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SUMMARY

Inspection	
Operation ID and Name	232696: FY23 Infant Formula / HR Tier 12 Dairy Farmers of America

Summary Data	
This is a comprehensive report.	
Inspection Basis	(b) (5)
Inspection Basis Comment	This follow-up inspection was conducted in response to the 2022 inspection which: *"The firm disclosed it had manufactured an infant formula powdered milk (b) (4) ingredient on (b) (4) dryer (b) (that tested positive for Cronobacter spp; (b) (4) was the intended customer. A comprehensive review of the firm's environmental monitoring program revealed the firm collected over (b) (4) environmental samples in the 2022 calendar year; over 10%, or (b) (4) of those samples were positive for Cronobacter spp. A high percentage of these collected samples were in the firm's control room, which is a high traffic area between the (b) (4) room (b) (4) and (b) (4) dryer (b) (4). FDA inspection teams collected environmental samples from (b) (4) dryer (b) (4) & (b) (4) and the firm's (b) (4) finished product packaging rooms. Environmental swab samples were collected and analyzed for Salmonella spp and Cronobacter spp. Sample # INV 1169897 subsample 6 was collected from zone (b) (near (b) (4) dryer (b) (4) and tested positive for Cronobacter sakazakii. Sample # INV 1192164 subsample 95 was collected from an (b) (4) that feeds the (b) (4) and tested positive for Cronobacter sakazakii. DairiConcepts manufactured approximately (b) (4) of (b) (4) (lot (b) (4) & (b) (4)) and (b) (4) of (b) (4) infant formula base powder (b) (4) (lot (b) (4) while the sampling team collected environmental samples."* *"An FDA 483 was issued for:* *1. not having a written sanitation preventive control, monitoring, corrective action and verification procedures appropriate to significantly minimize or prevent the hazard requiring a preventive control* *2. having a person who conducted an audit relating to infant formula quality control procedures was directly responsible for matters that the person was auditing* *3. measuring devices were not calibrated, which were used to verify that ingredient weights for infant formula bases were accurate* *4. not maintaining a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition."*

Summary
This follow up, full scope preventive controls of a powdered infant formula, powdered baby formula, powdered (b) (4) and (b) (4) manufacturer inspection was conducted in accordance with the FY23 HAFW2 workplan, Operation ID 232696, and compliance program(s) 7303.040 Preventive Controls and Sanitary Human Food Operations. The previous inspection was conducted by FDA on May 15, 2022. That inspection was classified as VAI. The following observations were observed during the last inspection: 1. Not having a written sanitation preventive control, monitoring, corrective action and verification procedures appropriate to significantly minimize or prevent the hazard requiring a preventive control 2. Having a person who conducted an audit relating to infant formula quality control procedures was directly responsible for matters that the person was auditing 3. Measuring devices were not calibrated, which were used to verify that ingredient weights for infant formula

Summary

bases were accurate

4. Not maintaining a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

DairiConcepts was acquired by ByHeart in January 2023 and was rebranded as Blendhouse Allerton. The firm had not manufactured infant formula since the previous inspection; however, the firm was manufacturing(b) (4) (b) (4) for(b) (4) ByHeart management indicated they anticipated manufacturing powdered infant formula (PIF) for market sometime between August and September 2023. The current inspection focused on the firm's corrective actions to the previous inspection. The firm's food safety plan and hazard analysis were reviewed; the plan was not updated with the current ownership. Local firm management stated the firm's processes and procedures are currently under review by ByHeart corporate leaders and will be updated before Blendhouse Allerton manufactures PIF. Environmental monitoring program (EMP), records and procedures were reviewed; the firms EMP is significantly more robust compared to the plan during the previous inspection. The firm's supply chain program has not changed. The firm has an agreement with Dairy Farmers of America that allows then to use their current computer systems and supply chain partners during the transition from DFA to ByHeart; this agreement is set to expire in November 2023. The observations from previous inspection were corrected and verified:

Having a person who conducted an audit relating to infant formula quality control procedures was directly responsible for matters that the person was auditing

Measuring devices were not calibrated, which were used to verify that ingredient weights for infant formula bases were accurate

Refusals were not encountered. The firm has a valid food facility registration. Samples were not collected. An FDA 483 was not issued. Verbal observations were not issued to the firm. The firm does not qualify for 21 CFR 117 PC attestation. The Intentional Adulteration Quick Check Questionnaire was collected during the inspection.
The inspection was closed with the following firm representatives present: Hillary Sibert - Senior VP for Quality, Devon Kuehn - Chief Medical Officer, Katleen (Katie) E Whitesell - Senior Director of Food Safety, John Van Der Hulle - Plant Manager, Julie M Mckechnie - HR Manager for Redding (PA) Facility, Julie Fry - Quality Manager. All individuals present were provided a verbal warning to comply with the FD&C Act and the consequences for non-compliance.

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03R897	FSMA INTENTIONAL ADULTERATION INSPECTION - QUICK CHECK
03040	FOOD CGMP INSPECTIONS
03040F	FULL SCOPE PCHF INSPECTIONS

Summary of Past Observations

CFR Number:	Citation Text:
21 CFR 117.135(c)(3)	Your written sanitation preventive control, monitoring, corrective action and verification procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.
Corrective Actions:	2. On 5/23/2022 the firm retrained their employees on the difference between the recording thermometer and indicating thermometer (exhibit 9). A review of randomly selected records to include the dates of the inspection demonstrated the firm had corrected the deviation; however, the firm does not measure the recording chart with calipers. The firm created a plastic cutout that operators place over the recording chart to ensure pasteurization time is correct (exhibit 9 page 9). When management was asked why pasteurization operators are not issued an appropriate measuring device, management personnel stated operators would drop them and the measurements would

Summary of Past Observations	
CFR Number:	**Citation Text:**
	not be correct. I encouraged firm management to teach the operators how to use proper measuring devices such as calipers.
Correction Status:	Corrected & Verified
21 CFR 106.30(d)	An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.
Corrective Actions:	On 07/06/2022, The firm calibrated the flow meter located on the product line between the (b) (4) silo and the (b) (4) tank, the (b) (4) located on the (b) (4) tank, the flow meter located on the product line between the (b) (4) tank and the (b) (4) , the flow meter located on the product line between the (b) (4) silo and the (b) (4) (exhibit 4, page 3-8). Additionally, the firm added these calibrations to their maintenance system to ensure timely calibration (exhibit 4, pages 1-2). The next inspection should verify the meters were calibrated in 2023.
Correction Status:	Pending Review
21 CFR 106.92(b)	A person who conducted an audit relating to quality control procedures was directly responsible for matters that the person was auditing.
Corrective Actions:	The corrective action to this observation could not be viewed at the time of the inspection; the firm had not manufactured infant formula since the last inspection. The firm provided the revised quality audit procedure (exhibit 8). Ms. Fry stated the firm's corporate officers would conduct the review so there would no longer be a conflict of interest in Ms. Fry auditing her own work. This observation will need to be verified when the firm beginsmanufacturing infant formula.
Correction Status:	Pending Review
21 CFR 106.20(a)	You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.
Corrective Actions:	The firm insulated the (b) (4) system with an appropriate insulation that mitigates standing water issues. Exhibit 3 pages 1 & 2 show the insulated equipment. Further, the firm revised their unplanned water event SOP to address standing water and sanitation in the facility. Exhibit 11 page 2-3 states: "4.2.1. Condensate/Moisture/ Water Control - (Environment) 4.2.1.1. If condensation/moisture/water from ductwork, piping, fans, hose stations, pumps, etc. is running/leaking to floor is observed in generally dry areas of the facility (taking into account that this is beyond instances when environmental cleans are occurring), it is required that the moisture on the floor or surfaces is to be absorbed, area cleaned and then sprayed with (b) (4) (b) (4) application must be utilized to protect environment from possible contamination that could potentially lead to product contamination from foot traffic. 4.2.1.2. In the event of a hose station leaking, pump, valve, etc. (an item in which production personnel cannot fix) a reactive work order/notification needs to be entered promptly as well as communicated through email. This allows ID) maintenance to address the issue as soon as possible."

Summary of Past Observations	
CFR Number:	**Citation Text:**
	These procedures and application were deficient in the previoius inspection. Standing water was not observed during the current inspection.
Correction Status:	Corrected & Verified

Correction Statuses current at time report was signed.

ADMINISTRATIVE DATA

Administrative Data	
Firm	ByHeart Inc dba Blendhouse Allerton
Physical Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Phone	641-873-4121
Fax	641-873-4574
Mailing Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Email Address	jvanderhulle@byheart.com
Website	byheart.com
Inspection Date(s)	6/27/2023, 6/28/2023

FDA Inspection Participants
Participant Name and Title
Michael Feingold, Investigator

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**
6/27/2023	John van der Hulle

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

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

Guidance Documents Given to the Firm
Ms. Julie Fry still had the QR Handout from the previous inspection. She also stated she received Commissioner Califf's Call to Industry Letter.

Industry Portal Representative	
Person's Name and Title	John van der Hulle, Plant Manager
Email Address	jvanderhulle@byheart.com

HISTORY

Hours of Operation	Standard Business Hours	
New or Current Firm Legal Name	ByHeart Inc dba Blendhouse Allerton	
Legal Status	Inc	

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	Interstate commerce practices have not changed since the last inspection with regards to (b) (4) products. The firm no longer manufactures or distributes (b) (4) products.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	The firm is not currently manufacturing PIF products and no longer manufactures (b) (4) (b) (4) products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	John van der Hulle, Plant Manager
Roles and Authorities	Mr. John van der Hulle has been employed at the facility for 41 years; plant manager for 15 years. Mr. van der Hulle stated he was responsible for the overall management of the facility, personnel management, and production runs. He stated he has the authority to make capital improvements and personnel employment decisions.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, FMD 145 Recipient, Accompanied During the Inspection
Email Address	(b) (6), (b) (7)(C)
Mailing Address	The same as the firm's mailing address.
Person #2	
Person's Name and Title	Julie L Fry, Quality Manager
Roles and Authorities	Ms. Julie L Fry has been employed at the firm for 10 years; she has held her current position for 3 years. Ms. Fry stated she is responsible for the oversight and codevelopment of the firm's quality and food safety programs including procedures, work instructions, and audits. She stated she has the authority to make capital

	improvements and personnel employment decisions.
The following are applicable to this person	Interviewed, Accompanied During the Inspection

FIRM'S TRAINING PROGRAM

No changes since the previous inspection.

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage
The process flow for powdered (b) (4) products has not changed since the previous inspection. See Food Safety Plan Summary (below) and Exhibit 19.

Food Safety Plan Summary		
Product #1		
Basic Food Information		
Product Name	(b) (4)	
Product Description with Packaging	From the firm's product specification sheet: *(b) (4) from (b) (4) is a (b) (4) milk (b) (4) powder derived from cow's milk. It has very good functionality and is suitable for a wide range of applications. The bland flavour and excellent flavour stability of the (b) (4) makes it suitable for use in flavour sensitive formulations."*	
Ingredients	(b) (4)	
Intended Use		
Storage and Distribution	Ambient	
Finished Product Hazard Analysis		
Process Step	**Hazards Requiring Preventive Control**	**Preventive Control Program**
Ingredient Receiving	Bacterial pathogen survival of a lethal treatment	Sanitation
Ingredient Receiving	Recontamination with environmental pathogens	Sanitation
Ingredient Receiving	Chemical hazards due to mis-formulation	Process
Warehouse Ambient Storage	Recontamination with environmental pathogens	Sanitation
Ingredient Staging	Recontamination with environmental pathogens	Sanitation
Powder Dump	Bacterial pathogen survival of a lethal treatment	Process
Powder Dump	Recontamination with environmental pathogens	Sanitation
Powder Dump	Chemical hazards due to mis-formulation	Process
Processing/Pasteurization	Bacterial pathogen survival of a lethal treatment	Process
Processing/Pasteurization	Chemical hazards due to mis-formulation	Process
Dryer Surge Tank/Holding	Bacterial pathogen survival of a lethal treatment	Sanitation
(b) (4) -Heater	Recontamination with environmental pathogens	Sanitation

Food Safety Plan Summary		
(b) (4)	Recontamination with environmental pathogens	Sanitation
(b) (4)	Metal	Process
(b) (4) Pressure Pumping	Recontamination with environmental pathogens	Sanitation
(b) (4) Pressure Pumping	Metal	Process
(b) (4) Pressure Heater	Recontamination with environmental pathogens	Sanitation
(b) (4) Pressure Heater	Recontamination with environmental pathogens	Process
(b) (4) Chamber/(b) (4) Dry	Bacterial pathogen survival of a lethal treatment	Process
(b) (4) Chamber/(b) (4) Dry	Recontamination with environmental pathogens	Sanitation
(b) (4)	Bacterial pathogen survival of a lethal treatment	Process
(b) (4)	Recontamination with environmental pathogens	Sanitation
(b) (4)	Metal	Process
Storage	Bacterial pathogen survival of a lethal treatment	Process
Storage	Recontamination with environmental pathogens	Sanitation
Packing	Recontamination with environmental pathogens	Sanitation
Packing	Metal	Process
Warehouse Storage/Distribution	Recontamination with environmental pathogens	Sanitation

Ingredient Hazard Analysis

Ingredient	**Hazards Requiring Preventive Control**	**Preventive Control Program**
(b) (4)	Bacillus cereus	Supply Chain
	E. coli - pathogenic	Supply Chain
	Listeria monocytogenes	Supply Chain
	Salmonella	Supply Chain
	Staphylococcus aureus	Supply Chain
	Bacterial pathogen survival of a lethal treatment	Supply Chain

Comparison with Firm's Hazard Analysis

All hazards requiring a preventive control were identified by the firm.

Since the last inspection, the firm identified cronobacter as a pathogen likely to occur due to cross contamination. There were minor discrepancies between my hazard analysis and the firm hazard analysis; these discrepancies are controlled by the firm's maintenance and sanitation prerequisite programs.

Summary of Preventive Controls

Supply-Chain Preventive Controls

The firm is currently transitioning from Dairy Farmers of America (DFA) to ByHeart. The firm is currently using DFA's supply chain program until the transition is complete; November 2023. There have been no changes to the firm supply chain program.

Mr. van der Hulle and Ms. Fry explained that the firm's raw materials are vetted and approved by (b) (4) quality department. Each raw material shipment is analyzed for pathogenic microorganisms and quality factors. Ms. Fry explained each COA is reviewed before shipments are accepted.

Process Preventive Controls

The firm has identified two major process controls: Pasteurization and Metal Detection. I reviewed the manufacturing records for the (b) (4) products manufactured on 06/17/2023 and 06/27/2023. There were no discrepancies with the firm's metal detection and challenge. In addition, the firm's pasteurization time and temperature were aligned with the firm's hazard analysis (see corrective actions and exhibit 9).

The firm no longer manufactures with soy; allergen cross-contamination is not a foreseeable hazard in this facility.

Food Safety Plan Summary
Sanitation Preventive Controls
I reviewed the firm's sanitation control SOP (exhibit 1) and environmental monitoring SOP (exhibit 17). Neither document changed since the last inspection. The system is cleaned with an (b) (4) that has not significantly changed since the last inspection. Although the environmental monitoring procedures have no changed since the last inspection, the firm has expanded its program and number of environmental locations. See corrective action and exhibit 15 & 16.
Other Areas Covered
Environmental Monitoring
The firm expanded its environmental monitoring program since last year to swab for Cronobacter spp (b) (4) In 2023 the firm collected (b) (4) environmental swabs for Cronobacter (exhibit 15); 53 were positive hits. I reviewed the firm's swab locations; it appears the firm is actively searching for pathogens with relevant swab locations. Areas/Events of Concern: Dryer (b) (4) had a water leak along the wall in the (b) (4) tower; the area was swabbed and cronobacter was found. This location was on the (b) (4) near the (b) (4) room. The floor was flooded with (b) (4) and clean. Because the floor is hard to clean and unnecessary, Ms. Fry stated the entire floor will be removed on October. The hallway to the silos returned positive results for Cronobacter spp. The floor was replaced June 1, 2023. There have been no positive swab results since. The previous inspection's review of environmental records indicated numerous positives throughout the firm's (b) (4) storage warehouse. The firm has not manufactured PIF since the last inspection and had maintained a small inventory in the warehouse. The firm was able to completely (b) (4), and (b) (4) the entire (b) (4) storage warehouse. Ms. Fry stated the firm's aggressive sanitation and monitoring program was able to drop CB positive rates from 6% to 1%. The firm collects approximately (b) (4) swabs a (b) (4) to be analyzed for pathogens.

MANUFACTURING CODES

The firm changed their plant number to (b) (4)
All finished products manufactured at this facility utilize the following lot code format:

(b) (4)

COMPLAINTS

Review of firm's complaint file(s)
The firm has not received any complaints from (b) (4).

RECALL PROCEDURES

No changes since the previous inspection.

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

I closed the inspection in-person with Katleen (Katie) E Whitesell - Sr Director of Food Safety, John Van Der Hulle – Plant Manager, Julie M Mckechnie - HR Manager for Redding (PA) Facility, Julie L Fry – Quality Director. Ms. Hillary Sibert - Sr VP for Quality and Ms. Devon Kuehn - Chief Medical Officer attended the closeout virtually.
I thanked all parties for the voluntary corrective actions they had made since the previous inspection. I informed all parties that continuous improvement and routine maintenance to this aging facility would be vital to prevent contamination of the powdered infant formula supply. Ms. Sibert affirmed the company's commitment to manufacturing quality food products. She stated the facility is currently beginning (b) (4) trails with the intention of sending product to market this year.
I thanked all parties present for their time and cooperation. I provided them with a verbal warning that they must comply with the FD&C Act and the consequences of non-compliance.

ADDITIONAL INFORMATION

The firm has not manufactured infant formula since the last inspection; however, the firm has continued to manufacture whey products sold to (b) (4). A comprehensive product list and totals can be viewed in exhibit 21.

Food Defense Plan Quick Check
I/we conducted a Food Defense Plan Quick Check during this inspection.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

Water Events

The firm revised their water event SOP. Water events must now be documented with a "Leak Reporting and Action Item Form" (exhibit 11 page 6). Areas that incur water events must be (b) (4). The firm retrained their employee on this procedure on 08//18/2022.

Water event records were reviewed, and Leak Reporting Action Items Form dated 08/31/2022 was submitted as a corrective action (exhibit 11 page 9). One swab returned a positive result for CB (exhibit 11 page 22). The area was (b) (4) .
The piece of equipment that caused the leak was repaired (exhibit 11 page 23)

Crack Testing

The firm changed their crack testing vendor to (b) (4) The firm's most recent crack tests are significantly more comprehensive than last year's report. The vendor found numerous "defects" or cracks in the firm's (b) (4) and (b) (4) (b) (4) detailed their methodology is detailed below (exhibits 13 & 14). The report provides a more comprehensive reports which include visuals of the defect and corrections. According to the report, the defects were corrected.

> *"Method of Testing: Clean surface visual and (b) (4) Testing to identify surface breaks in the equipment interior*
>
> *Interior surface must be clean and free of residual product.*
>
> (b) (4) *is a water soluble,* (b) (4) *approved product for food equipment and drinking water safe*
>
> *Step 1: Rigging and rappelling equipment set up to allow access to the various vessels through the available manholes of* (b) (4) *chamber,* (b) (4) (b) (4) *and baghouse. Extension ladder used in many areas of the* (b) (4) *chamber to access upper wall area.*
>
> *Step 2: Visual inspection with proper lighting to identify any stress cracking or fatigue that can be seen and repaired prior to next step.*
>
> *Step 3: Apply* (b) (4) *in excess using* (b) (4) *to* (b) (4) *and* (b) (4) *for* (b) (4) *to allow for penetration into any voids. Follow* (b) (4) *with a* (b) (4) *of* (b) (4) *to* (b) (4) *away* (b) (4) *. Enter inspection area with* (b) (4) *and* (b) (4) *The* (b) (4) *will glow in the breaks and pits under* (b) (4) *signaling further inspection and repair.*
>
> *Step 4: If repair is needed, the area must be* (b) (4) (b) (4) *repairs to be made with* (b) (4) *. Re-examine* (b) (4) *zone for further cracking and repair as needed.* (b) (4) (b) (4) *."*

Defects

> (b) (4)
>
> *There were 2 defects found in the* (b) (4) *chamber, both fatigue cracks*
> *There was 3 defects in the baghouse located at the lower* (b) (4) *sections, all fatigue cracks*
> *There were 3 defects in the burner to air disperser ducting, all fatigue cracks*
> *There were no defects in the* (b) (4) (b) (4)
>
> (b) (4)
> *There were 5 defects found in the* (b) (4) *chamber. Three fatigue cracks and two pinholes*

There was 1 defect in the form of a fatigue crack on the south primary (b) (4) *and one old weld repair cleaned up.*
There were no defects in the baghouse
There were no defect on the duct work from (b) (4) *chamber to primary* (b) (4) *or primary* (b) (4) *to baghouse ducting.*
There was 1 defect in the form of fatigue crack in the external (b) (4)

Process Intrusion

The firm rewrote in implemented their process intrusion SOP. The SOP includes a more detailed intrusion checklist (exhibit 7 page 6). All employee were trained on the updated procedure on 08/15/2022.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Corrective Action Cleaning SOP	
2	Corrective Action Cooler Alarm Challenge	
3	Corrective Action Facility Maintenance	
4	Corrective Action Flow Meter Calibration	
5	Corrective Action Hazard Analysis	
6	Corrective Action Pasteurization SOP	
7	Corrective Action Process Intrusion	
8	Corrective Action Quality Audit Procedure	
9	Corrective Action Recording Thermometer	
10	Corrective Action Training Records	
11	Corrective Action Water Event SOP	
12	Product COAs	
13	Crack Testing	
14	Crack Testing	
15	Environmental Monitoring Records	
16	Environmental Monitoring Records	
17	Environmental Monitoring SOP	
18	Hazard Analysis	
19	Process Flow	
20	Product Specifications	
21	Production Totals Since Last Inspection	

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FDA 482	

SIGNATURE

Michael A Feingold
Investigator
Signed By: Michael Feingold -S
Date Signed: 08-15-2023 15:16:30