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SUMMARY

Inspection	
Operation ID and Subject	335244: CORE RT3 - Blendhouse Allerton - C.botulinum/PIF/Nov2025

Summary Data	
This is a summary of findings report.	
Inspection Basis	Consumer Complaint
Inspection Basis Comment	This inspection was part of a Coordinated Outbreak Response and Evaluation Network (CORE) assignment associated with a *Clostridium botulinum* outbreak. The Centers for Disease Control and Prevention (CDC) notified the FDA after receiving about multiple consumer complaints of apparent infant botulism developing after the consumption of ByHeart powdered infant formula. Blendhouse Allerton, LLC's is the sole producer of the base powder used to make this product.

Summary

This was a directed consumer complaint inspection at Blendhouse Allerton, LLC a powdered infant formula manufacturer in Allerton, Iowa. This inspection was part of a Coordinated Outbreak Response and Evaluation Network (CORE) assignment associated with a *Clostridium botulinum* outbreak. Multiple consumer complaints were received by the U.S. Food and Drug Administration (FDA) about apparent infant botulism developing after consuming Blendhouse Allerton, LLC's sole product, ByHeart powdered infant formula. Blendhouse Allerton, LLC will hereinafter be referred to "BHA" or "the firm."

Upon notification from FDA on 11/7/25, BHA began shutting down infant formula production and initiated their investigation of their manufacturing processes, equipment, and raw materials for any deviations. All infant formula production was stopped at the start of the inspection.

This inspection was conducted in accordance with Compliance Programs: 7321.006 Infant Formula Program, 03C001 CORE Human (Response) Food Incidents - Microbiological Hazards, and 7303.040 Preventative Controls and Sanitary Human Food Operations.

Blendhouse Allerton, LLC operates (b) (4) dryers and (b) (4) packaging lines at this location. Operations can be segregated into (b) (4) operations, (b) (4) operation consists of (b) (4) line that is used exclusively to produce dairy-based ingredients. The (b) (4) consist of an (b) (4) (b) (4) line that is used to produce infant formula powder. Infant formula is only made on the (b) (4) dryer; however, in rare instances, dairy ingredients are also made (b) (4). The firm made the base powder ((b) (4)) for their single product at this location until May 20, 2025. On May 26, 2025, the firm began producing their new completed infant formula ((b) (4) . Since Blendhouse Allerton, LLC's inception, infant formulas have been packaged into bulk totes that were later transferred to other locations for additional blending and/or packaging. The ByHeart infant formula is characterized as non-exempt infant formula.

The previous comprehensive inspection was conducted by the FDA from 2/11/2025 to 2/20/2025 and was classified as Voluntary Action Indicated (VAI). A 3-pt FDA-483, Inspectional Observation, was issued for:

1. Receiving, and releasing whole organic dried milk powder ingredient used in infant formula base powder that was not held under conditions to prevent adulteration.

Summary

2. Not taking actions to eliminate all potential harborage areas when issues with rodent arose during the year 2024-2025; and
3. Not monitoring the floor conditions adequately at the dryer (b) (4) (level (b) (4) and level (b) (4) when there were findings of confirmed *Cronobacter sakazakii*.

Nine additional items were discussed with firm management during the close out meeting. Please see the voluntary correction section for additional details.

The current inspection resulted in a 3-pt FDA-483, Inspectional Observation, being issued for:

1. During the production of base powder Lot Code (b) (4), a powder flush was not performed after a process intrusion as the firm's procedure specifies.
2. On 11/5/2024, only (b) (4) cycle was documented on the (b) (4) for (b) (4) and (b) during cleaning activities. Procedures require (b) (4) (b) (4) during cleaning activities.
3. On 3/17/2025, during the manufacture of Base Mix (b) (4) of Day Lot Code (b) (4), between (b) (4), the temperature of the base mix dropped (b) (4) The mix was fed forward with no management approval at the time of manufacture, as specified in the firm's procedures.

Twelve retain samples of different base powder lots were collected under sample numbers INV1313131, INV1313132, INV1313133, INV1316847, INV1316848, INV1316849, INV1316850, INV1218194, INV1218195, INV1316851, INV1316852, and INV1316853.

Multiple consumer complaints were addressed during this assignment. Please see the consumer complaint section of the report for details.

(b) (3) (A)

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03C001	CORE HUMAN (RESPONSE) FOOD INCIDENTS - MICROBIOLOGICAL HAZARDS
03040U	FOCUSED PCHF INSPECTIONS
21006	INFANT FORMULA SURVEY

Summary of Past Observations

CFR Number:	Citation Text:
21 CFR 117.35(c)	You did not exclude pests from your food plant to protect against contamination of food.
Correction Status:	Corrected & Verified
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.
Correction Status:	Not Corrected
21 CFR 106.40(f)(3)	You approved and released for use an ingredient that was not

Summary of Past Observations	
CFR Number:	**Citation Text:**
	manufactured, packaged, labeled, or held under conditions to prevent adulteration.
Correction Status:	Not Corrected
21 CFR 117.20(b)	Your plant was not designed to facilitate maintenance and sanitary operations.
Correction Status:	Correction Requires Onsite Verification
21 CFR 106.50(d)(2)	You did not include controls for the (b) (4) drying process for a powdered infant formula.
Correction Status:	Correction Requires Onsite Verification

Summary of Objectionable Conditions on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 106.50(a)(1)	You did not have a qualified individual document corrective actions taken after an investigation of a deviation from the master manufacturing order.	No Firm Response Submitted
21 CFR 106.30(b)	You did not ensure that all surfaces that contacted ingredients were cleaned and sanitized.	No Firm Response Submitted
21 CFR 106.6(c)(4)	You did not review and evaluate the public health significance of a deviation from a specification established for your production process.	No Firm Response Submitted

Correction Statuses current at time report was signed.

Consumer Complaints Review

(DT)

The firm's Complaint Management Policy remains unchanged since the last routine inspection. All complaints are initially handled by the corporate office who categorize them. Complaints are sorted into 3 categories:

- Health – complaints related to gastro illnesses
- Quality – complaints that reference tastes, smells, appearance, packaging damages, or the presence of foreign materials.
- Sensitive/Serious – any complaint associated with Salmonella or a pathogen.

All sensitive or serious complaint cases are reviewed by medical professionals during root cause investigations. Blendhouse's Portland, OR facility manufactures the final ByHeart product, and most complaints received are route through that location according to Ms. Casey, Quality Compliance Manager. BHA is only aware of complaint if the corporate office shares specifics and requests information on base powder lots. Ms. Casey stated that BHA was unaware of any pathogen complaints until FDA consumer complaint coordinator contacted them.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
192895	(b) (6), (b) (7)(C)) complaint. Refer to the EIR and FDA memo for follow up information.
193207	This is a general compliant that captures the specifics of start of the outbreak investigation.
193226	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193227	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193228	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193229	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193230	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193231	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193232	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193233	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193234	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193235	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193236	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193237	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193238	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.
193239	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/05/2025.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
193346	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193347	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193348	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193350	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193352	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193354	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025. Awaiting further details if possible.
193355	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193358	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193360	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193361	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193364	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193366	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193368	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193371	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193373	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.
193376	This Blendhouse location was unaware of this complaint. Details from

Consumer Complaints	
Complaint ID	**Complaint Coverage**
	this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025. Awaiting further details if they become available.
193378	This Blendhouse location was unaware of this complaint. Details from this complaint were relayed to Ms. Casey, the Quality Compliance Manager, on 12/18/2025.

Inspection Recalls	
Recall Number(s)	H-0249-2026

Inspection Samples	
Sample Number(s)	1218194; 1218195; 1313131; 1313132; 1313133; 1316847; 1316848; 1316849; 1316850; 1316851; 1316852; 1316853

ADMINISTRATIVE DATA

Administrative Data	
Firm	Blendhouse Allerton,LLC
Physical Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Phone	641-221-2854
Fax	(b) (4)
Mailing Address	
Address Line 1	211 N Central Ave
City / State / ZIP	Allerton, IA 50008
Email Address	(b) (6), (b) (7)(C) @byheart.com
Website	byheart.com
Inspection Date(s)	11/11/2025, 11/12/2025, 11/13/2025, 11/14/2025, 11/17/2025, 11/18/2025, 11/19/2025, 11/20/2025, 11/21/2025, 12/3/2025, 12/4/2025, 12/5/2025, 12/17/2025, 12/18/2025, 12/19/2025, 1/21/2026, 1/22/2026

FDA Inspection Participants
Participant Name and Title
Karen Labounty, Investigator
Danny Tuntevski, Investigator

FDA Team Members Not Present for the Whole Inspection
Investigator LaBounty was present on the following dates, 11/11/25, 11/12/25, 11/13/25, 11/14/25, 11/17/25, 11/18/25, 11/19/25, 12/3/25, 12/4/25, 12/5/25, 12/17/25, 12/18/25, 12/19/25, 1/21/26, and 1/22/26.

Issued 482 Forms	
On the date(s) below, credentials were presented and a "Form FDA 482, Notice of Inspection" (attached) was issued to the person listed.	
Date Issued	**Issued To**
1/21/2026	Michael S. Brennecke, Interim Plant Director

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Michael S. Brennecke, Interim Plant Director
Person's Name and Title	Julie L. Fry, Director of Quality
Person's Name and Title	Katleen E. Whitesell, Vice President of Quality
Person's Name and Title	John van der Hulle, Sr. Director of Third-Party Technical Operations
Person's Name and Title	Alan Estrella, Quality Performance Director
Person's Name and Title	Faris Malouf, former Plant Director
Person's Name and Title	Erin E. Casey, Quality Compliance Manager

FDA Form 483		
Description	**Date Issued**	**Issued To**
Original	Jan 22 2026 04:43PM (ET)	Michael S. Brennecke, Interim Plant Director

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Michael S. Brennecke, Interim Plant Director	Industry Portal Representative and FMD-145 Recipient
Email Address	(b) (6), (b) (7)(C)@byheart.com	
Mailing Address	The same as the firm's mailing address.	
Phone Number	641-221-2854	
*If a corporation		

HISTORY

Food Firm Registration Status	Current
Hours of Operation	(DT) The firm manufactures (b) (4) The warehouse (b) (4) (b) (4). Office hours for the firm are from 8:00am - 4:00pm Monday through Friday.
Additional Information	(DT) (b) (4) FMD-145 and future FDA correspondence should be sent to: Mr. Michael S. Brennecke, Interim Plant Director email: (b) (6), (b) (7)(C)@byheart.com Blendhouse Allerton, LLC

	211 N Central Ave Allerton, IA 50008 Correspondence with the firm can be sent to the headquarters at ByHeart Inc.: Mr. Ron Belldegrun, Chief Executive Officer ByHeart Inc. 131 Arick Street 11th Floor New York, NY 20013 ByHeart operates two other food manufacturing facilities in the U.S. A manufacturing facility (idled since 2024) at: Blendhouse Reading, LLC 61 Vanguard Dr. Reading PA 19606 FEI: 3015728839 A blending and canning facility at: Blendhouse Portland, LLC 19217 NE San Rafael St. Portland OR 97230 FEI: 3013670080 This report was written by Investigators Danny Tuntevski (DT) and Karen Labounty (KML). Each section contains the initials of the author of that section.

Recalls	
Recalls Not Previously Known to FDA	
Recall Description	(DT) Blendhouse, LLC corporate office initiated their recall procedures on 11/08/2025, one day after being notified by the FDA of multiple infant botulism complaints. Early reports indicated that there were 13 cases that were linked to the consumption of ByHeart infant formula. Blendhouse, LLC's initial recall was for two lots: • Batch Code: 251261P2, Use by: 01 Dec 2026 • Batch Code: 251131P2, Use by: 01 Dec 2026 At that time testing by ByHeart or regulatory agencies had not confirmed the presence of *Clostridium botulinum* spores or toxin in any ByHeart product. On 11/19/2025, ByHeart expanded their recall to all lots of ByHeart

Recalls	
Recalls Not Previously Known to FDA	
	infant formula. The recall was expanded when *Clostridium botulinum* was identified by ByHeart, INC in some samples of its formula. Multiple public notices were issued stating that the recall now included all lot of ByHeart infant formula as reports indicated that the formula was still being found on store shelved. FDA has assigned the following indentifiers to this recal: • Recall Enterprise System (RES) Event ID 97959, • Recall number H-0249-2026, This Class I recall was ongoing at the close of this inspection.

INTERSTATE (I.S.) COMMERCE

Firm engages in interstate commerce	Yes		
Incoming	Yes	**Outgoing**	Yes
Description of Interstate Commerce	(DT) All the ingredients that the firm uses in their manufacture of base powder infant formula or completed infant formula (b) (4) (b) (4) On 03/28/2026, BHA began using a third-party (b) (4) for the storage of raw materials. Prior to 3/28/2026, BHA contacted with (b) (4) in (b) (4) for warehousing their raw materials. Because of these warehouses, most of the raw materials (b) (4) (b) (4) (b) (4) BHA ships all their manufactured base powder infant formula and completed infant formula out of the State of Iowa to the Blendhouse facility in Portland, OR. The following table lists interstate documents for finished product and base powder samples of interest. It includes interstate documents for organic whole milk powder (WMP) from (b) (4) (b) (4) and whey protein hydrolysate (WPH) from (b) (4) Table Answer_28_1 *- outbound documentation for these was not collected due to product testing and tracebacks were incomplete at the time of closeout.		

Tables and Figures

Table: Answer_28_1

Finished Product	Base Powder Lot	FP Production Date	WMP Lot	Exhibit	WPH Lot	Exhibit	Outbound BOL Exhibit
(b) (4)				Ex 1	(b) (4)	Ex 10	Ex 19 & 20
(b) (4)				Ex 2	1548671	Ex 11	Ex 23
(b) (4)					(b) (4)	Ex 12	Ex 21
(b) (4)					(b) (4)		Ex 22
(b) (4)				Ex 3	(b) (4)	Ex 13	Ex 17
(b) (4) 2	(b) (4)	(b) (4)	(b) (4)	Ex 2	(b) (4)	Ex 12	Ex 22*
	(b) (4)		(b) (4)	Ex 6	(b) (4)	Ex 14	
(b) (4)		(b) (4)	(b) (4)	Ex 3	(b) (4)	Ex 13	Ex 18*
	(b) (4)		(b) (4)	Ex 4			
(b) (4)	(b) (4)	(b) (4)	(b) (4)	Ex 4	(b) (4)	Ex 13	Ex 18*
(b) (4)	(b) (4)	(b) (4)	(b) (4)	Ex 6	(b) (4)	Ex 12	*
	(b) (4)		(b) (4)	Ex 4	(b) (4)	Ex 13	
(b) (4)	(b) (4)	(b) (4)	(b) (4)	Ex 5	(b) (4)	Ex 13	*
	(b) (4)		2127251111		(b) (4)	Ex 16	
	(b) (4)			Ex 8	(b) (4)	Ex 15	
N/A, was not used in production			(b) (4)	Ex 7	N/A	----------	----------
N/A, was not used in production			N/A	----------	(b) (4)	Ex 9	----------

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Changes to Jurisdiction	Yes
Description of Jurisdiction	(DT) The firm manufactures (b) (4) infant formula product. Until 5/25/2025, this (b) (4) product was a powdered infant formula base powder, Blendhouse product code (b) (4) This product was shipped in bulk totes to the Blendhouse facility in Portland, OR for further (b) (4) and final packaging. Tote labels from base powder lots (b) (4) and (b) (4) were collected (**Ex 24**). On 5/26/2025, BHA began the production of a complete infant formula, (b) (4) . (b) (4) BHA also produces (b) (4) powdered dairy ingredients: (b) (4)

	powder for a (b) (4), (b) (4). These ingredients are primarily made on the (b) (4) dryer and were not covered during this inspection. The infant formula base powder, complete infant formula powder, and dairy ingredients are subject to the FD&C Act.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Michael S. Brennecke, Interim Plant Director
Roles and Authorities	Mr. Michael S. Brennecke, currently is the Interim Plant Director and most responsible person onsite. (b) (4) . Mr. Brennecke began working at the facility in 2002 and has worked in numerous positions, including: Operations, Facility Supervisor, Maintenance Manager, and Senior Engineer, his latest role that he held since 2023. In this role he was responsible for the management of capital projects, including starting the canning operation at Blendhouse's Portland, OR facility. Mr. Brennecke is responsible for all of the operations at the facility. He reports to Mr. William "Bill" Thomas, Sr. Director of Manufacturing, who reports to Mr. Marcus Jordan, VP of Supply Operations. Mr. Jordan reports to Mr. Neil Betteridge, Chief Operating Officer. Mr. Betteridge reports to Mr. Ron Belldegrun, Chief Executive Officer. Mr. Brennecke was issued Form FDA 482, Notice of Inspections on 12/17/25 (**Att 5**) and on 1/21/26 (**Att 2**). At the conclusion of the inspection, Mr. Brennecke was issued a Form FDA 483, Inspectional Observations, (**Att 1**) and a Form FDA 484, Receipt for Sample, (**Att 6**). The firm provided a Production and Quality leadership organization chart (**Ex 25**) for the facility.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Industry Portal Representative, FMD 145 Recipient, Accompanied During the Inspection
Email Address	(b) (6), (b) (7)(C) @byheart.com
Mailing Address	The same as the firm's mailing address.
Phone Number	641-221-2854
Person #2	
Person's Name and Title	Julie L. Fry, Director of Quality
Roles and Authorities	Ms. Julie L. Fry is the Director of Quality at the firm. She was present throughout the inspection and is a major source of the information in this report. Ms. Fry has been in this role for ~ 3-years. She oversees the onsite Quality department and all their activities. She (b) (4) direct reports and herself reports to Ms. Katleen E Whitesell, Vice President of Quality.

	Ms. Fry was issued Form FDA 482, Notice of Inspections on 12/3/25 (**Att 3**). (b) (4) .
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	Katleen E. Whitesell, Vice President of Quality
Roles and Authorities	Ms. Katleen E Whitesell, Vice President of Quality, is commonly referred to as "Katie." She is a member of the Blendhouse corporate management team. Ms. Whitesell oversees food safety and quality operations at the three BlendHouse facilities (Allerton, IA; Portland, OR; and Reading, PA). In her role, she supports the onsite quality assurance teams which, includes inspectional and regulatory affairs support. Ms. Whitesell provided updates on Blendhouse's investigation during this inspection. She reports to Mr. Niall Mullane, Chief Quality Officer.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #4	
Person's Name and Title	John van der Hulle, Sr. Director of Third-Party Technical Operations
Roles and Authorities	Mr. John van der Hulle, Sr. Director of Third-Party Technical Operations, is formerly the Plant Director at this facility a position that he held for over 5-years. In his new role, Mr. van der Hulle is designated as a subject matter expert for the firm. He has over 40 years of experience working at this location. Mr. van der Hulle provided information on the firm's manufacturing process and the Blendhouse investigation.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #5	
Person's Name and Title	Niall Mullane, Chief Quality Officer
Roles and Authorities	Mr. Niall Mullane, Chief Quality Officer, was present at the facility during the early weeks of the outbreak. He briefly spoke with us during the early phase of the inspection. Mr. Mullane actively participated in the sharing of information with FDA during the weekly calls. He reports to Mr. Ron Belldegrun, Chief Executive Officer.
The following are applicable to this person	
Person #6	
Person's Name and Title	Alan Estrella, Quality Performance Director
Roles and Authorities	Mr. Allan Estrella, Quality Performance Director, is a member of Blendhouse's corporate team that conducted the onsite investigation. He provided updates on the investigation at different points of the inspection.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #7	
Person's Name and Title	Ron Belldegrun, Chief Executive Officer
Roles and Authorities	Mr. Ron Belldegrun is the firm's Chief Executive Officer (CEO), Co-Founder, and most responsible person for the overall operation of the firm. Blendhouse was cofounded by Mr. Belldegrun and his sister, Ms. Mia Funt. Mr. Belldegrun was not present at the firm and did not

	participate in the inspection.
The following are applicable to this person	
Person #8	
Person's Name and Title	Mia Funt, President
Roles and Authorities	Ms. Mia Funt is the firm's President and Co-founder. Blendhouse was cofounded by Ms. Mia Funt and her brother, Mr. Ron Belldegrun. Ms. Funt was not present at the firm and did not participate in the inspection.
The following are applicable to this person	
Person #9	
Person's Name and Title	Faris Malouf, former Plant Director
Roles and Authorities	Mr. Faris "Frank" Malouf was the Plant Director at the start of the inspection. (b) (4) (b) (4) . Mr. Malouf had taken over the Plant Director position from Mr. van der Hulle in June of 2025. Mr. Malouf was issued Form FDA 482, Notice of Inspections on 11/11/25 (**Att 4**).
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #10	
Person's Name and Title	Erin E. Casey, Quality Compliance Manager
Roles and Authorities	Ms. Erin E. Casey is the firm's Quality Compliance Manager. She assumed this role, which had been vacant at the time, in August of 2025. Ms. Casey oversees the firm's corrective and preventive action (CAPA) and document control program. She also updates the policy and procedures on the firm's food safety plan, works on consumer complaints, internal audits, and works with the corporate team on the supplier program. Ms. Casey reports to Ms. Fry. During the inspection, Ms. Casey and her (b)(4) reports, (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) Document Control Specialist, and (b) (6), (b) (7)(C), Internal Auditor, played a large role in providing information used in this report. They were instrumental is uploading documents into box.com along with explaining shipping documents. The firm provided an updated organizational chart, the included the changes made (furloughed employees) after the start of the inspection (**Ex 26**).
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage
(KML)

Process Flow, Operations, and Product Coverage

Facility Overview
Blendhouse Allerton (BHA) facility consists of approximately (b) (4) of production space and (b) (4) f warehouse space (warehouse (b) (4) as well as offices, receiving, laboratory, and maintenance shop. Access to the facility (b) (4) authorized personnel only; all visitor entry is via the front office, where ID and visitor sign-in is required. The firm has (b) (4) processing areas (b) (4) dryers, (b) (4) side and (b) (4) These areas are known as their (b) (4) line (b) (4) processing line (b) (4) Firm continues to manufacture food ingredients including (b) (4) (b) (4) using the (b) (4) production line for their customer (b) (4) . These ingredients are further processed/pasteurized (b) (4) customers.

The (b) (4) production line can be used (b) (4)

Hygiene Zones and Traffic Patterns (KML)
(b) (4)

(b) (4)

Our walk through focused on (b) (4) area, (b) (4) he (b) (4) dryer or the (b) (4) area, (b) (4) dryer and (b) (4) packaging (b) (4) r were not in operation.

Process Flow, Operations, and Product Coverage

Firm provides zone specific personal protective equipment (PPE). All employees access the (b) (4) (b) (4) areas through the (b) (4) rooms. Employees change into firm provided uniform and captive shoes. At the (b) (4) entry point, (b) (4) prior to entering the dryer (b) (4)

To enter the (b) (4) (b) (4)) zones.

Supply Chain (KML)

The firm maintains a supply chain program and follows SOP QUAL-2505-SOP, Supplier Quality Management (see **Ex 73**) for the supplier approval. In summary, suppliers are approved through a (b) (4) system is used for supplier approval, management, and communication. Based on the risk assessment performed, a (b) (4) category (b) (4) . For example, QUAL-2509.06FM, Supplier Quality Management form for the audit of (b) (4) was provided (b) (4) level supplier and requires an audit (b) (4) . See **Ex 81**.

Even though BHA receives a vendor COA for each ingredients lot, the firm will perform a confirmation testing to ensure the raw material meets the established specifications. See **Ex 74** for QUAL-2510.11-PMS, ByHeart Ingredient Confirmation Testing.

Supplier deviations are monitored via non-conformance reports. The firm provided their 2023, 2024 and 2025 summaries of all Supplier Nonconformances (SNC). See **Ex 75**.

1. SNC25-002-BHA: While staging organic whole milk powder (WMP) from (b) (4) , (b) (4)), on 1/21/25 and 1/23/25, pallets containing (b) (4) bags of lot code (b) (4) and lot code (b) (4) had visible gnaw holes, powder, and potential rodent droppings. An investigation was started. This product was manufactured (b) (4) and sold to (b) (4) who had the product stored at (b) (4) warehouse. (b) (4) (b) (4) then shipped the product to (b) (4) where it was held until shipment to BHA for production. The most probable root cause identified both (b) (4) as sources of the rodents since both had reports of pest activity. Corrective actions include BHA rejecting all pallets with any pest activity,

Process Flow, Operations, and Product Coverage

and ongoing inspections of all (b) (4) bags of WMP. (b) (4) will no longer use (b) (4) productions will be shipped directly (b) (4)) to (b) (4) See **Ex 77**. An audit of (b) (4) was done between 2/18-28/25, wher (b) (4) ; all remaining inventory was removed. This CAPA is documented in SNC25-006-BHA. See **Ex 78**. This investigation was included as the firm's corrective actions related to an Inspectional Observation issued during the previous FDA inspection. See Voluntary Corrections.

2. SNC25-008-BHA: During production of lots (b) (4) , metal dusting was identified on the (b) (4) magnets. After their investigation, the firm identified the metal dusting came from whey protein hydrolysate (WPH) supplied by (b) (4) (b) (4) lot codes (b) (4) manufactured (b) (4) using Silo (b) (4) (b) (4) (manufactured (b) (4) and (b) (4) (manufactured (b) (4) using Silo (b) (4) . (b) (4) completed an investigation and found that a post-CIP inspection conducted on 1/9/25 identified possible metal dust in Silo (b) . At the time, (b) (4) was taken offline and was out of service through 1/25/25 while the (b) (4) were replaced, and the (b) (4) was repaired. In addition, a crack repair was completed. Sediment testing during the production of the (b) (4) lots were within product specification. (b) (4) were also clean during the production dates and the (b) (4) strength was above the minimum requirements. No metal kick-outs were identified during the production of the lots in question. Equipment with potential metal-on-metal contact, including (b) (4) , packaging (b) (4) were inspected with no findings. The Root Cause may be attributed to Silo (b) (4) and Silo (b) (4) . In addition to the repairs and equipment replacements on Silo (b) , additional corrective actions implemented include (b)(4) silo preventive maintenance inspections. See **Ex 79**.

The remaining SNC reports were reviewed, and no issues were noted. Vendors performance is reviewed and evaluated for vendor maintenance. The firm maintains an approved supplier list along with their addresses. See **Ex 80**. The firm's Quality team is responsible for all release decisions for raw materials and finished bulk base. A list of supplier changes since 2023 was provided. See **Ex 110**.

<u>Receiving (KML)</u>
The firm may receive raw ingredients and packaging materials at their facility directly from their suppliers; however, due to the space constraints, the firm also uses third-party warehousing and logistics companies. Since the previous inspection, the firm has used (b) (4) (b) (4) Ms. Fry explained that they ceased using (b) (4) on 3/28/2025 after identifying rodent issues on incoming ingredients. This issue was identified in the previous inspection and has been

Process Flow, Operations, and Product Coverage

corrected. See **Voluntary Corrections**.

Material procurement is performed by the Byheart Corporate office. All ingredients are released when ingredient specifications are met based on the supplier Certificate of Analysis (CoA) and raw material testing. The testing results are kept in (b) (4) system if tested by the firm. A library sample is maintained for ingredients tested by BHA; suppliers will hold samples for any testing they perform. CoA's are reviewed. See **Ex 82** for the CoA from (b) (4) for whole milk powder (WMP) Lot Code (b) (4) and **Ex 83** for CoA from (b) (4) for Whey Protein Hydrolysate (WPH) Lot Code (b) (4).

Ingredients are received in (b) (4), (b) (4)). Upon receipt, a truck inspection is completed, and incoming documents are reviewed. Inventory is maintained through (b) (4) (b) (4), which is generated by (b) (4) The label (b) (4) (b) (4). Any ingredients with incoming issues are placed on hold in (b) (4) and the product is identified with an (b) (4) hold tag. (b) (4) (b) (4) Quality is responsible for releasing all ingredients for production. Warehouse (b) (4) utilized for infant formula raw material and finish base storage. (b) (4) (b) (4)

The (b) (4) is received in bulk. At the time of arrival, the seals on the tanker are verified and compared to the bill of lading; wash tickets and certificates of analysis are also reviewed. The (b) (4) lot is tested by ByHeart. See **Ex 85**. Each shipment of the (b) (4) (b) (4) by the supplier, (b) (4) See **Ex 86**. A retain sample is also collected but no additional analysis is done. Once accepted, the driver unloads the tanker using (b) (4) (b) (4)

Production (KML)

The non-exempt infant formula base powders are manufactured on the (b) (4) (b) (4) dryer (b) (4). The base powder (b) (4) was covered during the inspection. This base formula was used to manufacture finished Byheart Infant Formula noted in the consumer complaints related to the *Clostridium botulinum* illnesses and involved in the recall. The firm was currently manufacturing (b) (4). This product was not covered during the inspection. The (b) (4) line was not in operation during this inspection.

Mr. Hulle stated that since 2022 the firm has not made any process and equipment related changes to their infant formula manufacturing line. As part of the plant improvement project, they replaced all the (b) (4) with new (b) (4) (b) (4) **Ex 109** for the (b) (4) Room (b) (4) Validation. This replacement project was completed between 9/30/2024 and 10/5/2024. For all other facility improvements refer to **Ex 72**.

Process Flow, Operations, and Product Coverage

The firm has a food safety plan signed by the Plant Director on 11/10/25. A process flow chart is included within the food safety plan. See **Ex 84, page 6**. General overview of the process flow for infant formula base powder includes the following steps:

(b) (4)

(b) (4) Processing (KML)

The firm maintains Manufacturing Batch Records (MBR) to mix the base. See **Ex 87** and **Ex 88** for the MBR (b)(4), Lot Code (b) (4) and **Ex 89** for Lot Code (b) (4) Processor Tank (b) (4) Charts. Each production batch consists (b) (4)
(b) (4)
:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

(b) (4)

(b) (4)

(see **Ex 89**).

(b) (4)

.

(b) (4)

(b) (4)

(b) (4) Drying (KML)

(b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4) Filters

(b) (4)

Packaging (KML)

(b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4) . See **Ex 104**. (b) (4)
(b) (4)

Batch Record Review (KML)
Infant formula records are primarily paper based; manual entries of critical and operational parameters are documented. Charting systems are also used to capture critical and operational parameters; they are printed, reviewed, and included with the batch records.

Process Flow, Operations, and Product Coverage

During this inspection, we reviewed the batch records for the day lot codes that were used to manufacture 206VABP/251131P2 and 206VABP/251261P2. See **Ex 112**. These two finished can lot codes were initially implicated in the *Clostridium botulinum* outbreak. The batch records reviewed for can code 206VABP/251131P2 included:

Lot Code (b) (4) 1 (manufactured on (b) (4)
Lot Code (b) (4) (manufactured on (b) (4)
Lot Code (b) (4) (manufactured on (b) (4))

The batch records reviewed for can code 206VABP/251261P2 included:

Lot Code (b) (4) (manufactured on (b) (4))
Lot Code (b) (4) (manufactured on (b) (4))
Lot Code (b) (4) (manufactured on (b) (4))
Lot Code (b) (4) (manufactured on (b) (4)

(b) (4) See **Ex 93**. A full production schedule for the (b) (4) line from (b) (4) was provided. The schedule includes the (b) (4) . See **Ex 94**.

During review of MBR (b) (4) Lot Code (b) (4) the following was noted. The MBR instructions state, "Mix tank TEMPERATURE (b) (4) . The Mix tank in question (b) (4) Management approval based on ByHeart Q.A. consultation." On (b)(4) , during the manufacture of Base Mix (b) (4) Day Lot Code (b) (4) the temperature of the base mix (b) (4) See **Ex 88, page 11 and 89, page 1**. The (b) (4) with no management approval at the time of manufacture. See **Inspectional Observations #3**.

Crack Inspections (DT)

The firm have a third-party contractor (b) (4) , to (b) (4) inspect their (b) (4) dryer and the associated equipment including (b) (4) (b) (4) (b) (4) (b) (4) uses the (b) (4) defaults like cracks, incomplete welds, cavities caused by corrosion, porosities, and other defects which can cause cross-contamination and/or bacteria in the finished product. The inspections were completed during the plant shutdowns during the weeks (b) (4) We reviewed the inspectional reports for the equipment used to manufacture the infant formula base. All the adverse findings were addressed, and repairs were made. The following table summarizes the crack inspection reports that were reviewed. The 2025 Crack inspections included a cover page (**Ex 27**).

Table Answer_13_1

Deviations and Events (KML)

QUAL-2532-SOP, Investigation and Root Cause Analysis, establishes a comprehensive framework for conducting investigations, performing root cause analysis, and implementing corrective and preventive actions (CAPA) for deviations across the organization. See **Ex 105**. The procedure establishes (b) (4) levels: (b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

(b) (4)

An annual summary of all deviations and events was provided for 2023 (see **Ex 106**), 2024 (see **Ex 107**), and 2025 (see **Ex 108**). We reviewed the following reports that occurred during the production of lot codes (b) (4), and (b) (4).

1. (b) (4)

(b) (4)

(b) (4)

Process Flow, Operations, and Product Coverage

2. (b) (4)

3. (b) (4)

(b) (4)

4. (b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

5. (b) (4) BHA (See **Ex 116**): (b) (4)

(b) (4)

(b) (4)

(b) (4)

6. (b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

Water Events (KML)
QUAL-6510.22-WI, Unplanned Water Event Reporting and Process (v.05) describes the measures required to control the environment when unplanned water events occur. See **Ex 119**. The Leak Notification and Risk Assessment form is used to document the event and immediately communicates with management. The procedure outlines (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

A list of all water events was provided. See **Ex 120**. This list shows water leaks in the (b) (4), (b) (4). No product was impacted for any of the water leaks. Leak Report LN-25-021-BHA (see **Ex 121**) identified an internal water leak on March 4, 2025. The leak originated from groundwater seeping through the concrete floor (b) (4) a (b) (4) The affected area was immediately quarantined to minimize traffic flow, and the water leak team was notified via email. (b)(4) investigative swabs were collected. At the time of the event, (b) (4) production lots were active: (b) (4) lot (b) (4) lot (b) (4) The investigation revealed that during a heavy rain event, groundwater found a pathway through the concrete (b) (4) pooling in a small area approximately the size of a quarter. The maintenance team explored various potential sources, including water retention from past cleaning activities, but ultimately determined that moisture was percolating through the floor covering just off the (b) (4). The leak produced minimal water accumulation with very limited environmental impact.

The sanitation team executed a comprehensive (b) (4) cleaning protocol. Initial cleaning on March 6, 2025, involved removing contaminated absorbent materials and cleaning the affected area (b) (4)

environmental swabs were collected across the (b) (4) surfaces. All swabs tested negative for *Cronobacter, Salmonella*, and *Listeria* species.

Maintenance performed controlled (b) (4) preparation of the floor surface, followed by (b) (4) (b) (4) was applied to the affected area to reseal the floor and provide hydraulic resistance against future water intrusion. Quality management determined the overall risk to be low with a minor impact rating. The assessment concluded there was minimal impact to the facility environment, no contact between the leak water and any equipment, and no contact with product or materials. The affected production lots (b) (4) (b) (4) from (b) (4)) were identified, but no other lots were impacted as none were in production during the event.

Process Intrusions (KML)
PROD-6324-WI, Process Intrusion (v.01) describes the steps required when a process intrusion occurs within the manufacturing system. See **Ex 122**. Before any intrusion occurs, mandatory action planning must be conducted to assess all risks and concerns. This planning phase addresses critical questions about the urgency of the work, safety concerns, potential microbiological hazards, foreign material risks, tool requirements, and contamination prevention measures. All tools (b) (4)

After completing any intrusion, (b) (4)

Process Flow, Operations, and Product Coverage

(b) (4)

Throughout the entire process, documentation is maintained using the Process Intrusion Checklist form, which must be completed with appropriate signoffs and submitted to Quality Assurance. This ensures complete traceability and accountability for all intrusion activities relative to product manufacture.

The following table summarizes the process intrusion reports that were reviewed.
Table Answer_13_2

On March 14, 2025, while producing base powder Lot Code (b) (4), a black piece of rubber gasket was discovered in the (b) (4). The (b) (4) were opened and inspected for missing gaskets. On the Process Intrusion Checklist, a (b)(4) flush was documented as not being sufficient prior to resuming production, and in the box asking, "If no-how much flush is required?" N/A was documented. See **Ex 123**. See **Inspectional Observations #1.**

Environmental Monitoring Program (KML)
We were provided QUAL-6510-SOP, Environmental Monitoring Program (v.04), which describes their program. See **Ex 124**. No procedural changes have been made to the procedure since the previous inspection. The firm provided a list of all testing since the previous inspection. See **Ex 125**. We did not focus on the environmental monitoring program during this inspection.

It was explained that the program is the same as noted during the previous inspection. The firm

(b) (4)

(b) (4)

confirmed environmental pathogens are identified using

(b) (4)

(b) (4)

Other Areas Covered

The Blendhouse Allerton Investigation

(DT)

Initial Investigation

BHA was notified on 11/7/2025 of an apparent infant botulism outbreak associated with finished product lots 251131P2 and 251261P2 by FDA officials. After receiving the news, management began winding down production operations over the following weekend. They initiated a traceback investigation into the base powder lots used in the manufacture of finished product lots 251131P2 and 251261P2. This table captures the base powder lots used in each of these finish products.

Table Answer_99_1

Once the base powder lots were identified, the firm sent out retain samples for *Clostridium botulinum* testing. The firm collects retain samples from each bulk tote that is filled. (b) (4) (b) (4) . The retain samples from each of mixes used in the base powder lots were sent to a third-party lab, (b) (4) . At this point (b) (4) retains were sent out for testing.

The Blendhouse team reviewed the manufacturing information, which is included in the batch records, for any anomalies for each of the base powder lots. The sanitation records associated with those base powder lots were also reviewed. Not all production runs of base powder lots were directly preceded by a sanitation break, however the sanitation break that occurred prior that production campaign (multiple lot codes produced over approximately nine days) was reviewed. Management stated that the environmental monitoring records appeared normal as well, with results being steady over the last two years.

The raw materials used in the production of these base powder lots were included in the firm's traceback. The firm shared this document ((b) (4)) with the FDA (**Ex 41**). Retain samples from raw material ingredient that BHA collected samples from during their normal course of operations are typically (b) (4) (b) (4) . BHA began checking their inventory for raw material retain samples that they still had. They also contacted their ingredient suppliers to obtain raw material samples that the manufacturers themselves pull as a part of routine raw material shipments. Ms. Whitesell explained that BHA would not have retains samples of these ingredients (b) (4) (b) (4) .

For raw material lots, that they did not have and could not obtain samples for, BHA substituted samples collected from current inventory for a representative sample. The goal was to send at least (b) (4) lots of each raw material ingredient in for *Clostridium botulinum* testing by (b) (4) in (b) (4) .

On 11/11/25, the firm began evaluating their approximate (b) (4) on their (b) (4) operations. Management was confident that their (b) (4) activities perform as intended due to the (b) (4) circuits (b) (4) validation (b) (4) circuits were paused (b)(4) (b) (4) step in the (b) (4) inspections with a (b) (4)) swabbing to occur. Mr. van der Hulle stated that this was to assess for any potential biofilms. After nothing

Other Areas Covered

was found during these inspections and (b) (4) swabbings, swabs were collected for *Clostridium botulinum* testing. Following the initial investigation, additional experts were brought in by ByHeart's leadership to assess the equipment and perform on the floor investigation. With the initial investigation over, Mr. van der Hulle explained that the next phase would involve a deeper dive into the equipment and evaluation of the valves on the (b) (4)

The (b) (4) dryer entered a schedule sanitation break ((b) (4) (b)(4) of the inspection. The (b) (4) dryer and associated equipment was visually inspected (b)(4) (b) (4) (b)(4). On 11/14/25 after the conclusion of the sanitation, swabs for *Clostridium botulinum* were collected from the (b) (4).

Additionally, the investigation included sampling the water inputs and (b)(4) used in production; portions of filters used were collected; and the packaging components (b) (4)) used at the Blendhouse Portland, OR facility were sent off for *Clostridium botulinum* testing.

Mr. Niall Mullane, Chief Quality Officer, informed us on the progress of the investigation along with the BHA Quality team. He stated that experts in *Clostridium botulinum* were being brought in to help with their investigation. (b) (4) at the (b) (4) was brought in to inspect the (b) (4) dryer.

Second week of the Investigation

BHA continued their investigation of their manufacturing equipment by cleaning, inspecting, and swabbing the (b) (4). After the 11/18/2025 FDA inspection of the processing area that led to questions about the (b) (4) line that travels from the (b) (4) to the (b) (4) dryer, management cut the (b) (4) line out. Swabs were taken from the (b) (4) line where the (b) (4) for *Clostridium botulinum* analysis. The firm also brought in another expert to assist in their investigation. (b) (4) is a (b) (4) that has worked with *Clostridium botulinum* according to the firm.

On 11/19/25, Ms. Katie Whitesell informed us that (b) (4) had notified ByHeart that one of the finished product infant formula samples has tested presumptive positive for *Clostridium botulinum*. Finish product (b) (4) was sampled by Blendhouse after being notified by FDA that it was associated with an illness complaint. Ms. Whitesell stated that the presumptive positive result from (b) (4) has widened the investigation from the two lots the FDA initially reported. She informed us that the investigation into the base powder lots (b) (4), used to make finish produc (b) (4) had already begun.

Fourth week of the Investigation

On 12/3/25, we met with Mr. Alan Estrella, Quality Performance Director to discuss the status of ByHeart's investigation. He informed us that the investigation was still active. The investigation continued on 2-front approach. One front was testing the raw materials and base powders. At this point they had not received any confirmed results. The firm was still sending in samples of ingredients for testing. Ms. Fry reported that they were continuing to work with raw material

Other Areas Covered

suppliers to collect retain samples of the lot they used in the production of the base powders in question. A list of raw materials sampled was provided by the firm (**Ex 42**). She reported that some suppliers were not providing retain samples of raw materials because they were expecting FDA to visit them for an inspection. One of the retain samples that the firm no longer had in their possession and was attempting to recollect was lot (b) (4), Organic Whole Dry Milk Powder supplied by (b) (4) would not provide BHA with a retain sample of lot (b) (4).

The other front was continuing assess the processing equipment as the potential source of the outbreak. Firm personnel were continuing to search for biofilms and collecting swabs inside of equipment, such as (b) (4). Mr. Estrella stated that every surface they have swabbed ((b) (4) have all been negative. Swabs were also taken from the (b) (4) of the (b) (4) consultation with experts. The (b) (4) are (b) (4) (b) (4). According to Mr. Estrella this is the (b) (4) condition at the facility.

In assessing the processing equipment, the firm collected samples of (b) (4) used for temperature control, for *Clostridium botulinum* analysis. (b) (4), (b) (4) samples were also collected from the water system prior to (b) (4) treatment. (b) (4) (b) (4).

Sixth Week of the Investigation

Ms. Whitesell informed us that (b) (4)) of a *Clostridium botulinum* isolate discovered in a base powder retain sample from (b) (4) matched a *Clostridium botulinum* isolate obtained from a finish product sample, (b) (4). Finished product (b) (4) one of the initial finish product lots that started the outbreak investigation, was made with base powder lots (b) (4). Base powder lot (b) (4) was one of the lots used in finish product lot (b) (4).

At this point, the firm had notified that in total (b) base powder lots have been found presumptively positive (b) (4). Two of the lots (b) (4) still needed to have isolates pulled from them. Ms. Whitesell stated that (b) (4) had informed them of challenges in pulling isolates from those cultures.

This table was created to summarize the presumptive positive *Clostridium botulinum* testing.

Table Answer_99_2

Ms. Fry stated that the firm was still awaiting results of their additional product contact swab taken form equipment. To date, all the results that they have received for swabs taken from equipment have been negative. No ingredients have tested positive.

Eleventh Week of the Investigation

On 1/21/26, the firm notified us that two presumptive positives had been identified in two

Other Areas Covered

separated raw materials since our last visit. Lot (b) (4) of whey protein hydrolysate (WPH) from (b) (4) ~~tested~~ **was presumptive** positive for *Clostridium botulinum*. The lot had not been used in the production of any ByHeart products. **Testing was ongoing and no isolates were recovered.** A second raw ingredient lot (b) (4) of organic whole dry milk powder (WMP) supplied by (b) (4) tested positive for *Clostridium botulinum*. The lot also had not been used in the production of any ByHeart products. (b) (4) informed ByHeart that one of the isolates from this sample match two isolates in the (b) (4) (b) (4) . Ms. Whitesell indicated that one of these isolates was from a clinical sample and the other isolate was from a ByHeart finish product. She was currently working with FDA to identify which finished product sample it was.

In both instances, BHA decided to send in samples of ingredients existing in their inventory even though neither had been used in base powder yet. Firm management stated even with these results their investigation would continue to move forward as they await further sample results. They would perform tracebacks as needed based on any new positive results.

The Core Assignment

(DT)

On 11/10/2025, FDA's Office of Coordinated Outbreak Response and Evaluation Network (CORE) Response Team 3 issued the BlendHouse Allerton, LLC (IOWA) – Clostridium botulinum/Powdered Infant Formula/Nov 2025 assignment. The assignment included a questionnaire requesting information on traceability records, the firm's manufacturing practices, stock rotation practices, cleaning and sanitation, consumer complaints, and for FDA to conduct retain sampling. Please see the sample collection section for details on the retain samples collected.

Traceability Records

The following information collected under this section is listed below.

A description of firm's operations, including their 3 locations in the U.S.

Table Answer_99_1

BHA only produces bulk base (b) (4)) or finished product (b) (4)) infant formula for their operations. They do not export any of the bulk base powder/finished powder.

The initial CORE request concerned the traceback of ingredients that went into the base powder that went into the production of two finished product lots:

- (b) (4) – made with base powder lots (b) (4) , and (b) (4)
- (b) (4) – made with base powder lots (b) (4) , (b) (4) and (b) (4) .

A list of raw ingredient suppliers was provided by the firm (**Ex 43**). BHA's traceback of the ingredients used in base powder lot listed above was collected (**Ex 44**). A pie chart showing the

Other Areas Covered

questionnaire (**Att 7**).

The batch records for the base powder lots: (b) (4) , (b) (4) were reviewed for any anomalies.

Firm's Manufacturing Process

A simplified review of the firm's manufacturing process flow was provided to CORE RT3 team. This included holding time and temperatures for the (b) (4) tanks.

The current version, version 3, of the Food Safety Plan-East Infant Formula and the one in use during the production of base powders in question, version 1, were collected and submitted to CORE for review (**Ex 45 and 46**).

Nonconformances associated with raw material supplies were reviewed.

Stock Rotation Practices

Firm management explained that shelf-life for raw materials vary by product with a maximum of 3-years. Ingredients are rarely stored for that long before use according to management. They also could theoretically use a product the next day after it is received if product testing for that lot has been completed.

The base powder produced at the Allerton, IA facility has a (b) (4) shelf-life. Ms. Fry stated that on occasion a base powder will ship to the third-party warehouse used to store base powders for the Portland, OR facility on a quality hold.

Cleaning and Sanitation

Core requested a breakdown of the firm's sanitation practices. During (b) (4) production (b) (4) during production. A (b) (4) contains (b) (4) equipment.

BHA's master sanitation documents were collected for the assignment:

- CIP Cleaning Procedure (b) (4) Facility, PROD-6332.06-WI, version 1 (**Ex 47**). This document contains work instructions for cleaning all processing equipment and tanks used in the (b) (4) operations.
- CIP of the (b) (4) CIP Tanks, PROD-6332.06.09-WI, version 2 (**Ex 48**). This procedure is from cleaning the CIP tanks, used during CIP.
- (b) (4) Filler CIP & Hook-Up, PROD-6332.08-WI, version 2 (**Ex 49**). These work instructions are for performing CIP on the (b) (4) Filler that is in the infant formula (b) (4) .
- Cleaning Procedure (b) (4) Dryer, PROD-6332.09.09-WI, version 1 (**Ex 50**). These procedures define the cleaning of the (b) (4) dryer used in infant formula production.

Other Areas Covered

The table of CIP chemicals generated by BHA staff and found in the sanitation section was provided to the CORE team.

Consumer Complaints

At the time of notification from the FDA's Consumer Complaint Coordinator, BHA had not received any complaints associated with the 206VABP/251131P2 and 206VABP/251261P2. The firm opened investigations into these two finished product batches after being notified. Management stated that all received complaints with be included in the ongoing investigation. As part of that investigation, a report will be completed for each complaint.

Retain Sampling

Sampling information, including finish product lot numbers, base powder lot numbers, dates, and totes sampled was captured in a spreadsheet (**Att 8**). The spreadsheet includes the totes that BHA sampled, depicted in green, on the document. Please see the sample collection section of the report for additional details on the retain samples collected.

Onsite Investigation

On 11/20/2025, answers to the initial CORE question were emailed to Response Team 3. Files associated with those topics were uploaded to the team's sharepoint page. After that point, the onsite investigation continued under our direction and any additional questions were handled on an ad hoc basis. The onsite investigation focused on a review of the manufacturing process and associated batch records as potential contributing factors to the outbreak. No link between the process and the outbreak was observed. Please see manufacturing design/operations for further details. Review of the batch records associated with the base powder lots in question let to concerns with the records but not having contributed to the outbreak. Please see OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE for full details.

Along with the manufacturing process, the building was evaluated for potentially contributing to the outbreak. The 11/18/2025 inspection of the building, did not identify any issues in the any of the warehouse/ingredient staging areas, main production areas (b) (4) plant (b) (4)) manufacturing areas, the (b) (4) Dryer building, or the (b) (4) . Management explained that they had completed upgrades to the building during each of the last (b) (4) . The timeline of the upgrades and the manufacturing dates of the base powder lots in question were compared. No link was noted. A list of those projects was collected (**Ex 51**).

Both CORE and the onsite team investigated the ingredients used in the manufacture of the base powder lots in question. The CORE team identified organic whole milk powder (WMP) as an ingredient of concern. The onsite team worked with BHA's quality team to report information on the sourcing, storage, and use of WMP. BHA's firm's traceback document (**Ex 41**), shared by Ms. Fry, helped identify lots of concern for the CORE team.

The primary focus for the onsite team was to evaluate the ingredients located at the facility as potential contributing factors to the outbreak. A thorough review of the water and (b) (4) occurred during the first two weeks of the investigation. The firm's (b) (4) tanks, all located outside of the facility were reviewed the following week. The (b) (4) storage tanks undergo

Other Areas Covered

cleaning and sanitizing (b) (4) through a CIP system. This activity is usually associated with a crack inspection of the tanks, where all (b) (4) tanks are (b) (4) checked for cracks or deformities. The (b) (4) tank, used to batch (b) (4) as an ingredient during (b) (4) formulations, is cleaned at the same frequency as the mix tanks (b) (4) s). The (b) (4) system that (b) (4) (b) (4) tanks appeared to be adequately filtered and functioning as intended. Raw materials stored in the onsite warehouse appeared in good condition and free of damage, tampering, or pest activity. No evidence was found that the (b) (4) raw materials stored onsite contributed to the outbreak.

In assessing the raw materials as potential contributing factors, certificates of analysis (COAs) for each batch of ingredients used in the manufacture of base powders used in 251131P2 and 251261P2 were reviewed. During the review, instances of damaged bags of ingredients were noted. Next supplier non-conformances (SNCs) were reviewed. The instances of incoming raw materials with signs of pest activity on the pallets were noted for WMP, WPH, (b) (4) We evaluated the firm's corrective actions to these SNCs, which was to perform a bag-to-bag inspection these pallets. Please see supply chain for additional details on the SNCs. While unlikely that pest contamination would be the cause of the outbreak, the potentially contaminated raw material arriving during the manufacturing time frame in question was evidence enough to retain this a potential contributing factor.

On 1/21/2026, Ms. Whitesell informed us of the WMP and WPH lots that tested positive for *Clostridium botulinum*. Those ingredients were received at a later date and stored at a different warehouse than the lots identified in the SNCs. Therefore, ingredients contaminated by pest activity was no longer considered a potential contributing factor. In addition, the (b) (4) (b) (4) match between the positive *Clostridium botulinum* ingredients with both a clinical illness and with a prior manufactured finish product appears to indicate that raw materials were more likely the source of the outbreak than the firm's processing equipment and storage practices.

Sanitation

(KML)

This inspection focused on the sanitation operations of the (b) (4) facility (b) (4) processing equipment, the (b) (4) dryer production line equipment and the (b) (4) system. The firm has cleaning and sanitizing procedures for each processing area. A full sanitation break is completed between campaigns. See **Ex 94** for the 2023-2025 production sanitation break schedule. Sanitation Break Procedure, PROD-6318-SOP version 6 defines the sanitation break as (b)(4) ; a sanitation break may occur as scheduled or following an event. This procedure covers the cleaning of the entire (b) (4) system and lists all forms used to document this cleaning. See **Ex 95**. This includes the (b) (4) area (processor mix tanks, (b) (4) (b) (4) tank, (b) (4) tank, (b) (4) tank, (b) (4) , (b) (4) , and associated product contact surfaces), the dryer (b) (4) (b) (4) and associated product contact surfaces as well as (b)(4) the (b) (4) dryer (b) (4) environment surfaces, the transfer system, and the (b) (4) , and associated product contract surfaces).

CIP Cleaning Procedure (b) (4) Facility, PROD-6332.06-WI, version 1 (**Ex 47**) governs how

Other Areas Covered

cleaning and sanitation is performed in the (b) (4) processing area (liquefier, processor mix tanks, (b) (4) tank, (b) (4) tank, (b) (4) tank, (b) (4) tank, (b) (4) , and corresponding product lines). Work instructions for accurate pipe connections and cleaning parameters for all processing equipment and tanks used are found in this procedure. There are multiple circuits depending on what equipment is being cleaned. In addition, the operator may select a (b) (4) . Each batch day code (b) (4) . Each of the (b) (4) The chemical concentrations and cleanliness of the equipment after washing is required and documented in the CIP Registers.

Cleaning Procedure (b) (4) t Dryer, PROD-6332.09.09-WI, version 1 includes the instructions and procedures for cleaning the (b) (4) dryer, (b) (4) bag (b) (4) See **Ex 50**. This procedure outlines the steps of performing the CIP including the correct hook-ups. The operator is responsible for maintaining the correct concentration of the (b) (4) The (b) (4) is cleaned between non-infant formula products to infant formula or if an allergen changeover is required.

Cleaning Procedure (b) (4) CIP and Hook-Up, PROD-6323.08-WI, version 2, includes the instructions for utilizing CIP to wash all lines and equipment included in the (b) (4) in the (b) (4) . See **Ex 49**. This procedure outlines the steps of performing the CIP including the correct hook-ups. The operator is responsible for maintaining the correct concentration of the (b) (4) to the (b) (4) . After the completion of the (b) (4) to ensure proper cleaning was completed. In addition, (b) (4) are collected; results are recorded. The sanitizer strength is verified (b) (4) procedure starts. The (b) (4) CIP Nozzle (b) (4) the (b) (4) dryer occurs for a minimum of (b) (4) This information is documented on the IF (b) (4) Log.

The following table of the chemicals used during CIP was generated by BHA staff.

Table Answer_100_1

The sanitation break forms were reviewed during this inspection. As an example, see **Ex 96** for the January 21-26, 2025, records. The CIP cycles are charted. See **Ex 97.** Environmental cleaning is

Other Areas Covered

(b) (4)

(b) (4)

(b) (4)

See **Ex 100**. See **Inspectional Observations #2**.

(b) (4)

See **Ex 101**, QUAL-6518.01-FM, Change Control Assessment Form and the ByHeart Allerton Site (b) (4) Validation Swab Results.

In January 2025, th (b) (4) operations, (b) (4) dryer and bulk packaging equipment. See **Ex 102**.

In June 2025, a CIP validation was completed for the (b) (4) CIP to verify an increase in total solids of the product does not compromise the cleanability of the equipment. See **Ex 103**.

Tables and Figures

Table: Answer_13_1

2025 Crack Inspection Reports		
Area	Reports	Exhibit Number
(b) (4) Dryer Ingredient Tanks	◦ (b) (4) Tank	**Ex 28**

Tables and Figures

	◦ (b) (4) Tank ◦ (b) (4) Tank ◦ (b) (4) Silos	
(b) (4)	(b) (4)	**Ex 29**
(b) (4)	(b) (4) (b) (4)	**Ex 30**
(b) (4)	(b) (4)	**Ex 31**
(b) (4)	(b) (4)	**Ex 32**

2024 Crack Inspection Reports

Area	Reports	Exhibit Number
(b) (4)	(b) (4)	**Ex 33**
(b) (4)	(b) (4)	**Ex 34**
(b) (4)	(b) (4)	**Ex 35**
(b) (4)	(b) (4)	**Ex 36**

Tables and Figures

(b) (4)	(b) (4)	Ex 37

Table: Answer_13_2

2025 Process Intrusion Reports		
Date	Description	Product Lot
1/9/25	Failed magnet check. Opened (b) (4) pump to inspect for damage.	(b) (4)
1/9/25	Failed magnet check. Opened (b) (4) supply pump.	(b) (4)
2/1/25	Opened (b) (4) pump to ensure pump was not clogged.	(b) (4)
2/2/25	(b) (4) torn down to inspect for wear. Checking the for (b) (4) from packings.	(b) (4)
2/22/25	Black material found in (b) (4) (b) (4). Opened everywhere (b) (4) gaskets are used.	(b) (4)
3/2/25	Plug at the (b) (4). Opened to remove clog.	(b) (4)
3/8/25	Clog at the (b) (4) pump. Opened pump to unclog.	(b) (4)
3/13/25	Opened pumps as part of an investigation because of magnet findings	(b) (4)
3/14/25	Black piece of rubber discovered in (b) (4). Open (b) (4) valve to investigate.	(b) (4)
3/15/25	Leak on the (b) (4) l pump seal. Replaced damaged seal.	(b) (4)
3/16/25	Leak on the (b) (4) pump. Rebuilt pump.	(b) (4)
2024 Process Intrusion Reports		
Date	Description	Product Lot
8/8/24	Rebuilt the (b) (4) pump.	(b) (4)
8/15/24	Changed gasket on the (b) (4) (b) (4)	(b) (4)
12/18/24	Checked (b) (4) pump because it was not running.	(b) (4)
12/20/24	Replaced the (b) (4) tank (b) (4) (b) (4)	(b) (4)

Table: Answer_98_1

Firm Name	Address	Operations

Tables and Figures

Blendhouse	61 Vanguard Dr. Reading PA 19606	Manufacturing operations are on hold. Currently, only warehousing raw materials.
Blendhouse Allerton, LLC	211 N Central Ave Allerton IA 50008	Manufactures the base powder. As of 7/7/25 manufacture finished product packed in bulk totes.
Blendhouse Portland (Cascadia Nutrition)	19217 Ne San Rafael St Portland OR97230	Blend and packages powdered infant formula in consumer size. In the summer of 2025, ceased blending and now only packaged finished product.

Table: Answer_99_1

	Base Powder Lots
251131P2	(b) (4)
251261P2	(b) (4)

Table: Answer_99_2

Positive sample	Comments
251131P2	◦ One isolate matches (b) (4) ◦ (b) (4) other isolates only match themselves
251261P2	◦ (b) (4) isolate that does not match anything else
(b) (4)	◦ Isolates have not been pulled from this sample
(b) (4)	◦ Isolates have not been pulled from this sample
(b) (4)	◦ Isolate matches 251131P2

Table: Answer_100_1

Chemical	Concentration	Purpose
(b) (4)		

MANUFACTURING CODES

(DT)

Bulk totes of base powder or finished infant formula receive the same label. No change since the last annual inspection. Lot code (b) (4) would have the following breakdown:

(b) (4)

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Inspection Observations	
Observation	1
Citation Text	You did not have a qualified individual document corrective actions taken after an investigation of a deviation from the master manufacturing order.
Observation Details	Specifically, PROD-6324-WI, Process Intrusion, requires a minimum (b) (4) . Production of base powder Lot Code (b) (4) 1 resumed with (b) (4)
Citation Reference	21 CFR 106.50(a)(1)
Supporting Evidence and Relevance	(DT) The process intrusion that occurred during the production of (b) (4) on 03/14/25 to investigate black rubber pieces found in the (b) (4) was documented on Process Intrusion Checklist PROD-6324.01-FM (**Ex 38**). At the bottom of page 2 of PROD-6324.01, "NO" is circled as an answer to the question "(b) (4) prior to resuming production?". The next question on the checklist, "If no-how much flush is required?" was marked "N/A". (b) (4) Procedures in your Process Intrusion Procedure, PROD-6324-WI, (**Ex 39 page 4**) it states "Perform, (b) (4) system. More flush may be needed depending on circumstance, as determined in action planning". If a flush was not necessary, the rationale was not provided on the checklist.
Discussion With Management	(DT) Management acknowledged our concerns with Checklist not containing a justification for a flush not occurring. They stated that they were working on updating their forms and procedures to prevent instances like this from reccuring in the future.
Correction Status	No Firm Response Submitted

Inspection Observations	
Observation	**2**
Citation Text	You did not ensure that all surfaces that contacted ingredients were cleaned and sanitized.
Observation Details	Specifically, PROD-6332.06.04-WI, Ingredient Silo CIP/Chemical Addition states, "(b) (4) of (b) (4) Register for Bulk (b) (4)
Citation Reference	21 CFR 106.30(b)
Supporting Evidence and Relevance	(KMF) Ingredient Silo CIP/Chemical Addition, PROD-6332.06.04-WI, Version 1, addressed the requirements to clean the bulk(b) (4) silos(b) (4). See **Ex 99**. The CIP cycle include (b) (4) Register. See **Ex 100**. The (b) (4) . During review of the 11/5/2024(b) (4) CIP (b) (4) cycle was only documented once on the(b) (4) CIP Register for Silo(b) and Silo(b) (4) See **Ex 100**.
Discussion With Management	(DT) Management acknowledged that record did not indicate that the procedure was followed. Ms. Annie Piepenhagen, Sr. Director of Quality Compliance and Systems expressed concern with the language on the Form FDA 483, Inspectional Observations, that was read aloud. That they language used for Observation 2 may be interpreted that the surface of the(b) (4) storage silo contributed to the outbreak event. The inspectional software that FDA uses, enspect, truncated section 21 CFR part 106.30 (b) to read, "You did not ensure that all surfaces that contacted ingredients were cleaned and sanitized." We agreed that the language used by the software was not the language in the provision that we are associating with the observation. The complete section of 21 CFR part 106.30 (b) reads: A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. **A manufacturer shall ensure** that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and **that all surfaces that contact ingredients,** in-process materials, or infant formula **are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source.** All

Inspection Observations	
	sanitizing agents used on such equipment and utensils that are regulated as pesticide chemicals under 21 U.S.C. 346a(a) shall comply with the Environmental Protection Agency's regulations established under such section, and all other such sanitizers shall comply with all applicable Food and Drug Administration laws and regulations. I explained that changing the language used by the software was out of our control. FDA has streamline some of the sections of CFRs for reasons unknow to us. We explained that our observation was that oil storage silo did not receive a second caustic wash that was specified in the procedure and that we would capture their concerns with the language printed on the Form FDA 483, Inspectional Observations.
Correction Status	No Firm Response Submitted
Observation	**3**
Citation Text	You did not review and evaluate the public health significance of a deviation from a specification established for your production process.
Observation Details	Specifically, the Master Batch Record instructions state, "Mix tank TEMPERATURE must NOT(b) (4) The Mix tank in question will not be fed forward to (b) (4) without Management approval based on ByHeart Q.A. consultation." On March 17, 2025, during the manufacture of Base Mix(b) (4) of(b)(4) Lot Code (b) (4) the temperature of the base mix dropped below(b) (4) The mix was fed forward with no management approval at the time of manufacture.
Citation Reference	21 CFR 106.6(c)(4)
Supporting Evidence and Relevance	(KMF) During review of Master Batch Record (MBR) with the Day Lot Code (b) (4), the following was noted. The MBR instructions state, "Mix tank TEMPERATURE must NOT go below (b) (4) The Mix tank in question will not be fed forward to the Homogenizer without Management approval based on ByHeart Q.A. consultation." On March 17, 2025, during the manufacture of Base Mix(b) (4) Day Lot Code (b) (4), the temperature of the base mix dropped below (b) (4). See **Ex 88, page 11 and 89, page 1**. The mix was fed forward with no management approval at the time of manufacture.
Discussion With Management	(DT) We explained that there were two issues with this observation. One, was that the mix was allowed to be fed forward without management approval. This observation was discussed through the inspection. On 12/5/2025, we were provided with a risk assessment for the temperature excursion (**Ex 40**). The risk assessment that the mix spent (b) (4) minutes below(b) (4) "the product is in a (b) (4) that prevents proliferation; the (b) (4) hold therefore does not increase microbial load relative to immediately entering (b) (4) ". We explained that our second concern was that temperature excursion was not discovered

Inspection Observations	
	during record review. Ms. Fry, who supplied us with the temperature excursion document, stated that they were working on updating the forms and procedures they use during MBR review.
Correction Status	No Firm Response Submitted

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

(DT)

Mr. Michael S. Brennecke, Interim Plant Director; Mr. John van der Hulle, Sr. Director of 3rd Party Technical Operations; Ms. Katleen W. Whitesell, VP of Quality; Ms. Julie L. Fry, Director of Quality; Ms. Erin E. Casey, Quality Compliance Manager; and (b) (6), (b) (7)(C) , Document Control Specialist were present at the firm during the closeout meeting.

Mr. Devon Kuehn, Chief Medical & Scientific Officer; Mr. Niall Mullane, Chief Quality Officer; Mr. Neil Betteridge, Chief Operating Officer; Mr. William Thomas, Sr. Director of Manufacturing; Mr. Marcus Jordan, VP of Supply Operations; Ms. Annie Piepenhagen, Sr. Director of Quality Compliance and Systems; and Mr. Alan Estrella, Director of Quality Performance attended the closeout meeting virtually. Collectively, these ByHeart and Blendhouse employees represented the firm during the closeout meeting and general discussion with management portion of the evaluation.

A three-point Form FDA 483, Inspectional Observations, (**Att 1)** along with a Form FDA 484, Receipt for Sample (**Att 6**) was issued to Mr. Brennecke during the closeout meeting. See objectional conditions and management response section for details.

Management was informed that these observations were ours and may, after further review by the agency, be considered violations of the FD&C Act or other statutes. Legal sanctions available to the FDA may include seizure, injunction, civil money penalties, and prosecution. Blendhouse's management was advised that if FDA receives an adequate response to the FDA-483, within 15 business days of the end date of the inspection, it may impact FDA's determination of the need for subsequent action. Management indicated that they were planning on responding.

(b) (5)

During the close out meeting with the firm, please state the following "Separate from this inspection, the agency will also be following up with you regarding the provisions of the Food and Drug Omnibus Reform Act (FDORA) of 2022 section 3401 as codified at 21 USC 350a-1(i)(1)."

This was read aloud to the firm personnel that were physically present in the room.

ADDITIONAL INFORMATION

Water System
(DT)

The source of the firm's water is (b) (4) (b) (4) that is used in the office and other non-production area is branched off. The water used in production first undergoes (b) (4) (b) (4)). Mr. Brennecke, Interim Plant Director, explained that this (b) (4) , allowing the firm to (b) (4) performing preventative maintenance. Next the water (b) (4) l (b) (4) the (b) (4) The safety sheet for the (b) (4) provided by the firm contains the product speciation for the CDG (**Ex 52**). A (b) (4) , located on the (b) (4) , ensures that (b) (4) (b) (4) l in the ingredient water. Ingredient water is pulled from the storage tank in the formulation of infant formula batches.

The storage tank has an integrated CIP system for cleaning. Mr. Brennecke explained that CIP can only be done (b) (4) . He stated as long as (b) (4) cleaned. A diagram of the water system was collected (**Ex 53**).

Maintenance

The firm's maintenance team checks on the water system, water softener operations, and the (b) (4) system for integrity, leaks, and basic chemistry parameter, like water hardness, (b) (4) . The (b) (4) system specifically is checked for (b) (4) . An example of daily check of the (b) (4) system was collected (**Ex 54**). The firm contracts with (b) (4) (b) (4) service of the (b) (4) system. A copy of the last service record was provided by the firm (**Ex 55**). The (b) (4) are changed (b) (4) They were last changed on 2/26/25 according to Mr. Malouf.

The backflow prevention devices in the facility are tested on a (b) (4) basis, as required. A copy of that testing was collected (**Ex 56**).

Water Testing

The testing performed by the firm is dictated by the procedure Water Sampling, QUAL-6527.07-WI, version 3 (**Ex 57**). This procedure calls out for the (b) (4), and (b) (4) sampling requirements. The 2024 annual testing (2025 testing report was not available yet), the last quarterly test report, and the firm's internal testing results were collected (**Ex 58-60**).

Filter Maintenance – (b) (4)
(DT)

The (b) (4) used in production of infant formula (IF), is sourced from (b) (4) (b) (4) was evaluated for potentially contributing to the outbreak. BHA's quality team generated a table listing the (b) (4) units (**Ex 61**):

Table Answer_20_1

A copy of the filter label and manufacturer's filter specs were collected (**Ex 62 & 63**). The firm provided documentation of filter changes for areas of (b) (4) Plant (**Ex 65**), the (b) (4) Mix areas (**Ex 66**), and (b) (4) room (**Ex 67**). The (b) (4) Plant or (b) (4) Facility dryer side filter changes are documented on the (b) (4) Facility Filter Log. The firm provided an example of the log from January 2025 (**Ex 68**). The inlet (b) (4) for the (b) (4) dryer undergoes (b) (4). The (b) (4) level is (b) (4) and the (b) (4) filter is a (b) (4) filter with a (b) (4) Speciation's sheets for both filters were provided by the firm (**Ex 69 & 70**).

(b) (4) silos an (b) (4) tank. The (b) (4) filter at point of use at the (b) (4) silos and (b) (4) tanks are (b) (4) and are changed (b) (4). The (b) (4) filters were changed on 3/21/2025 (**Ex 71**).

Pest Control
(DT)

There have been no changes in the pest control service at BHA since the 2025 (b)(4) inspection. They continue to contract with (b) (4) continues to perform visits to check interior rodent traps, insect zone monitors, insect light traps, pheromone traps, exterior rodent traps, and exterior bait stations. Service visits generally occur every (b) (4); however, they are less frequent in the winter and colder months. Service reports during these date ranges, November-December 2024 and January-April 2025, were reviewed. Those ranges were associated with supplier non-conformances (SNCs) that involved ingredient packages showing signs of pest activity. The reports indicated that BHA was free of a pest activity during those periods. No rodents were found in the interior traps. The pest activity that was contaminating ingredient shipments most likely occurred at different location (i.e. third-party warehouse, during shipment).

Electronic Records
(DT)

Electronic records provided by the firm during the inspection were obtained via box.com and true

copies of these files were stored on FDA servers in accordance with record management procedures.

Tables and Figures

Table: Answer_20_1

Name	Area	Filter Spec	Maintenance Date	Exhibit
(b) (4)	Dryer building	(b) (4)	9/22/25	(**Ex 64**)
(b) (4)	Dryer (b) (4) room	(b) (4)	9/22/25	
(b) (4)	IF (b) (4) (b) (4) room	(b) (4)	9/18/25	
(b) (4)	IF (b) (4) room	(b) (4)	9/18/25	
(b) (4)	(b) (4)	(b) (4)	9/23/25	

SAMPLES COLLECTED

Sample Number	**INV1313131**
Description	Sample INV1313131 consists of 8 subs of base powder lot code (b) (4) collected on 11/13/2025, used to manufacture finished product lot code 251131P2. Sample was shipped to Arkansas Human and Animal Food Laboratory (ARHAFL) to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1313132**
Description	Sample INV1313132 consists of 8 subs of base powder lot code (b) (4) collected on 11/13/2025, used to manufacture finished product lot code 251261P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1313133**
Description	Sample INV1313133 consists of 8 subs of base powder lot code (b) (4) collected on 11/18/2025, used to manufacture finished product lot code 251261P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316847**
Description	Sample INV1316847 consists of 8 subs of base powder lot code (b) (4) collected on 11/18/2025, used to manufacture finished product lot code 251131P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316848**

Description	Sample INV1316848 consists of 8 subs of base powder lot code (b) (4) collected on 11/18/2025, used to manufacture finished product lot code 251131P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum.*
Sample Number	**INV1316849**
Description	Sample INV1316849 consists of 7 subs of base powder lot code (b) (4) collected on 11/18/2025, used to manufacture finished product lot code 251261P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316850**
Description	Sample INV1316850 consists of 8 subs of base powder lot code (b) (4) collected on 11/18/2025, used to manufacture finished product lot code 251261P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1218194**
Description	Sample INV1218194 consists of 7 subs of base powder lot code (b) (4) collected on 11/21/2025, used to make finished product lot 243201P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1218195**
Description	Sample INV1218195 consists of 7 subs of base powder lot code (b) (4) collected on 11/21/2025, used to make finished product lot 243201P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316851**
Description	Sample INV1316851 consists of 8 subs of base powder lot code (b) (4) collected on 12/03/2025, used to manufacture finished product lot code 251481P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316852**
Description	Sample INV1316852 consists of 8 subs of base powder lot code (b) (4) collected on 12/03/2025, used to manufacture finished product lot code 251481P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.
Sample Number	**INV1316853**
Description	Sample INV1316853 consists of 8 subs of base powder lot code (b) (4) collected on 12/03/2025, used to manufacture finished product lot code 251481P2. Sample was shipped to ARHAFL to be analyzed for *Clostridium botulinum*.

VOLUNTARY CORRECTIONS

(DT)

The verification of corrections put in place by the firm was not the objective of this CORE assignment; However, corrections/corrective actions that came up during the outbreak investigation were noted below.

These are the additional observations from the 2025 annual inspection that were not on the last annual 483.

The two additional observations were not included on the Inspectional Observations consisted of the firm not having clear barriers separating hygiene zones; and not monitoring (b) (4) differential pressures.

- *These observations require further follow up. Due to the directed inspection, corrections to these items were not verified.*

Seven items were also discussed with management at the conclusion of the 2025 annual inspection:

1. The firm allowing for significant pest activity in (b) (4) hygiene areas;

- *No signs of pests were observed during the walk through on 11/18/25. A review of the pest control records going back to 2024 did not indicate any concerning obsrevations.*

2. QA personnel missing final QA reviews and checks for records;

- *This issue was again observed. See Observation 2.*

3. Not securing the double doors to the (b) (4) processing to not allow employee access;

- *This discussion item requires further follow up. Due to the directed inspection, corrections to this item were not verified.*

4. Not collecting routine swabs during production;

- *This discussion item requires further follow up. Due to the directed inspection, corrections to this item were not verified.*

5. Written procedures for environmental monitoring did not capture corrective actions and the event reports populated from deviations pertaining to environmental positives were not clear, nor included all information;

- *This discussion item requires further follow up. Due to the directed inspection, corrections to this item were not verified.*

6. The dryer (b) (4) floors had stains throughout; and the caulking placed on the (b) (4) (b) (4) tank due to an water event is not on a preventive maintenance program; and

- *Floors in the (b) (4) dryer (b) (4) appeared in good condition. The evidence of water events were not observed in the facility.*

7. Rust stains passing through open caulking on the ceiling on level (b) (4) on the dryer (b) (4)

- *The ceiling on level (b) (4) of the (b) (4) dryer (b)(4) appeared in good condition.*

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	IS docs for WMP lot (b) (4)	5
2	IS docs for WMP lot (b) (4)	20
3	IS docs for WMP lot (b) (4)	17
4	IS docs for WMP lot (b) (4)	30
5	IS docs for WMP lot (b) (4)	8
6	IS docs for WMP lot (b) (4)	17
7	IS docs for WMP lot (b) (4)	14
8	IS docs for WMP lots (b) (4)	18
9	IS docs for WPH lot (b) (4)	8
10	IS docs for WPH lot (b) (4)	6
11	IS docs for WPH lot (b) (4)	23
12	IS docs for WPH lots (b) (4)	23
13	IS docs for WPH lots (b) (4)	4
14	IS docs for WPH lot (b) (4)	8
15	IS docs for WPH lots (b) (4)	4
16	IS docs for WPH lot (b) (4)	4
17	Outbound IS (b) (4)	4
18	Outbound IS (b) (4)	2
19	Outbound IS (b) (4)	2
20	Outbound IS (b) (4)	2
21	Outbound IS (b) (4)	3
22	Outbound IS (b) (4)	3
23	Outbound IS (b) (4)	3
24	Tote Labels	2
25	Org chart	1
26	Chain of command and Org chart	7
27	2025 Crack insp. cover page	9
28	2025 Crack Insp. Dryer	12
29	2025 Crack Insp Processors	13
30	2025 Crack Insp Feed tanks	9
31	2025 Crack Insp. Dryer ductwork	43
32	2025 Crack Insp Dryer components	27
33	2024 Crack Insp ing. tanks	15
34	2024 Crack Insp processors	17
35	2024 Crack Insp feed tanks	6
36	2024 Crack Insp Dryer ductwork	48
37	2024 Crack Insp Dryer components	45
38	Process Intrusion checklist	3
39	Process Intrusion procedure	7

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
40	Temperature Excursion in MBR	1
41	Traceback for (b) (4) Base powders	2
42	BHA sampling of raw materials	15
43	ByHeart supplier contact info	1
44	Traceback for (b) (4) base powders	1
45	Food Safety Plan older version	44
46	Food Safety Plan current version	46
47	CIP procesure (b) (4) plant	31
48	CIP procesure (b) (4) CIP tanks	6
49	CIP procedures for (b) (4) filler	17
50	CIP procedure for (b) (4) dryer	19
51	BHA project list	1
52	(b) (4)	12
53	Water diagram	1
54	(b) (4) daily sheet	1
55	(b) (4) quarterly PM	1
56	Backflow testing	3
57	Water sampling procedure	4
58	2024 water report	39
59	(b) (4) water report	15
60	Internal water testing results	4
61	Allerton (b) (4) list	1
62	(b) (4)	1
63	(b) (4) spec	4
64	(b) (4) changes	2
65	IF (b) (4) filter	3
66	(b) (4) mix area filter	3
67	(b) (4) air	2
68	(b)(4) Filter log	2
69	(b) (4) (b) (4) -filter	4
70	(b) (4) f(b) (4) filter	3
71	(b) (4) filter	3
72	Project list	1
73	Supplier Managment SOP	9
74	Ingredient testing	7
75	SNC 2023-2025	3
76	BHA productin schedule	9
77	SNC WMP(b) (4)	8
78	SNC (b) (4)	12
79	SNC WPH(b) (4)	32
80	Approved Supplier List with address	6
81	Audit Observations at DFA	3

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
82	WMP(b) (4) COA	2
83	WPH (b) (4) COA	1
84	HACCP (b) (4) Plant for Infant Forumla	46
85	(b) (4) COA	3
86	(b) (4) COA	2
87	MBR(b) (4) tank	7
88	MBR (b) (4)	22
89	Charts for MBR (b) (4)	4
90	Dryer logbook (b) (4)	4
91	Base powder testing	1
92	(b) (4) base powder test results	32
93	Expiration dates	8
94	BHA production schedule 2023-2025	9
95	Sanitation break SOPs	4
96	Sanitation break CIP forms	79
97	Sanitation break CIP charts	8
98	COP cleaning procedure	8
99	Ingredient silo CIP	7
100	(b) (4) CIP register	1
101	(b) (4) clean and swab results	14
102	(b) (4) CIP validation	47
103	(b) (4) Dryer CIP validation	42
104	Tote labels	2
105	RCA and RCI SOP	28
106	2023 Devation and Events summary	1
107	2024 Deviation and Events summary	1
108	2025 Deviation and Event summary	3
109	(b) (4) pump	49
110	Supplier approval changes since 2023	1
111	Base powder release spec	5
112	BHA lot codes used in BHP can codes	1
113	Invalidated SAL result	24
114	BHA missing magnet check	6
115	BHA use of unreleased premix	8
116	BHA (b) (4)	7
117	Dev and Event investigation E25-025-BHA	8
118	BHA OOS Fat	8
119	Unplanned water event reporting	6
120	Water leaks	7
121	(b) (4) water leak	10
122	Process Intrusion procedure	7
123	Process Intrusion checklist 3-14-25	3

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
124	EMP SOP	19
125	EMP test results	235

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	Issued 483	3
2	Notice of Insp.	3
3	Notice of Insp.	3
4	Notice of Insp.	3
5	Notice of Insp.	3
6	Receipt for Samples	3
7	206 Percentage	1
8	Totes Sampled	1
9	482	3

SIGNATURE

Danny Tuntevski
Investigator
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Karen M Labounty
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