Director of Regulatory Audit Compliance
Roles and Authorities	Ms. MacNaughton is responsible for corporate level audits, supply chain contractors, internal audits and document control. Ms. MacNaughton is also one of the firm's PCQI and completed her training in March 2016. Ms. MacNaughton primary office is at the corporate address in New York but does split her time between New York and 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
Roles and Authorities	Ms. Fallon is responsible for quality systems, complaints and events/deviations. 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) at the firm per month.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #8	
Person's Name and Title	Ron Belldegrun, CEO and Co-Founder
Roles and Authorities	Mr. Belldegrun oversees all the day to day operations of the firm. Mr. Belldegrun is located at the firm's corporate office in New York. Mr. Belldegrun was only present during the closeout meeting via video conference.
The following are applicable to this person	
Person #9	
Person's Name and Title	Marcus Jordan, VP Supply Operations
Roles and Authorities	Mr. Jordan is responsible for supply chain and fulfillment. Mr. Jordan is located at the firm's corporate office in New York. Mr. Jordan reports to Ron Belldegrun, CEO and Co-Founder. Mr. Jordan was only present during the closeout with the firm via video conference.
The following are applicable to this person	

FIRM'S TRAINING PROGRAM

Begin Investigator Schafer

I reviewed the training of three different individuals who work in different hygiene areas of the firm. The first employee (b) (6) a dryer operator, this area is considered a (b) (4) area. The second employee (b) (6).) is a batch operator this area is considered a (b) (4) area. The third employee (b) (6).) is a packer and this area is considered to be a (b) (4) area. All employees receive training in areas such as safety, GMPs, documentation, adulteration, food defense, recall, HACCP, allergens, etc. Employees further receive specialized trained for their specific job. No discrepancies were noted from their training records. The firm also provides continuous training for all employees (b) (4) and as needed for any situations that may

arise. See **Exhibit # 1** for the location and explanation of the different hygiene zones.

End Investigator Schafer

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

Begin Investigator DiFiore

Manufacturing Design and Operations

A walk-through inspection of the firm's warehouse, located at 51 Vanguard Drive, Reading PA, and manufacturing facility, located at 61 Vanguard Drive, Reading PA was initially conducted on 05/23/22 and again on 6/8/22 when I joined the inspection.

Warehouse Inspection

The warehouse is a (b) (4) square foot facility that is currently not temperature controlled. During the walk-through inspection we observed the firm was in the process of having (b) (4) installed for (b) (4) system that was scheduled to go online approximately one month from the date of the inspection. The firm currently monitors the temperature and humidity from (b) (4) locations within the warehouse. 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 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 will visually examine the product against the purchase order to determine that the correct product and quantity was received from the correct manufacturer. The firm currently does not receive any ingredients that have a SAHCODHA hazard requiring a supply chain control. The list of approved suppliers is managed by ByHeart which is set up in the firms (b) (4) system. At the time of receiving all product is physically moved to a designated quarantine area and entered into the firm's (b) (4) system in a quarantine status. The (b) (4) system will notify quality for the need for QC testing.

The received material is transported from the 51 Vanguard Drive facility in a firm owned truck to the 61 Vanguard St facility where material for sampling is collected in the "Ingredient Dispensing Room" following the firm's written procedures for collecting materials for product testing.

After sampling the material 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 case the product will be identified and held in the warehouse pending disposition by quality. Each 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 fluid milk, in-process bulk "infant formula" as well as (b) (4) and (b) (4)

At the time of the plant inspection on 06/08/22 the '(b) (4) " equipment was in a CIP mode and the dryer was not operating. We reviewed the processing equipment and Heather MacNaughton explained the production process to us which was the same as the process flow diagram

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

Individual ingredients are weighed in the Ingredient Dispensing Room (b) (4) verifying the identity and amount of each ingredient that is weighed. The weighed ingredients are documented on a "Dispensal Sheet". The ingredients are placed in bags and identified with the following information: part number; firm's lot number; vendor lot

Process Flow, Operations, and Product Coverage

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. Bulk ingredients are added to a (b) (4) hopper. The ingredients are pumped to a mixing tank, (b) (4) water is added and the mixed and then pumped to (b) (4) holding tanks. The firm has a (b) (4) process and therefore the liquid blend does not (b) (4) (b) (4) . The blend is pumped to a homogenizer and then to a (b) (4) tank. The firm monitors the temperature of the liquid in the (b) (4) tank (specification is ≥ (b) (4) °F). The liquid blend is pumped to a (b) (4)) and pasteurized at (b) (4) °F for ≥ (b) (4) . The firm records the temperature on a (b) (4) chart and Production will visually monitor and record the parameters of the (b) (4) every (b) (4) including (b) (4) (min (b) (4) °F); (b) (4) (b) (4) (min (b) (4) F); (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 pumped via a (b) (4) pump 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: conditions of the dryer operations (b) (4) including inlet temperature (operating range (b) (4) F); (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 (b) (4) then a metal detector. The firm inspects the sifter (b) (4) and (b) (4) located below the sifter for the presence of foreign material (b) (4) . The firm conducts a pre-op check on the metal detector and then (b) (4) The powder is fed into (b) (4) on pallets. The inner linking of the (b) (4) are heat sealed and identified with a label and quarantined pending release (or rejection) by Quality Control. After release the product is shipped in refer trucks to the firm's third-party canning facility (or a third-party warehouse).

The firm typically manufactures (b) (4) per day. A production aggregate typically consists of (b) batches (production units).

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

The firm does not currently use any rework.

The inspection included a comprehensive review of the production process monitoring records for production aggregate (b) (4) that was selected from a list of production aggregates used in canned lot # (b) (4) . The review covered the following items related to this production aggregate: master batch record(s); identity and strength testing of pre-mix nutrients and individual nutrients received by the firm; in-process bulk microbiological and nutrient test results; sanitation monitoring records for equipment used to manufacture the production aggregate including (b) (4) and (b) (4) testing; finished product (canned) microbiological and nutrient test results; results of out of specification/deviation investigations conducted by the firm.

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". The firm was not manufacturing pasteurized dried milk powder at the time of the inspection. 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. The firm provided me with a copy of the most recent Milk Plant Inspection Report for an inspection conducted on 04/22/22. All inspected components of the pasteurization equipment were reported as "in compliance" with the exception of a crack noted on a (b) (4) located between two pipes on the (b) (4) of the (b) (4) dryer. The item was replaced by the firm on the same day of the inspection.

Water Quality/Water Testing

The firm uses (b) (4) water provided by (b) (4) . The water does not (b) (4) , however, (b) (4) . The firm uses (b) (4) source water for cleaning/sanitizing operations. The firm has a (b) (4) and (b) (4) is used for process water, and also for rinse water for equipment on the "(b) (4) " side of manufacturing operations. The (b) (4) is serviced (b) (4) by a third-party company.

The firm has a written procedure for water testing entitled, "Water Analysis Program" (QUAL-508-SOP) that was reviewed without comment. The firm's water testing program describes the frequency and location of collection of water for testing for APC;

Process Flow, Operations, and Product Coverage

coliforms; yeast and mold ((b) (4)); Coliforms, E. coli, yeast and mold ((b) (4)); organic contaminants; inorganic contaminants; (b) (4) ; microbiological contaminants; (b) (4) ((b) (4)). Third-party, (b) (4) water quality test results for a sample of water collected from a batching room (b) (4) were reviewed without comment or observation.

Cleaning and Sanitation

The "(b) (4) of production equipment is cleaned (b) (4) and the "(b) (4) " equipment is cleaned at least (b) (4) , or more frequently if scorched particles are forming on the inside of the dryer.

The firm verifies the effectiveness of cleaning on the (b) (4) by conducting visual inspection and examination of the equipment, and by conducting (b) (4) swabbing of food contact equipment and surface allergen testing on multiple pieces of equipment and rinse water for (b) (4) regardless of when (b) (4) was last processed.
The firm has a written sanitation SOP for cleaning and sanitizing the (b) (4) dryer, (b) (4) and sifter that entitled "(b) (4) Dryer Procedure –(b) (4)" (PROD-300.25 QI) that was reviewed without comment. After cleaning and sanitizing the dryer, the dryer is (b) (4) . After (b) (4) the firm purges (b) (4) pounds of dried product. The product is packaged in a (b) (4) and sent to waste.

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

In-Process Bulk Testing

The firm (b) (4) , collects (b) (4) samples of in-process bulk during filling of (b) (4) (b) (4) . The (b) (4) samples are designated as "(b) (4) " samples. (b) (4) samples are composited and for microbiological samples and (b) (4) is sent to a third-party lab for nutrient analysis. The sample sizes for each production aggregate are as follows: Cronobacter (b) (4) g; Salmonella spp. (b) (4) g; Listeria monocytogenes (b) (4) g. The in-process bulk is also tested for the following: yeast and mold; Staphylococcus aureus; (b) (4) ; B. cereus; E. coli and Enterobacteriaceae. The firm also tests in-process bulk for all (b) (4) nutrients. I reviewed the firm's third-party test results for in-process bulk material for both microbiological and nutrient testing for the production aggregate covered during the inspection (Production aggregate (b) (4)). The test results were compared to the firm's specifications and all microbiological and nutrient testing were within specifications.

Additional in-process testing of in-process bulk include pH, fat, (b) (4) , (b) (4) moisture, reconstitution, taste, and color.

Finished Product Testing

Finished microbial testing is conducted from (b) (4) cans collected across the batch at the time canning operations are conducted. The samples are sent by (b) (4) to (b) (4) for testing for Salmonella (Method: AOAC 2004.03) and Cronobacter (Method: FDA BAM Chp. 29). 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) (cans collected across the batch at the time canning operations are conducted. The samples are sent by (b) (4) (b) (4) to (b) (4) for nutrient analysis for all (b) (4) nutrients. I reviewed the firm's third-party finished product test results for both microbiological and nutrient testing for the production aggregate covered during the inspection (Production aggregate (b) (4)). The test results were compared to the firm's specifications and all microbiological and nutrient testing were within specifications.

Stability Testing

According to Heather MacNaughton, since BlendHouse began manufacturing operations, there have been (b) (4) canning campaigns in 2021 that were conducted by the firm's contract canner from approximately (b) (4) production aggregates manufactured by BlendHouse. The product was canned (b) (4) . The firm has conducted stability testing on these (b) (4) lots of finished/canned infant formula (b) (4) for all (b) (4) nutrients, including testing of other nutrients added by manufacturer (e.g., (b) (4) , lactoferrin), with the exception of minerals. See **Exhibit # 10** for table of table of the stability test results for the products canned on (b) (4)

Process Flow, Operations, and Product Coverage

Product Release

According to Health MacNaughon, BlendHouse is responsible for releasing the product after each stage of manufacturing, including after bulk in-process material is manufactured by BlendHouse, after blending and canning is conducted by (b) (4), (b) (4) and after final packaging by (b) (4). For each production aggregate of in-process bulk, Quality Assurance conducts a review the production process related monitoring records and documents the review on the "Blend House Master Batch Record Checklist" before releasing (or rejecting) the production aggregate for canning. See **Exhibit #11** for "Master Batch Record Checklist" for production (b) (4) covered during the inspection. After final review and approval of the production aggregate the firm issues a Certificate of Conformance to (b) (4)) for dry blending and canning.

After canning operations are completed, BlendHouse reviews the canning batch records and finished product testing results, and if the BlendHouse determines the product has met its specifications, BlendHouse will provide an Authorization Release Certificate to (b) (4) so product can be released for shipment to (b) (4) for final packaging (collar, lid and scoop placement).

After final packaging is completed, BlendHouse will review (b) (4) batch production records, and if the packaged batch meets its specifications, BlendHouse will submit an Authorization Release Certificate to (b) (4), which authorizes (b) (4) (b) (4) to distribute the product.

Product Retains

The firm's contract blender and canner collects (b) (4) of canned product per (b) (4) (which is equal to (b) (4) (b) (4) and the product is shipped to a third party logistics company and kept for (b) (4) past the product expiration date.

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

Complaints

The firm has a written procedure for handling complaints (QUAL-2503-POL) that was reviewed without comment.

ByHeart is responsible for receiving product complaints and BlendHouse is responsible for conducting complaint investigations, corrective and preventive actions (CAPAs) and trending of complaints.

Complaints are categories as either health related or quality complaints. The firm has established thresholds for each complaint type (health-related, quality related, foreign body, severe or unusual) that requires further investigations.

The Chief Medical Officer (CMO) of ByHeart is responsible for evaluating all health-related complaints and making a determination if there is a potential for a health hazard, if there is potential for serious adverse health consequences, or if FDA's reportability criteria are met.

BlendHouse's Quality Management reviews all health-related complaints for batch information accuracy and to determine the thresholds for each complaint case. Investigations for each health-related complaint includes a batch record review, review of finished product release test results, a review of any deviations related to a production aggregate used to manufacture the finished product.

(b) (4) and (b) (4) complaint reports including trending are provided to the Senior VP of Quality

Health related complains are reviewed (b) (4) for each production aggregate to identify any "safety signals" for a production aggregate.

According to Heather MacNaughton, the firm has not had any complaints that meet the definition of a reportable event.

I reviewed all health related and product quality complaints (in a spreadsheet format) received since 3/28/22, which was the date the

Process Flow, Operations, and Product Coverage

firm received its first complaint). The firm received a total of 194 health related complaints and 188 product quality related complaints.

I reviewed the results of the firm's complaint investigations for three complaints where the complainant reported an allergic reaction (CN-000054; CN-000113 and CN-000340) and two complaints where the complainant reported hair in the product (CN-000340 and CN-000331). My review of the firm's complaint investigations revealed the firm followed its written procedure, and that, where the complainant provided complete information related to the canned lot, the firm's investigation determined that the batches related to these complaints were within their specifications.

Audits

According to Heather MacNaughton, Senior Director of Regulatory Audit Compliance, the firm conducts (b) (4) GMP audits to ensure employees are following GMPs such as wearing of appropriate personal protective equipment and are following appropriate hygienic zone practices. Healther MacNaughton conducts audits of the firm's quality control procedures per 21 CFR 106.92 and has a written audit plan per 21 CFR 106.94. I reviewed the firm's audit schedule for internal audits conducted from January-May of 2021 without comment, however the firm's written audit plan was not reviewed.

In preparation for operating as an infant formula manufacturer, the firm had a third-party audit conducted on 4/20/21 to review production process and microbiological hazards. The audit was conducted by (b) (4) . The firm also had a third-party audit conducted from 6/2/21-6/3/21 by FDA/QRC to assess the firm's compliance with 21 CFR 106 and 31 CFR 107.

Calibration of Scales

The firm has a program for equipment calibration that alerts the firm when equipment is due for calibration. The firm uses a third-party metrology firm for calibrating scales/balances. I reviewed the most recent third-party calibration records for the (b) (4) and (b) (4) scales located in the ingredient dispensing room and both scales were within calibration.

End Investigator DiFiore

Begin Investigator Schafer

Metal Detection

I reviewed the firm's Metal Detector Check Procedure. PROD-307-SOP. The firm utilizes the following metal detector (b) (4); (b) (4) Metal detection checks are conducted (b) (4) (b) (4) I noted no discrepancies will reviewing production records from April 30, 2022, and May 2, 4, 5, 9, 11, 12, 2022.

Environmental Monitoring Program

The following SOPs for Environmental Monitoring were reviewed; "Environmental Monitoring Program" (QUAL-510-SOP), "Environmental Surface Sampling" (QUAL-510.07 WI) and "Environmental Monitoring Positive Response Action Plan" (QUAL-510.06-WI).

The firm's written procedure "Environmental Surface Sampling" (QUAL-510.07 WI) describes the method for aseptic collection of environmental samples and testing of sponge, swab samples from environmental surfaces and the corrective actions the firm will take in the event of a positive finding which includes vector swabbing.

The firm collects the following swabs (b) (4) Cronobacter ((b) (4) swabs); Salmonella ((b) (4) swabs); Listeria ((b) (4 swabs); and Enterobacter ((b) (4 swabs). Pathogen testing is not performed on Zone (b) surfaces only indicator organisms are tested for this zone. An exception to this would be if the product was determined to have been contaminated with a pathogen. Zones (b) (4) are tested for indicator and pathogens. The sample locations are picked randomly with each site sample being tested at least (b) (4) The majority of the firms swabs are collected from Zones (b) (4) The firm's sample sites and test results are recorded on their "Master Environmental Log."

Process Flow, Operations, and Product Coverage

The firm provided a copy of their tracking for positive swabs, see **Exhibit # 12.** The firm had one positive finding of Listeria spp. on the week of 02/17/22 located on the inside of an exterior door and a positive finding for Cronobacter on the week 05/05/22 located in a floor drain in a floor adjacent to the dryer.

The positive Listeria finding was located on the interior side of an exterior door that was replaced on 02/11/22. The firm had the positive sample Listeria sample speciated and the lab provided the following possible organisms L. saeligeri; L. ivanovii; L.welshimeri. On 02/18/22, 02/19/22, 02/20/22, 02/21/22 and 02/22/22 the firm conducted vector swabbing (b) (4) around the area of the initial presumptive positive and there were no additional positive findings. The firm's root cause investigation determined that the potential source of Listeria spp. was from the contractor who replaced the door. The firm's corrective action included requiring visitors entering the facility to wear rubber boot covers (the previous requirement was for cloth boot covers) and the creation of a project risk assessment procedure whereby the firm will assess the potential hazards related to future projects and the mitigation factors the firm can take to avoid potential hazards.

The positive Cronobacter finding was located in a floor drain in the floor adjacent to the dryer identified as sample site (b) (4) by the firm. The area was recleaned and sanitized and the firm began re-swabbing the site. On 05/05/22, (b) (4) and (b) (4) the firm conducted vector swabbing (b) (4) around the area of the initial presumptive positive and there were no additional positive findings.

During the walk-through inspection of the facility a visual inspection of the door and floor drain areas where the firm had positive environmental swab results for Listeria and Cronobacter was unremarkable.

Water Event

The firm experienced a water event 05/04/2022. According to the firm during a heavy rain period a water leak from the roof near the dryer occurred. The firm explained the leak was above the bulk packaging (b) (4) ; the roof hatch handle and the overlap where the two halves meet were repaired on the same day. The repair was confirmed by reviewing the work order certificate.

The firm's "Facility Water Leak Control" MAIN-414-SOP describes the area of the water event is to be cleaned and sanitized after the leak has been controlled and swabs are to be taken for (b) days.

The firm does not test for the same (b) (4) pathogens as in their environmental program. The firm only tested for Salmonella and Listeria for this water event . The firm conducted the first day swabs on 05/04/22, (b) (4) and day (b) (4) swabs were not taken until (b) (4) (13 days later). The firm acknowledged they realized day (b) (4) swabs were not done when the records pertaining to the water event were requested.

Dryer

I reviewed the firm's (b) (4) Infant Formula Operation" PROD-304-SOP. The SOP provides the detailed instructions for the start up of the dryer after a CIP cycle. Al (b) (4) temperatures are set a (b) (4) F for (b) (4) , furthermore "(b) (4) (b) (4) ."

I asked the firm to provide the documentation of this (b) (4) time frame. Ms. MacNaughton explained the firm does not record this (b) (4) time frame. Ms. MacNaughton further explained the dryer is running at high temperatures and (b) (4) (b) (4) On 06/08, firm realized there is a record called (b) (4) which actually captures this info even though firm was not confirming. Ms. MacNaughton confirmed this record will now be included in batch records.

The dryer is inspected (b) (4) by an outside vendor who specializes in this type of equipment. The last inspection was conducted on 03/15/22, see **Exhibit # 13** for a copy of this report.

End Investigator Schafer

MANUFACTURING CODES

Begin Investigator DiFiore

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 current (b) (4) infant formula manufactured by the firm on 1/1/22 would have a product code as follows: "**001 22 D1 P2 203 VA-BR**", where (b) (4) ; and the letters "**BR**" refer to the BlendHouse Reading, PA facility where the product was manufactured.

End Investigator DiFiore

RECALL PROCEDURES

Begin Investigator Schafer

The firm has a written recall plan which was reviewed with no discrepancies noted. The firm also conducts mock recalls (b) (4) (b) (4) The most recent mock recall as conducted on 04/21/22. The mock recall was for organic lactose received on 01/18/22 and was completed in under 2 hours with no discrepancies noted.

End Investigator Schafer

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

Begin Investigator Schafer

The firm did not follow their "Facility Water Leak Control " MAIN-414-SOP for a water event. 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) and (b) was 13 days. Also, 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, cronobacter and listeria.

Discussion with Ms. McNaughton regarding these issues revealed the following; Ms. MacNaughton pointed out that the SOP does not state to swab consecutive days only to swab for (b) (4) days. I explained that waiting two weeks between swabs would not be best practices for the high risk product the firm manufactures nor is forgetting to conduct the final day of swabbing. Ms. MacNaughton stated the SOP would be reviewed and updates made.

Productions records were also reviewed for the following days of April 30, 2022, and May 2, 4, 5, 9, 11, 12, 2022. I noted the following; the illegibility/incompletion of records, 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 production forms at the times. Finally the acceptable ranges for testing were not always listed on QA testing forms and the range or actual reading were not to the same decimal point and "rounding" was used a justification for a recording to be in spec. The production records for 05/02/2022 are summarized as follows for these discrepancies:

- Master Batch Record -for the (b) batches manufactured there was a total of 26 cross outs of (b) (4) job numbers, customer lot number, weights and temperatures due to incorrect or ineligible recordings.
- Floaters and Sinkers form does not indicate the range for the water temperature and it was noted the water temperature was crossed out on one line and the weight of (b) (4) was crossed out/changed on one line.
- pH and scorched particles form does not list the range for weight. Also it was noted that there were 3 cross outs on this record. pH range target is listed as (b) (4)-(b) (4) but recorded as two decimal points.
- Powder (b) (4) form- noted there were 4 cross outs, 3 of which were incorrect calculations.
- Post Homogenizer Liquid Mix form- noted there were 4 cross outs and one out of spec recording was deemed acceptable because after "rounding" the reading was within spec. (b) (4) Target is listed as (b) (4)-(b) (4) but recorded as two decimal points.
- Analytical Results- Powder - Moisture % Target is listed as (b) (4)-(b) (4) but recorded as three decimal points
- Pre-Op Sanitation Checklist it was noted there were 3 cross outs.
- Pre-OP (b) (4) Checklist- Special testing it was noted there were 3 cross outs.

Discussion with Ms. MacNaughton regarding these issues revealed the following; retraining of employees who are not properly recording information may be necessary and the firm would determine whether this is just one or two employees making these errors or an overall issue. In regards to the target ranges either not being listed on the form or the recordings not matching to the same decimal point as the target, Ms. MacNaughton stated the forms would be reviewed and updated as necessary.

I reviewed the firm's (b) (4) Infant Formula Operation" PROD-304-SOP. The SOP provides the detailed instructions for the start up of the dryer after a CIP cycle. All (b) (4) temperatures are set at (b) (4) F for all (b) (4) zones to aid in dry out, furthermore "allow the system to run this way (b) (4) to ensure (b) (4) ." I asked the firm to provide the documentation of this (b) (4) time frame.

Discussion with Ms. MacNaughton she explained the firm does not record this (b) (4) time frame. Ms. MacNaughton further explained the dryer is running at high temperatures and the moisture would be removed due to thr high temperature. On 06/08/2022, the firm realized there is a record called (b) (4) which actually captures this info even though firm was not confirming the (b) (4) time frame. Ms. MacNaughton confirmed this record will now be included in batch records.

End Investigator Schafer

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Facility map and hygiene areas	17
2	Firm Organizational Chart	1

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
3	Corporate Organizational Chart	1
4	Corporate Detail Organizational Chart	1
5	Case Label Infant Formula	1
6	Can Label	1
7	Marketing Label Information	4
8	Food Safety Plan and Hazard Analysis	50
9	Process Authority Letter	3
10	Bulk Product Testing Release Criteria	1
11	Master Batch Record Checklist	1
12	Positive Environmental Swabs for 2022	1
13	Dryer Inspection	18

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FORM FDA 482 Notice of Inspection	3
5	Infant Formula Attachment B	1
6	FORM FDA 482 Notice of Inspection	3
7	FORM FDA 482 Notice of Inspection	3
8	FORM FDA 482 Notice of Inspection	3

SIGNATURE

Melissa M Schafer
Investigator
Signed By: Melissa M. Schafer -S
Date Signed: 07-25-2022 12:46:01

Gerard D Difiore
Investigator
Signed By: Gerard D. Difiore -S
Date Signed: 07-25-2022 14:53:23