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SUMMARY

Inspection	
Operation ID and Subject	335237: BlendHouse Portland, LLC - C. botulinum/PIF/Nov(2025)

Summary Data	
This is a summary of findings report.	
Inspection Basis	Consumer Complaint

Summary

This Coordinated Outbreak & Response Evaluation Network (CORE), mission critical, comprehensive inspection of a powdered infant formula manufacturer was conducted in response to multiple reports of *Clostridium botulinum* (*C. bot*) in infants who consumed ByHeart Whole Nutrition Infant Formula Milk Based Powder. The inspection was conducted in accordance with the *Infant Formula Program – Inspection, Sample Collection, and Examination* Compliance Program Guidance Manual 7321.006, the *Preventive Controls and Sanitary Human Food Operations* Compliance Program Guidance Manual 7303.040, and eNSpect Operation #335237.

The previous inspection was conducted from 03/17/25 – 03/27/25 and was classified as no action indicated (NAI). There was one discussion item regarding the firm's identification of critical devices so Quality Assurance can conduct a risk assessment of potentially impacted product in the event critical devices are found to be out of calibration. The current inspection revealed the firm implemented corrective actions to this previous discussion item.

BlendHouse Portland continues to operate as a repacker (canning/filling) of bulk infant formula powder for the firm's parent company ByHeart (New York, NY). There have been no major changes to the production process, or the infant formula manufactured by the firm. BlendHouse Portland's operations consist of receiving base powder from its sister facility located in Allerton, IA, (b) (4) the base powder with lactoferrin*, and filling cans and stick packs. BlendHouse Portland began canning operations for ByHeart in July 2023. The first production date of stick pack manufacturing was 12/02/24. BlendHouse Portland has not received any base powder from the firm's Reading, PA facility since 12/01/23. The cans and stick packs are sent to the firm's co-packer, (b)(4) for final packaging. The finished product is sent from (b)(4) to (b)(4) for distribution to stores, and to e-commerce customers who order from the websites www.byheart.com, www.thrive.com, and www.babylist.com. The infant formula is distributed under the brand name "ByHeart Whole Nutrition Infant Formula".

On 11/8/25, ByHeart, Inc. agreed to initiate a recall (recall #H-0249-2026/Event ID 97959) of two lots (lots 251131P2 manufactured (b)(4) on and 251261P2 manufactured on (b)(4)) of ByHeart Whole Nutrition Infant formula after the California Department of Public Health (CDPH), Infant Botulism Treatment and Prevention Program (IBTPP), and state and local partners, reported an increase in the number of *C. bot* type A infections among infants consuming ByHeart Whole Nutrition Infant formula from August 2025 to November 2025. On 11/11/25 the firm expanded the recall to include all product and lots due to additional illness cases and epidemiological evidence, and the firm subsequently ceased all manufacturing.

At the time of the inspection, BlendHouse Portland continued to conduct a root cause investigation of potential sources of contamination of the powdered infant formula from within the BlendHouse Portland facility. The root cause investigation included a review of all production records related to finished product lots 251131P2 and 251261P2, and disassembly and inspection the equipment and plant for potential sources of contamination.

The current inspection included a comprehensive review of the batch production records for finished product lots 251131P2 and 251261P2 including, the manufacturing batch records, component testing, finished product microbiological and nutrient testing, deviations, and unplanned interventions and sanitation

Summary

records.

The inspection also included a review of consumer complaints received by FDA, consumer complaints received by the firm, transportation and holding of components and finished product, food and non-food contact air and gas, sanitation/sanitation monitoring, and supply chain.

At the close of the current inspection there was one discussion item regarding the frequency of monitoring of the (b) (4) sensors between hygiene zones. The firm was provided with instructions for responding to the discussion item, and firm management stated that they would consider the discussion item on the frequency of monitoring the (b) (4) sensors and would provide a written response.

The following samples were collected:

Sample 1304819 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot 251261P2. Sample was sent to Arkansas Human and Animal Food Laboratory (ARHAFL) for analysis for *C. bot.* (b)(4)

Sample 1304820 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot 251131P2. Sample was sent to ARHAFL for analysis for *C. bot.* (b)(4)

Sample 1304821 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b) (4) . Sample was sent to ARHAFL for analysis for C. bot. (b)(4)

Sample 1304822 was collected at BlendHouse Portland on 11/17/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b) (4) Sample was sent to ARHAFL for analysis for *C. bot.* Sample Results: (b)(4)

Sample 1316268 was collected at BlendHouse Portland on 11/24/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b)(4) Sample was sent to ARHAFL for analysis for *C. bot.* (b)(4)

Sample 1316269 was collected at BlendHouse Portland on 12/02/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b)(4) . Sample was sent to ARHAFL for analysis for *C. bot.* (b)(4)

(b) (3) (A)

There were no refusals, and a reconciliation exam was not conducted.

This report was written by Gerard D. DiFiore, Delanie M. Browning and Stephen G. McLane. Sections of this report written by Delanie M. Browning are denoted with the initials "DMB", and sections of this report written by Stephen G. McLane are denoted with the initials "SGM". All other sections of this report were

Summary
written by Gerard D. DiFiore. *As of 05/26/25, BlendHouse Allerton (BHA) began adding lactoferrin (b)(4) . The last batch of infant formula where BHP (b) (4) lactoferrin into a base powder was manufactured on (b)(4), and the first batch of infant formula processed by BHP where the lactoferrin was added by BHA was manufactured on (b)(4)

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
03C001	CORE HUMAN (RESPONSE) FOOD INCIDENTS - MICROBIOLOGICAL HAZARDS
03040	FOOD CGMP INSPECTIONS
03040Q	MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES
21006	INFANT FORMULA SURVEY

Correction Statuses current at time report was signed.

Consumer Complaints Review

FIRM COMPLAINTS COVERED DURING INSPECTION

There have been no changes to the firm's procedures for handling product complaints since the previous inspection that was conducted 03/17/25-03/27/25.

As previously reported, all complaints are initially received by ByHeart corporate. ByHeart corporate is responsible for the initial management, investigation, record maintenance and retention of complaints. ByHeart has a written procedure titled "Complaint Management Policy" (QUAL-2503-POL) that describes ByHeart's procedure for receipt, handling, and investigation of complaints. Complaints are initiated through ByHeart Customer Experience Group and are reviewed by ByHeart's Pharmacovigilance Group (PVG). The Director of Pharmacovigilance works closely with the Patient Experience Team and is responsible for reviewing all health-related complaint records and performing an assessment of complaints and conducting periodic reviews of complaints and for making the final determination of the complaint. The Chief Medical Officer (CMO) at ByHeart (or a designee) is responsible for reviewing all health-related complaints to determine if FDA-Reportability criteria are met, and if there is a potential for hazard to health, or if there a potential for serious adverse health consequences.

Complaints are categorized as either health related complaints or quality complaints. Health related complaints are complaints in which there is any sign, symptom, disease, or illness. Health related complaints include (b) (4) health related complaints that include the following: (b) (4)

(b) (4)

The Parent Experience Team is responsible for immediately notifying ByHeart Quality Management and Pharmacovigilance of any sensitive complaints. Sensitive complaints include those complaints where a (b) (4) Quality complaints are complaints related to the physical characteristics of the product or package. (b) (4)

The quality Management at the manufacturing sites (BlendHouse Portland, BlendHouse Allerton and BlendHouse Reading) are responsible for reviewing complaint information for accuracy, facilitating and conducting complaint investigations, including reviewing batch production records, implementing corrective and preventive actions and for conducting trending of complaints. Complaints can also be sent to

Consumer Complaints Review

the firm's contract manufacturer responsible (b) (4) on the on the finished product (b)(4) to conduct their own complaint investigation.

All investigations of health-related complaints include a review of the batch production records, component and finished product test results, and any deviations associated with the batch. The firm has established a threshold for the number of health-related and quality complaints that may trigger further investigation. The threshold for health-related complaints is (b)(4), the threshold for quality related complaints is (b)(4); the threshold for foreign body complaints is (b)(4); and the threshold for severe, unusual, or sensitive complaints is (b)(4). If the PVG identifies (b)(4) complaint records with a relatedness assessment of related or possibly related to a particular batch, then the PVG will notify Quality that the threshold has been met, and the batch may require further investigation.

Complaints received by ByHeart corporate are tracked in their system referred to as (b)(4), and those complaints receive a complaint number, or "CN". Complaints forwarded to the manufacturing sites are then assigned a complaint event reporting number, or "CER Number" by the manufacturing site.

At the time the inspection was initiated on 11/11/25, the Director of Quality at BlendHouse Portland reported that the firm has only ever received one complaint where the complainant reported hospitalization and suspected *C. botulinum,* however the complainant was lost to follow-up and no additional information, such as product batch/lot number, was provided by the complainant. The complaint was assigned complaint number CN-00-5563.

The following is a description of complaints received by the firm for batch #251131P2.

The investigation of these complaints conducted during the inspection included a review of the batch records, in-process tests and examinations, process interventions, deviations, sanitation, certificates of analysis for lactoferrin, authorized release certificate for the base powder, finished product microbiological testing, environmental monitoring and pest control associated with production of lot 251131P2.

CN-007818

The complaint report states, "A parent reported that ByHeart Whole Nutrition Infant Formula caused constipation, confirmed by pediatrician and corrected with a new formula brand. The parent denied any changes in the baby's feeding routine and was only feeding ByHeart at the time." TTO was reported as 4 days, de-challenge and re-challenge was positive; however, the parent reported that infant was evaluated by the HCP who confirmed diagnosis as constipation, and suggested to change formula. No root cause analysis was conducted.

CN-007873

A parent reported that their baby has been colicky, constipated and has a swollen belly on ByHeart Whole Nutrition Infant Formula. No additional information was provided to the firm. The firm made multiple attempts to contact the complainant, and the complaint was lost to follow up.

CN-008142 (CER #25-108)

A complaint received via FDA stated that it was reported to the agency by a parent that their infant on the ByHeart Whole Nutrition Infant Formula had infant botulism. The firm is conducting a root cause investigation that includes sending retained samples to (b)(4)

CN-008170

The complainant reported the following: "On (b) (4) my (b) (4) was admitted into (b)(4) hospital with GI and related concerns. He remained constipated until (b) (4). A sample was collected and sent to lab for testing for GI bacteria including botulism. Prior to this date, he consumed four canisters from a four-pack of ByHeart purchased on (b)(4) with the infected batch number. He consumes about two canisters of ByHeart a week, on average." The firm continues to conduct a root cause investigation that includes sending retained samples to (b)(4).

Consumer Complaints Review

CN-007377
The complainant reported the following: "I noticed the aluminum part under the lid was lightly puffed out and when I opened the can some of the formula exploded out as if under pressure." This was the only complaint of this type received by the firm for this batch of finished product. The firm conducted an investigation, and the root cause could not be determined.

CN-007737 (CER #25-095)
The complainant reported the following: "When I opened the can and found a black/brown something. Little black specs oval shaped". The firms root cause summary reported the following: A definitive root cause could not be identified. An extensive review of all production and packaging processes at ByHeart facilities strongly supports that it is highly improbable foreign material was introduced during manufacturing. All foreign material control measures were rigorously assessed, and no failures in the system were observed.

CN-008227
The complainant reported their baby experienced diarrhea and vomiting with the can of ByHeart Whole Nutrition Infant Formula, but specified no botulism. No additional information was provided by the complainant.

CN-008239
The complainant reported their baby had severe diarrhea after consuming a recent can of ByHeart Whole Nutrition Infant Formula. The parent reported they have a can that was listed with the recall batches. No additional information was provided by the complainant.

CER #25-095 (see FDA Consumer Complaint #191733).

The following is a description of complaints received by the firm for batch #251261P2.
The investigation of these complaints conducted during the inspection included a review of the batch records, in-process tests and examinations, process interventions, deviations, sanitation, certificates of analysis for lactoferrin, authorized release certificate for the base powder, finished product microbiological testing, environmental monitoring and pest control associated with production of lot 251261P2.

CN-007866
The complainant reported "Huge spit ups". No additional information was provided by the complainant.

CN-008141 (CER #25-107)
A complaint received via FDA stated that it was reported to the agency by a parent that their infant on the ByHeart Whole Nutrition Infant Formula had infant botulism. The firm continues to conduct a root cause investigation that includes sending retained samples to (b)(4) .

CN-008169
The complainant reported smelly gas, diarrhea, and complaints about the lid design and scoop size. There was no follow up investigation conducted by the firm for this complaint.

CN-008186
The complainant reported "My baby was fed recalled formula. No symptoms yet. I want my money back"

CN-008241
The complainant reported a ten-month-old infant as constipated for four days after consuming the recalled formula. No additional information was provided by the complainant.

CN-008380
The complainant reported that their infant on the ByHeart Whole Nutrition Infant Formula experienced symptoms of infant botulism and reported that the child is currently under the supervision of their

Consumer Complaints Review
pediatrician. The parent did not feel comfortable providing any additional information at the moment. **CN-008437** The complainant reported purchasing 15 cans of ByHeart Whole Nutrition Infant formula from a (b)(4) store in (b)(4) and that the infant got sick. No additional information was provided by the complainant. **CN-008453** The complainant reported a female infant consumed almost half of a can of ByHeart Whole Nutrition Infant Formula before the recall came out. While the infant was not diagnosed and treated for botulism, she was diagnosed and treated for intussusception and the complainant believed it to be linked. The complainant reported "We are having her formula tested and are waiting." No additional information was provided by the complainant. **CN-008203** The complainant reported infant is getting constipated. No further information was provided. The firm made three attempts to contact the complainant, and the complaint was lost to follow up. **CN-008191** The complainant reported their infant has been "having some of the symptoms and is going to be checked out by a doctor after consuming one can of ByHeart infant formula. The complainant did not describe the symptoms the infant was experiencing. No additional information was provided by the complainant. **CN-008192** The complainant reported "We are in the hospital with our daughter. She is being treated for botulism". No additional information was provided by the complainant.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
191414	The information in this consumer complaint was reported to the firm by FDA on 05/28/25. The Complaint Event Reporting and Investigation number assigned by the firm was 25-047. A review of the Complaint Event Reporting and Investigation record for this complaint was reviewed during the inspection without comment. This investigation included, but was not limited to, a complete review of the batch records (including production, process interventions, sanitation, certificates of analysis for lactoferrin, authorized release certificate for lots of base powder, in-process microbiological results and finished powder microbiological results), pest control, as well as environmental monitoring records (including air, water, and all hygiene zone swabs) associated with lot (b)(4) The firms root cause summary reported the following: The investigation indicates there is no evidence of contamination with this batch and that all process controls were effective at managing any risk. There were no environmental positives or product positives. This is the only illness-related complaint that has been received on this batch code. An extensive sampling and testing program for micro and other indicator organisms is in place for the Base Powder (QUAL-2521.21-PMS Infant Formula Base Powder Release Specification - 206-VA), Finished Goods (QUAL-2510.07-PMS Infant Formula Canned Finished Product Release Specification 206-VA) and Plant Environment (QUAL-4510-SOP Environmental Monitoring Program).
191733	The information in this consumer complaint was reported to the firm by FDA. The Complaint Event Reporting and Investigation number assigned to this complaint by the firm was 25-052.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
	The complainant reported this complaint to the firm and reported: I have found a foreign item in my sons formula. It appears to be mold. A review of the Complaint Event Reporting and Investigation record for this complaint was reviewed during the inspeciton without comment. The following is a description of the firms summary of findings and root cause summary: While the customer describes the observed material as mold, there is no indication that Lot (b)(4) was at risk for development of mold during storage. All cans were hermetically sealed, and a composite sample indicated that product moisture was within the specification (b) (4) with a result of (b) (4) Additionally, site subject matter experts indicate that material reported is dissimilar from commonly occurring food-based mold growth in coloration. Material most similarly (b) (4) es cardboard color that is known to be expelled during the can (b) (4) rinse from the (b)(4) . The can rinse (b)(4) . However, as BHP was unable to determine the characteristics of the reported foreign material within this complaint. Without the material being returned or additional information, the size is unable to determine physical characteristics such as size, density, or texture to support further assessment. The investigation indicates there is no evidence of foreign material entry into the processing system as all controls were in place.
193208	An inspection of BlendHouse Portland and BlendHouse Allerton were initiated on 11/11/25 due to potential contamination of the firms infant formula with Clostridium botulinum. Product samples were collected at both locations by FDA field investigators. The firm initiated a recall of all products from the marketplace. Coverage of these inspections is found in the respective establishment inspection reports.
193240	The firm received multiple complaints related to this lot of product (Lot # 251261P2), however the firm did not receive any similar complaints. See Consumer Complaints section of this establishment inspection report for information related to complaints received for lot/batch #251261P2.
193241	The firm did not receive any similar complaints. The complainant did not provide a lot/batch number for the product related to this complaint.
193242	Firm has not received any similar complaints related to salmonella. The complainant provided a product code 206VABP which indicates the product consisted of ByHeart Whole Nutrition Infant Formula, however the complainant did not provide lot/batch number.
193243	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lots/batches #251131P2 and #251261P2.
193244	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lots/batches #251131P2 and #251261P2.
193245	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lot/batch #251261P2.
193246	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lots/batches #251131P2 and #251261P2.
193247	The firm reports receiving complaint on 12/22/24 where the complainant reported hospitalization and suspected C. botulinum, however the complainant was lost to follow-up and no additional information, such as product batch/lot number, was provided by the complainant. The complaint was assigned

Consumer Complaints	
Complaint ID	**Complaint Coverage**
	complaint number CN-005563.
193248	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lots/batches #251131P2
193249	See Consumer Complaints section of this establishment inspection report for information related to complaints received for lots/batches #2512612.
193250	The firm continues to conduct a root cause investigation into complaints related to Clostridium botulinum reported in multiple infants.
193251	Consumer states product was used on 2/24/25. The affected lots were produced on 4/23/25 and 5/6/25. The firm continues to conduct a root cause invetigation into complaints related to Clostridium botulinum reported in multiple infants.
193252	The firm reported receiving multiple complaints related to the can collar spinning freely on the can body. The firm received two reports of spinning collars in January, 10 in February, 46 in March and 30 in April. The firm conducted an investigation (INV-00019) described as follows: During a site visit to (b)(4) representatives from R&D and Quality Release observed that over caps were being applied with excessive force prior to entering the capping machine. This aggressive (b)(4) placement was found to cause deformation or damage to the internal threads of both the cap and collar components. Additionally, during the PQ process it was noted that over caps were occasionally being placed at an angle (i.e., not properly aligned). When misaligned over caps enter the (b)(4) capping equipment, the applied mechanical pressure exacerbates thread damage, ultimately resulting in closure integrity issues. The root cause of the cap and collar complaints was determined to originate from process-related issues at (b)(4) where a can collar and cap are affixed to the can body. To mitigate further damage and standardize the process, several corrective actions were implemented, and work instructions were updated to ensure gentler placement of the over cap and prevent component damage. The calibrator was replaced and maintenance standards established. Additional in-process inspections were introduced by (b)(4) to detect cap and collar damage and ensure The investigation report concluded that that the root cause was attributable to activities at (b)(4) The over cap component is not designed to provide an airtight or sterile seal; rather, it functions solely as a protective cover for the can after opening. Product integrity remains unaffected, as the over cap has no role in maintaining sterility or preventing spoilage when the product is consumed within the recommended 30 day use period.
193253	The firm reports they did not receive similar complaints where the complainant reported an infant did not have a bowel movement for three weeks.
193263	See attached memorandum (ATT. 5).
193349	The firm did not have the complaint in their complaint system. Without a valid and complete lot code there is no trackable complaint in the firm's system
193351	No complaint in the system, no additional follow up or response. There are no other complaints on this lot code, but no indication of issues in the batch record.
193353	No complaint in the system, no additional follow up or response. There are no other complaints on this lot code, but no indication of issues in the batch record.
193356	Complaint was not found in the firm's system. The firm is not able to conduct additional follow up because no lot numbers or identifying information was provided with complaint.
193357	The complaint is in the firm's system. This was one of the recalled lots and investigation is ongoing.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
193359	The firm has additional complaints registered on the use by date but without a valid and complete lot code there is no trackable complaint in the firm's system. No additional response or follow up.
193362	The firm has additional complaints registered on the use by date but without a valid and complete lot code there is no trackable complaint in the firm's system. No additional response or follow up.
193363	The firm does not have a similar complaint in their system. No response or follow up can be conducted without a valid lot code and the complaint can not be traced in the firm's system.
193365	Complaint is in ByHeart system and documentation was reviewed without comment. Three contacts were with the family's legal team. No additional information was provided to firm. Reason for three separate records is for three separate cans with one complaont record per can. No additional contact was made. Ms. Boyd stated she was not sure why no additional contact attempts were made, but is reaching out to the complaints team (parent experience team) to try to discover more information. A deviation report was initiated by the firm to explain why the follow up did not occur.
193370	No complaint in the system, no additional follow up or response. There are other complaints on this lot code, but no indication of issues in the batch record.
193372	No response or follow up without a valid lot code, the complaint cannot be traced in the firm's system.
193374	No response or follow up without a valid lot code, the complaint cannot be traced in the firm's system.
193375	The complaint did not exist in the firm's system. There are no additional complaints on this lot code logged by the firm. No issues are indicated in the batch record.
193377	No response or follow up without a valid lot code, the complaint cannot be traced in the firm's system.
193379	The complaint did not exist in the firm's system. There are no additional complaints on this lot code logged by the firm. No issues are indicated in the batch record.

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

Inspection Samples	
Sample Number(s)	1304819; 1304820; 1304821; 1304822; 1316268; 1316269

ADMINISTRATIVE DATA

Administrative Data	
Firm	BlendHouse Portland LLC
Physical Address	
Address Line 1	19217 Ne San Rafael St
City / State / ZIP	Portland, OR 97230-7445
Phone	1-503-288-6502
Mailing Address	
Address Line 1	19217 Ne San Rafael St

Administrative Data	
City / State / ZIP	Portland, OR 97230-7445
Website	www.byheart.com
Inspection Date(s)	11/11/2025, 11/12/2025, 11/13/2025, 12/2/2025, 12/3/2025, 12/4/2025, 1/21/2026, 1/22/2026, 1/23/2026

FDA Inspection Participants
Participant Name and Title
Delanie Browning, Investigator
Gerard Difiore, Investigator
Stephen Mclane, Investigator

FDA Team Members Not Present for the Whole Inspection

CSO Gerard DiFiore was present in person on the following dates: 11/11/25, 11/12/25, 11/13/25, 12/02/25, 12/03/25, 12/04/25. CSO, DiFiore was present 01/23/26 via Microsoft Teams for the close out meeting.

CSO Delanie Browning was present in person on the following dates: 11/11/25, 11/12/25, 11/13/25, 12/02/25, 12/03/25, 12/04/25, 01/21/26, 01/22/26, 01/23/26.

CSO Stephen McLane was present in person on the following dates: 11/11/25, 11/12/25, 11/13/25.

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
11/11/2025	Lori Boyd, Director of Quality
11/11/2025	Lori Boyd, Director of Quality
12/2/2025	Robert Esquer, Plant Manager
1/21/2026	Robert Esquer, Plant Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Lori Boyd, Director of Quality
Person's Name and Title	Robert Esquer, Plant Manager

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Ron Belldegrun, CEO/Owner	Industry Portal Representative and FMD-145 Recipient
Email Address	ron@byheart.com	
Mailing Address	ByHeart 131 Varick St. 11th Floor. New York, NY 10013	
Phone Number	503-288-6502	
*If a corporation		

Guidance Documents Given to the Firm

The document “Electronic Submission of Correspondences” was provided to Lori Boyd on 01/23/26 via email l.boyd@byheart.com.

HISTORY

Food Firm Registration Status	Current
Hours of Operation	The firm operates (b)(4) : The (b)(4)
Additional Information	BlendHouse Portland was registered as a foreign LLC with the Oregon Secretary of State on 6/28/23. BlendHouse Portland is owned and operated by ByHeart 131 Varick St. 11th Floor New York, NY 10013. Gross annual sales for ByHeart for the year 2024 were approximately (b)(4) USD. ByHeart has approximately (b)(4) employees across all facilities.

INTERSTATE (I.S.) COMMERCE

Firm engages in interstate commerce	Yes		
Incoming	Yes	**Outgoing**	Yes
Description of Interstate Commerce	**GDD** (b)(4) percent of components and ingredients used to manufacture the infant formula are received from outside the State of Oregon, and (b)(4) of finished product is shipped outside the state of Oregon. Lactoferrin is supplied by (b)(4) . Base powder is supplied by BlendHouse Allerton, IA and is shipped directly to (b)(4) where the product is held for BlendHouse Portland (BHP). Base powder is shipped from (b)(4) (b)(4) to BlendHouse Portland for processing, where the based powder is (b)(4) with lactoferrin** and packaged in cans or stick packs. The finished product is shipped on (b)(4) trucks from BlendHouse Portland to (b)(4) under hold status. After the product is released by BlendHouse Portland, it is shipped from (b)(4) to (b)(4) for further packaging. Collars and lids are placed on the canned product and the product is case packed and palletized. For stick pack product, the individual stick packs are placed in pouches (14 stick packs per pouch) then case packed and palletized. Pallets of the infant formula are shipped from (b)(4) to (b)(4) (b)(4) or to (b)(4) for distribution to select (b)(4) stores and customers who order from the firm's website www.byheart.com and www.thrive.com, and www.babylost.com. ByHeart's top customers are (b)(4) , and the firm's direct to consumer channels. **Starting on 05/26/25, BlendHouse Allerton (BHA) began adding lactoferrin (b)(4) . The last batch of infant formula where BHP received a base powder and (b) (4) lactoferrin into base powder was manufactured on		

(b)(4), and the first batch of infant formula processed by BHP where the lactoferrin was added by BHA was manufactured on (b)(4) .

DMB/GDD
The interstate movement of the recalled infant formula lot 251131P2 is as follows:

Lactoferrin:
The lactoferrin used in lot 251131P2 was shipped to (b)(4) on (b)(4) (**Exhibit 1, page 5**) [File name: (b)(4)]. This product was then sent to BlendHouse Portland on (b)(4) to be blended with the base powder (**Exhibit 2 and 3**) [File name: Lactoferrin, (b)(4) to BHP_2] [File name: Lactoferrin, (b)(4) to BHP_1].

Base Powder:
(b)(4) lots of base powder were used in the manufacturing of 251131P2. These lots were identified as the following with the following shipment dates to (b)(4)

1. LOT (b)(4) : Sent to (b)(4) on 4/14/2025, with two different shipments (**Exhibits 4 and 5**) [File name: (b)(4) from Allerton (b) (4)) Lot (b)(4) totes 1-8] [File name: (b)(4) from Allerton (b) (4) Lot (b)(4) totes (b)(4).
2. LOT (b)(4) Sent to (b)(4) with 2 different shipments. The first shipment on (b)(4) (**Exhibit 6**) [File name: (b)(4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4)], and the second shipment on (b)(4) (**Exhibit 7**) [File name: (b)(4) (b)(4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4).
3. LOT (b)(4) : Sent to (b)(4) on (b)(4) with 2 different shipments (**Exhibits 8 and 9**) [File name: (b)(4) (b) (4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4) [File name: (b)(4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4).

This Base powder is shipped from (b)(4) to BlendHouse Portland for processing on the following dates:

1. LOT (b)(4) : Sent to BlendHouse Portland on 4/22/2025 and received the same day (**Exhibits 10 and 11**) [File name: (b)(4) to BHP (b) (4) Receipt 22APR2025] [File name: (b)(4) to BHP (b) (4) (b) (4) Receipt 22APR2025].
2. LOT (b)(4) : Sent to BlendHouse Portland on 4/21/2025 and received the same day (**Exhibit 12**) [File name: (b)(4) to BHP (b) (4) Receipt 21APR2025]. An additional shipment was sent to BlendHouse on 4/23/2025 (**Exhibit 13**)

[File name: (b)(4) to BHP (b) (4) Receipt 23APR2025].

3. LOT (b)(4) : Sent to BlendHouse Portland on (b)(4) and received the same day (**Exhibit 14**) [File name: (b)(4) to BHP (b) (4) Receipt 23APR2025]. An additional shipment was sent to BlendHouse on (b)(4) and received the same day (**Exhibit 15**) [File name: (b)(4) to BHP (b) (4) (b) (4) Receipt 28APR2025].

Finished Lot Shipping:

1. Lot 251131P2: Left BlendHouse Portland on (b)(4) and received at (b)(4) (**Exhibit 16**) [File name: Transfer records lot 251131P2 BHP to (b)(4)]
The finished product was held at (b)(4) until it was shipped to (b)(4) (b)(4) on (b)(4) , and was received at (b)(4) on (b)(4) and (b)(4) (**Exhibit 17**) [File name: (b)(4) (b) (4) from (b)(4)) Lot 251131P2]; (**Exhibit 18**) [File name: (b)(4)(b)(4) from Fulcrum (BOL (b)(4)) Lot 251131P2]; (**Exhibit 19**) [File name: (b)(4) (b) (4) from (b)(4) (BOL (b)(4) Lot 251131P2].

The interstate movement of the originally recalled Lot 251261P2 is as follows:
Lactoferrin:
The lactoferrin used in lot 251261P2 was shipped to (b)(4) on 12/12/23 (**Exhibit 20**) [File name: (b)(4) RCPT from (b)(4) Lot (b)(4) This product was then shipped from (b)(4) and sent to BlendHouse Portland on 5/1/2025 and received the same date (**Exhibits 21**) [File name: (b)(4) to BHP (b) (4) Receipt 01MAY2025].

Base Powder:
(b)(4) lots of base powder were used in the manufacturing of lot 251261P2. These lots were identified as the following with the following shipment dates to (b)(4) :

1. LOT (b)(4) : Sent to (b)(4) in one shipment on (b)(4) (**Exhibit 22**) [File name: 017 - (b)(4) (b) (4) from Allerton (b) (4)) Lot (b)(4) tote (b)(4) ; Lot (b)(4) totes (b)(4)

2. LOT (b)(4) : Sent to (b)(4) with 2 different shipments, both on (b)(4) (**Exhibit 23 and 24**) [File name: (b)(4) (b) (4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4)] [File name: (b)(4) from Allerton (b) (4)) Lot (b)(4) tote (b)(4) ; Lot (b)(4) totes (b)(4)

3. LOT (b)(4) : Sent to (b)(4) with 2 different shipments. The first shipment was on (b)(4) (**Exhibit 25 and 26**) [File name: (b)(4) from Allerton (b) (4) Lot (b)(4) totes (b)(4)] [File name: (b)(4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4) . The second shipment date was (b)(4) (**Exhibit 27 and 28**) [File name: (b)(4) to BHP (b) (4) Receipt 30APR2025] [File name: (b)(4) to BHP (b) (4) Receipt 29APR2025].

	4. LOT (b)(4) : Sent to (b)(4) with two different shipments. The first shipment date was on 4/29/2025 and was not received until 5/1/2025 (**Exhibit 29**) [File name: BHA to BHP (b) (4) Receipt 01MAY2025]. The second shipment was on 05/02/2025 (**Exhibit 30**) [file name in box: (b) (4) BHA To (b)(4)]. This Base powder is shipped from (b)(4) (b)(4) to BlendHouse Portland for processing on the following dates: 1. LOT (b)(4) : Sent to BlendHouse Portland from (b)(4) on (b)(4) and received on the same day (**Exhibit 31**) [File name: (b)(4) to BHP (b) (4) Receipt 30APR2025]. Base powder lot (b)(4) was also shipped directly from Allerton Iowa to BlendHouse Portland on (b)(4) (**Exhibit 32**) [File name: BHP (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4)]. 2. LOT (b)(4) : Sent to BlendHouse Portland from (b)(4) with 2 different shipments. The first shipment was on (b)(4) and received the same day (**Exhibit 33**) [File name: (b)(4) to BHP (b) (4) Receipt 30APR2025]. The second shipment was on (b)(4) and received the same day (**Exhibit 34**) [File name: (b)(4) to BHP (b) (4) Receipt 01MAY2025]. 3. LOT (b)(4) : Sent to BlendHouse Portland from (b)(4) with 2 different shipments. Both shipments left (b)(4) on (b)(4) and one was received the same day (**Exhibit 35**) [File name: (b)(4) to BHP (b) (4) Receipt 29APR2025], and the second shipment was received on 4/29/2025 (**Exhibit 36**) [File name: (b)(4) to BHP (b) (4) Receipt 30APR2025]. 4. LOT (b)(4) : Sent to BlendHouse Portland from (b)(4) on 05/08/2025 and was received the same day (**Exhibit 37**) [File name: (b)(4) (b)(4) To BHP]. Finished Lot Shipping: 1. Lot 251261P2: Left BlendHouse Portland on (b)(4) and received at (b)(4) (**Exhibit 38**) [File name: Transfer records lot 251261P2 BHP to (b)(4) The finished product was held at (b)(4) until it was shipped to (b)(4) on (b)(4) , and was received at (b)(4) on 6/9/2025 and 6/10/2025 (**Exhibit 39, 40 and 41**) [File name: (b)(4) (b) (4) from (b)(4) (BOL (b)(4)) Lot (b)(4) [File name: 026 (b)(4) (b) (4) from (b)(4) (BOL (b)(4) Lot (b)(4) [File name: (b)(4) (b) (4) from (b)(4) (BOL (b)(4) Lot (b)(4)].

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Changes to Jurisdiction	Yes
Description of Jurisdiction	The firm continues to operate as a manufacturer of a powdered infant formula labeled in part, "ByHeart Whole Nutrition Infant Formula Milk-Based Powder with Iron for 0-12 Months". The firm's operations consist of receiving bulk infant formula power from BlendHouse Allerton, IA and filling cans or stick

	packs. The stick packs are packaged by [redacted] into labeled pouches/bags.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Lori Boyd, Director of Quality
Roles and Authorities	Ms. Boyd is responsibilities include overseeing food safety and product quality, releasing and holding of product and the firm's environmental monitoring program. The Regulatory Compliance Manager, Release Services Manager, Environmental Monitoring Coordinator, and Lab Technicians Report to her. She reports to the Vice President of Quality Kathleen Whitesell, Vice President - Quality. Ms. Boyd has worked for the firm in the current position since June 2023. Ms. Boyd provided all records and documents requested during the inspection.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #2	
Person's Name and Title	Robert Esquer, Plant Manager
Roles and Authorities	Mr. Esquer is responsible for overseeing the entire production process from inbound of raw material through final packaging of the product and he is the most responsible person of the firm on a day-to-day basis. He has the authority to hire and fire employees. The Production Manager and Maintenance Manager's report to him. He reports to the Senior Director of Operations. He has worked for the firm in his current position since August 2023. During the inspection Mr. Esquer provided detailed description of the firm's manufacturing operations.
The following are applicable to this person	FDA Credentials Displayed to This Person, Accompanied During the Inspection
Person #3	
Person's Name and Title	Dhru Patel, Director of Pharmacovigilance
Roles and Authorities	Mr. Patel is responsible for receiving and reviewing health complaints and working with the Customer Experience Group. Mr. Patel is a (b)(4) and he reports having more than 10 year's experience in drug safety case processing and medical information. He reviews all complaint records, and he performs an assessment of complaints and conducts periodic reviews of complaints. During the inspection Mr. Patel answered questions and provided a detailed explanation of the firm's procedure for conducting investigations of health-related complaints. The Senior of Safety Assurance report to him and he reports to the Chief Medical Officer. He has worked for the firm for approximately 10 years. Ms. Patel joined the inspection remotely to discuss the firm's procedure for handling complaints.
The following are applicable to this person	Interviewed
Person #4	
Person's Name and Title	Ron Belldegrun, CEO/Owner
Roles and Authorities	According to firm management at Blend House Portland, Mr. Belldegrun is the CEO and most responsible person of ByHeart. Mr. Belldegrun was not present during the inspection and was not interviewed during the inspection.
The following are applicable to this person	Industry Portal Representative, FMD 145 Recipient
Email Address	ron@byheart.com
Mailing Address	ByHeart 131 Varick St. 11th Floor. New York, NY 10013

Phone Number	503-288-6502
Person #5	
Person's Name and Title	Dhru Patel, Director of Pharmacovigilance
Roles and Authorities	Mr. Patel is responsible for receiving and reviewing health complaints and working with the Customer Experience Group. Mr. Patel is a (b) (4) and he reports having nine years' experience in drug safety case processing and medical information. He reviews all complaint records, and he performs an assessment of complaints and conducts periodic reviews of complaints. During the inspection Mr. Patel answered questions and provided a detailed explanation of the firm's procedure for conducting investigations of health related complaints. The Senior of Safety Assurance report to him and he reports to the Chief Medical Officer. He has worked for the firm for nine years. Ms. Patel joined the inspection remotely to discuss the firm's handling of consumer complaints/product complaints.
The following are applicable to this person	

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

There have been no major changes to the firm's manufacturing design and operations, production and process controls, or types of products manufactured by the firm since the previous inspection.

The firm continues to operate from a single storied, (b)(4) square foot facility. Manufacturing operations consist of filling cans and stick packs with finished infant formula powder received from BlendHouse Portland.

There is no water used in the production facility for any reason, including when conducting cleaning and sanitizing operations. There are no floor drains located in high care areas. The only floor drains are located in the employee rest rooms, and behind the (b)(4) which is a low traffic area that has a dead end and is gated.

Production areas are designated as (b)(4) areas (**Exhibit 42 - Hygienic Zoning Floor Plan**).

The firm has written procedures that cover each point, step, or stage in the production process; the firm has implemented production and process controls at various points, step, or stages throughout production process; and conducts monitoring and verification of the production and process controls. The firm follows a master manufacturing record and documents manufacturing operations in a batch production record (**Exhibit 43 - Process Flow Diagram**).

Receiving Components

The facility has (b)(4) overhead doors for shipping and receiving. Components received include bulk base powder; lactoferrin; (b)(4) cans; can ends; can lids. Material Handlers inspect the seals on delivery vehicles and inspect the conditions and cleanliness of the delivery vehicle prior to offloading. The receiving of product/components is documented in the "Inbound Material Inspection" form. Material Handlers enter the product/component into the firm's (b)(4)) and the product/components are automatically put on hold in the (b)(4) . Each component is assigned a unique product code. The firm does not assign its own lot numbers to any components, but instead, uses the supplier lot number. The (b)(4) notifies QA who is responsible for conducting a review of the COA's against component specifications and making a disposition decision. The firm receives an Authorized Release Certificate (ARC) for base powder it receives from BHA. Product/components that meet the firm's specifications are

Process Flow, Operations, and Product Coverage

release by QA in the (b)(4) and "QA Approved" stickers are placed on each container of the received component(s). The status of rejected components is changed from "hold" to "rejected" in the (b)(4) and the rejected component(s) are identified with a quarantine sticker. Each component is assigned a unique product code. The firm does not assign its own lot numbers to any components, but instead, uses the supplier lot number.

Can Unloading

Cans are received on pallets with a cardboard slip in between each layer. Pallets of cans are moved to a depalletizer located in the main warehouse. The cardboard slip is removed from each layer and the cans are conveyed through a (b)(4) into the (b)(4) room. The cans are (b)(4) with (b)(4) (b)(4). The cans are (b)(4) The (b)(4) and (b)(4) intensity on the (b)(4) are set by the manufacturer and cannot be adjusted by BHP, and the (b)(4) . (b)(4) which checks cans for debris, punctures, out of round cans. The cans (b)(4) can filler.

Blending and Filling Operations

The following is a description of the manufacturing design and operations the firm followed when manufacturing batches 251131P2 and 251261P2. Batch 251131P2 was manufactured on (b)(4) and batch 251261P2 was manufactured on (b)(4) . Both of these batches had lactoferrin powder added at BlendHouse Portland (BHP). Starting on (b)(4) , BlendHouse Allerton (BHA) began adding lactoferrin (b)(4) The last batch of infant formula where BHP received a base powder and (b) (4) lactoferrin into base powder was manufactured on (b)(4), and the first batch of infant formula processed BHP where the lactoferrin was added by BHA was manufactured on (b)(4) .

Prior to start up the firm conducts a (b)(4) verification that the warehouse, (b)(4) room, (b)(4) room and (b)(4) rooms are clean and documents on a (b)(4) checklist. At (b)(4) a supervisor will walk-through and inspect the equipment and document the inspection on the "Supervisor (b)(4) Checklist"

(b)(4) (b)(4)

Process Flow, Operations, and Product Coverage

(b)(4)

(b)(4)

Process Flow, Operations, and Product Coverage

In-Process Product Label Verification form (QUAL-4515.02-FM). (b)(4) the firm conducts a verification of the scales production (except for the blender load cells) using (b)(4) weights. The verification is documented in the (b)(4) Scale Verification Form" (QUAL-4511.07.02- FM).

In-Process Tests and Examinations Conducted on Filled Cans

Can weight
(b)(4) cans are collected at the check weigher (b)(4)) during can filling and weighed on a (b)(4) scale to check the variance between the checkweigher at the filler (variance must be (b) (4)) which is documented in the "Product Weigh Verification Form" (PROD-4319.01-FM).

Loose and tapped density
Loose and tapped density of finished product powder is conducted (b)(4) thereafter, and (b)(4) and documented in the "Loose and Tapped Density Sheet" (QUAL-4513.47-FM).

Reconstitution and organoleptic evaluation
A reconstitution test is conducted (b)(4) . The reconstitution test checks for weight; flavor, odor, and undissolved particles by passing the reconstituted formula through a (b)(4) and is documented in the "Infant Formula Reconstitution Sheet" (QUAL-4513.38-FM).

Can leak detection
(b)(4) cans are collected (b)(4) and tested for leaks using a (b)(4) detector following the procedure (b)(4) Detection Test" (QUAL-4513.43-LM").

(b)(4)
(b)(4) cans are collected from (b)(4) and tested by for (b)(4) using the (b)(4) following work instruction (b)(4) Analysis WI" (QUAL-1511.23-WI).

Scoop weight
(b)(4) cans are collected (b)(4) and check the weight of each scoop to determine the scoop weight is within the acceptable range. Documented in the ByHeart Infant Formula: Determination of Scoop Weight form (QUAL-4513.38-FM).

Can seam inspections
(b)(4) cans (b)(4) (b)(4) evaluation of the cans for the following:
(b)(4)

Can head space
(b)(4) can is checked for head space and weight and documented in (b)(4) which is documented on the "Fill Weight, Head

Process Flow, Operations, and Product Coverage

Space, Verification Log" (QUAL-4513.37-FM).

(b) (4)
The firm no longer conducts (b) (4) test on finished product. The firm explained that they had never seen an issue with the (b) (4) step so the decision was made to stop testing finished product for (b) (4) after (b) (4) .

(b)(4) was purchased in 2022, as an extra layer of protection against *Cronobacter spp*. It was validated and put in line in August 2023, but further validation showed it wasn't operating at the factory certification. ByHeart reached out to the equipment manufacturer to address this issue. There has been ongoing trouble shooting Sept 2023 to June 2025. This trouble shooting consisted of multiple changes and system updates/improvements, and tech visits. It has been determined that the (b) (4) is still not performing at the expected rate. Because it is not functioning at the expected rate the (b) (4) is not considered a control at this time, (b)(4) . The firm is not (b) (4) The firm reports that, when a new (b) (4) is sourced, a validation would be conducted. The pathogen of concern would be *Cronobacter spp*. and a (b) (4) would be used again to validate a new system.

Other Areas Covered

Batch Record Reviews for lots 251131P2 and 251261P2

A review of the batch production records finished products lot 251131P2 and lot 251261P2 was conducted without comment or observation (**Exhibits 44 and 45**). The review covered certificates of analysis (COAs) for all components used to manufacture the batch including lactoferrin, base bulk powder, cans, can ends; cleaning, sanitation and (b)(4) ; CCP compliance; in-process tests and examinations; finished product COAs for microbiology (including indicator organisms, *Salmonella spp*. and *Cronobacter spp*.), 107.100 nutrients, and heavy metals. In addition, the environmental monitoring results between (b)(4) were also reviewed without comment or observation.

The review also covered deviations, rework, and product contact zone interventions for lots 251131P12 and 251261P2 as described below.

Lot 251131P2 Deviations
E-25-080-BHP
On 4/23/25 (lot 251131P2), routine QA Testing conducted on cans from time (b)(4) identified a measurement on (b)(4) outside of min/max. Overlap was (b)(4) on (b)(4) and was (b)(4) (b)(4) . The Overlap range is (b)(4) Upon identification of short overlaps during testing product was put on hold back to the last acceptable check. Adjustments were made in real time to bring the seam measurements back within the min/max range. The short overlap was identified during the last routine check of the day at (b)(4) . The previous check conducted at (b)(4) was within min/max range. All product from the (b)(4) back to (b)(4) was placed on hold, implicating pallets (b)(4) . Targeted re-testing was conducted near the (b)(4) short overlap result for seam and leak testing. (b)(4) additional samples were tested from pallet (b)(4) . (b)(4) samples identified at least one parameter outside of min/max range. All re-test cans were tested for leaks in the (b)(4) and all cans passed. Between re-tests and original sampling, (b)(4) leak tests were performed, all with passing results. A key factor identified as a direct cause of the short overlap was due to incorrect setup of seamer such as the distance between (b) (4) . Discussion with, and guidance from the (b) (4) (b) (4) the can and can end manufacturer, confirmed it is possible to have an adequate double seam with a slightly undersized overlap and it is possible for the overlap to vary about the circumference of the can and still provide an adequate double seam. If overlap drops below (b) (4) there is an increased risk of leaks, and leak testing remains the best indicator of performance, which is routinely performed in process at BlendHouse Portland. (b) (4) indicated that along with overlap and leak test performance, evaluation of the

Other Areas Covered

(b)(4) are all used together to determine if the seam is tight enough. Based on the evaluation of the results of all parameters on those cans, as well as leak results, (b)(4) results and the (b)(4) of the double seams the hermetic seal is intact on the cans with no concerns of leaking. The measurements which are outside of min/max range do not pose any impact to the safety, purity, quality or nutritive value (SIPQN) of the product. After compiling and reviewing the results of testing retesting, the firm wanted to test additional cans from around the time (b)(4) so the firm pulled (b)(4) that was closed to this time and tested additional cans for leaking using the (b)(4) and there were no leaks in the additional cans that were tested (**Exhibit 46**).

Lot 251131P2 Product Contact Zone Interventions
There were no product contact zone interventions during the manufacture of lot 251131P2

Lot 251261P2 Deviations
E-25-093-BHP
During routine batch review it was discovered that the expiration date of finished product lot 251261P2 was "01DEC2026" but should have been "01NOV2026". The calculation of the canned powder expiration date is (b)(4) from the base powder manufacturing date and applies when the base powder is canned prior to its own expiration date, which is set at (b)(4) from the date of manufacture. Lot 251261P2 was canned (b)(4) from the date of manufacture of the oldest base powder used to manufacture lot 251261P2. The shelf life of the canned product was tested at (b)(4), which includes the (b)(4)) for base powder and (b)(4) from the date of canning, which is within the (b)(4) shelf life. Additionally, stability data of the base powder shows no significant changes for a period up to (b)(4). The planned shelf-life buffer indicates that, even though the product should have been given an expiration date of 01NOV2026, three is no risk to the finished product being given a shelf life of 01DEC2026 as it remains under the total (b)(4). The firm conducted a root cause investigation and determined the assigned expiration date of "01DEC2026" was due to a miscommunication that an older base powder used in the manufacture of the lot 251261P2 had been completely used during manufacture of the previous batch of finished product. The firm's corrective action included formalizing a document for verification of the oldest base powder status after the previous run and before the next run (**Exhibit 47**).

E-25-094-BHP
While performing an end of run flush to purge remaining powder from lines to ensure a clean break between batches of finished goods, the Filler Operator reported hearing a noise coming from the filler hopper and the HMI display for the filler hopper was giving an auger fault message. End of run (b) (4) checks were performed with no findings. A filler hopper intervention was conducted, and it was discovered that one of the (b)(4) had dislodged and dropped down into the auger sleeve and contact with the agitator which was the most likely cause of the noise. Intervention procedures were conducted, and repairs were made in a sanitary manner. Augers, hoppers, agitators and funnels were inspected and verified to have no damage and not missing any metal. The last (b)(4) cases from the production run were sifted through a (b)(4) (b) (4) screen and inspected with a metal detector and there was no evidence of metal in the product. There was no impact on the SIPQN of the product as the issue occurred during an end of run product flush which is not sellable inventory. The root cause was determined to be a defective level sensor that was showing the hopper was empty when it was full, causing over-filling of the filler hopper and additional pressure on the sparger, which caused the sparger to dislocate and contact the auger (**Exhibit 48**).

Lot 251261P2 Rework
An operator monitoring the (b)(4) for defective cans observed 16 cans that were dented and had a visual defect that caused a gap between the can body and can lid during the can seam examination(s). The 16 rejected cans were documented in the batch production record on the "Product Examination (b)(4) System (b)(4) Rejection Log" (**Exhibit 45, pages 139-199**). The Production Manager was notified, and a pallet (b)(4) was put on hold for re-inspection. The following day (05/07/25) each can on the pallet was (b)(4) inspected ("reworked") and there were 18 additional cans with similar defects. (b)(4) from the 18 rejected cans was pulled and tested for leaking (tested via (b)(4)), (b)(4) and

Other Areas Covered

a can seam tear down was conducted. All cans were within specifications for leaking and can seam evaluation and five of the (b)(4) cans tested for residual oxygen were within specifications. An Authorized Destruction Notice (AND) was issued for the 18 additional cans, and the initial 16 cans were "discarded in process" as they had not been added to inventory. The Director of Quality, Lori Boyd, explained the firm did not escalate this issue to a deviation as this was a one-time occurrence that did not repeat, however the firm documented this event on a "Seam Sorting Rework" form (**Exhibit 49**).

Product Contact Zone Interventions

There were two product contact zone interventions during the manufacturing of lot 251261P2 described as follows:

1. During a routine GMP audit, the firm observed leaking powder coming from a pipe at the (b)(4) hopper. The (b)(4) hopper was removed, cleaned, sanitized and reassembled. Operators conducting the intervention donned PPE to prevent contamination of product, and all tools used during the intervention were sanitized. (b)(4) swabbing of the food contact equipment and was within specifications (b)(4)). The intervention was observed by QA per the firm's written procedure for conducting product contact zone interventions.

2. The top of the (b)(4) hopper, (b) (4) and gasket were removed due to abnormal functioning. Operators conducting the intervention donned PPE to prevent contamination of product and all tools used during the intervention were sanitized. (b)(4) swabbing of the food contact equipment and was within specifications (b)(4)). The intervention was observed by QA per the firm's written procedure for conducting product contact zone interventions.

Temperature and Holding

The (b)(4) rooms (high care areas) are temperature and humidity controlled but are not monitored. The temperature and relative humidity (RH) specifications for high care during the (b)(4) months is (b)(4) . The temperature and humidity specifications during the (b)(4) months is (b)(4) .

BlendHouse Portland (BHP) has a written procedure titled, "Requirements for Storage and Transport" (QUAL 2505.01-SOP) that establishes specifications for the storage and transportation conditions of ByHeart ingredients, packaging, infant formula powder in bulk and finished to protect the product from physical, chemical, and biological hazards, including temperature and humidity excursions.

All components and the finished product are considered by BHP to be "shelf stable" and do not require refrigeration to prevent microbial growth and toxin formation. The storage requirements for the base powder and infant formula powder received from BlendHouse Allerton (BHA) is (b)(4) and 65% RH for up to (b)(4) from the date of manufacture. Any bulk infant formula powder that is greater than (b)(4) old is discarded. For other ingredients, the SOP states (b)(4) The manufacturer's product data sheet for the product (b)(4) (lactoferrin) lists the storage conditions as "Store in a cool, dry environment below (b)(4) (b)(4) and at a relative humidity below (b)(4). Prior to 7/2/25, the lactoferrin was shipped from (b)(4) to either BHP or (b)(4) Bulk quantities of lactoferrin were stored at (b)(4) and smaller quantities were stored at BHP, however all infant formula powder processed by BHP after 07/2/25 has had the lactoferrin added at BHA. The storage requirements for the finished product in Cans/Stick Packs established by BHP is (b)(4) .

Other Areas Covered

Base powder from BlendHouse Allerton, IA (BHA) is shipped in totes in refrigerated trucks to (b)(4) facility located at (b)(4). The set temperature of the refrigerated trucks is (b)(4). According to the Director of Quality for BHP, the temperature of the delivery vehicles is monitored at the time of receiving but the temperature is not documented.

(b)(4) facility is not climate controlled, however, the temperature (but not humidity) is monitored at multiple points throughout the facility, and Director of Quality at BHP receives a (b)(4) email from (b)(4) of the temperature from a single temperature monitoring device and from a single point in time. The base powder and lactoferrin are transported in non-refrigerated dry trucks from (b)(4) approximately (b)(4) prior to manufacturing.

During the (b)(4) months BHP holds the component lactoferrin in the air-conditioned (b)(4). In addition, during the summer months the firm keeps (b)(4) nd keeps the rest of the material is held at (b)(4) warehouse. According to the Director of Quality for BHP, while the third-party logistics warehouse is not air conditioned, the facility is larger than the BlendHouse Portland facility and the facility has lower ambient operating temperatures in the (b)(4) months compared to BlendHouse Portland's facility.

The finished infant formula manufactured by BHP is shipped on non-refrigerated dry trucks from BHP to (b)(4) within (b)(4) of manufacturing. Cans and stick packs are normally shipped from (b)(4) to (b)(4) on refrigerated trucks. If the product is shipped in non-refrigerated dry trucks, temperature data loggers are shipped with the product and Director of Quality at BHP reviews the temperature collected from the temperature data loggers for temperature excursions.

The (b)(4) rooms (high care areas) are temperature and humidity controlled but are not monitored. The temperature and relative humidity (RH) specifications for high care during the (b)(4) months is (b)(4). The temperature and humidity specifications during the (b)(4) months is (b)(4).

BlendHouse Portland conducted a Temperature Monitoring Study of its facility to evaluate seasonal variations in temperature and humidity throughout the warehouse and to identify warehouse zones susceptible to temperature and humidity variations that could compromise product quality. The study was conducted over three time periods (b)(4). Temperature monitoring devices with data loggers were placed throughout the warehouse in high risk, medium, risk and low risk areas (**Exhibit 50 - Environmental Mapping Study of Temperature and Relative Humidity in a Transient Infant Formula Manufacturing Warehouse**).

Sanitation and Environmental Monitoring

(GDD)
There have been no significant changes to the firm's sanitation program since the previous inspection. The firm was not conducting manufacturing operations during the current inspection; therefore, cleaning and sanitation operations were not observed. A walk-though inspection of the facility was conducted and the previously cleaned and sanitized equipment was inspected. During this time, the firm explained the procedures for cleaning and sanitation operations to Stephen McLane.

(SGM)
The firm's sanitation program was reviewed. The firm has a written procedure titled, "Master Sanitation Procedure" (SAN-4700-SOP) that describes the firm's sanitation program. The firm maintains a master sanitation schedule that describes the frequency of cleaning of equipment, tools, containers, structures, and grounds. The firm has written SSOPs and work instructions that describe the procedures for each location and task listed in the master sanitation schedule that includes the frequency of cleaning, chemicals used for cleaning, and sanitation procedures. (b)(4) sanitation is conducted by production

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personnel and is documented on the respective forms (i.e., (b)(4) sanitation forms).

(b)(4) sanitation covers external areas of equipment, surfaces, platforms, walls, and floors. The firm conducts (b)(4) sanitation of the whole facility which is describe in the (b)(4) Sanitation Schedule" (SAN4700.01-FM). (b)(4) sanitation is described in the (b)(4) Sanitation Schedule – General Warehouse" (SAN-4700.02-FM).

Currently, sanitation breaks are conducted (b)(4) of production. The sanitation breaks last from (b)(4) and covers all of the rooms and equipment including (b)(4) equipment in medium care areas. Sanitation breaks are documented on the following forms: (b)(4) Cleaning Record, "Sanitary Break (b)(4) Inspection Stick Pak;" Filler and Conveyor Room Cleaning Record." A sanitation break consists of a (b)(4) . The firm maintains a list of approved chemicals "Approved Chemical List." The only food contact sanitizer used by the firm is (b)(4) , which is a (b)(4) sanitizer. The firm operates only a filling and packaging operation. All equipment is (b)(4) cleaned. Powder removal is completed through wiping, brushing away, and vacuuming surfaces. Then the (b)(4) sanitizer is applied to food contact surfaces.

After a sanitation break, the firm conducts a (b)(4) inspection that includes a detailed (b)(4) inspection of each piece of equipment (b)(4) . (b)(4) is (b)(4) inspected using a (b)(4) . A production employee is present during the (b) (4) inspection and is responsible for conducting "on the spot" recleaning of equipment that does not pass the inspection. The Sanitation Manager is responsible for reviewing all sanitation related records the day after sanitation is conducted.

After signing off on sanitation the firm conducts allergen swabbing for milk protein using (b)(4) (b)(4) The firm also swabs for pathogens using a (b)(4) swab for *Salmonella spp.* and *Cronobacter spp.*; and a (b)(4) swab for *Enterobacteracea* and (b)(4). After swabbing, the area swabbed is (b)(4) and wiped with a clean room cloth. The firm collects nearly (b)(4) (see "Environmental Monitoring" section below for more details).

Tools and utensils for cleaning and sanitizing are confined to each room and are color coded for the area of usage ((b)(4) Vacuums used for cleaning are tagged with a "Zone ID" which shows the zone the vacuum can be used. Small equipment pieces are stored in dedicated buckets.

(GDD)
There have been no significant changes to the firm's environmental monitoring program since the previous inspection. The firm continues to conduct environmental monitoring to verify the effectiveness of its sanitation program (see previous establishment inspection report for inspection conducted from 03/17/25-03/27/25 for a full description of the firm's environmental monitoring program). The firm monitors the environment for *Salmonella spp.*, *Cronobacter spp.*, *Enterobacteriaceae* (EB), (b)(4), Yeast and Mold. According to Lori Boyd, the firm as stopped monitoring for *Listeria spp.* since the previous inspection. The justification for not monitoring for *Listeria spp.* was based on a risk assessment of the operating conditions (no water used in the production of product nor wet cleaning of the equipment or facility), as well as a history of no positive swabs for *Listeria spp.* The firm reports having no positive environmental swabs results for *Cronobacter spp.* and *Salmonella* since the previous inspection.

Supply Chain

(SGM)
The firm's supply chain programs were reviewed. The firm has a written procedure titled "Ingredients and Packaging Material Receipt and Handling" (WHSE-4201-SOP) that outlines the requirements for receipt, identification, and storage of ingredients and packaging materials. The firm has written procedure titled,

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"QUAL-2520-SOP, ByHeart Infant Formula Supply Chain Release," which defines requirements for the release of ingredients, packaging components, and products used in the manufacturing, testing, holding, release, and distribution of ByHeart infant formula.

The firm utilizes an approved supplier list which is managed by ByHeart corporate, who approves suppliers and ordering of all materials and packaging components. Suppliers are audited and reviewed through corporate based audit teams. This firm currently only receives bulk base powder from BlendHouse Allerton sister facility and finished packaging components. The firm receives a COA with each shipment.

At the time of receiving a Material Handler inspects the condition of the delivery vehicle which is documented on the "Inbound/Outbound Load Inspection Checklist". The Material Handler will also inspect the ingredient and verifies that the ingredient/components being received are consistent with the purchase order and is from an approved supplier, which is documented on the "Material Inspection Checklist." An ingredient and packaging Status Form is applied to each pallet (if individual packages are received a Status Form is applied to each package). Status Forms are color coded which denotes the status of the component (b)(4)

At the time of receipt, all ingredients and components are entered into the firm's (b)(4) and a randomized lot code is generated for the ingredient/component. The default status when the ingredient/component is initially entered into the (b)(4) is "QC Pending", which prevents the ingredients and components from being used in production. After QC conducts an inspection of the product and reviews the certificate of analysis the component status is updated from "QC Pending" to (e.g. "QA Released", "QC Hold", "Rejected" etc.) and a (b) (4) Status Form is affixed to the product container. If an ingredient or component is rejected, the product is status is changed to "Rejected", a (b)(4) Form is affixed to the product container, the product is moved to the QA cage, and (b)(4) tape is wrapped around the product.

Food Contact Air/Non-Food Contact Air, Gases and Filtration

A walk-through inspection of the facility was conducted and included a review of the air handling systems and equipment which were described by the Plant Manager during the inspection.

As previously reported, the firm has a written procedure titled, "Compressed Air Quality Sampling" (QUAL-4510-WI) that describes the procedure for sampling of compressed air and gases that directly or indirectly contact food product for microbiological and physical contamination.

The filter for the (b)(4) internal can cleaner and external can cleaner is (b)(4) (b)(4) that supplies air to the air hoses used for (b)(4) is (b)(4) (b)(4) The (b)(4) are changed (b)(4) . (b)(4) is tested (b)(4) for microbiological contaminants (b)(4) Yeast and Mold). The samples are collected at the point of use on (b)(4) (b)(4) and are sent to a third-party laboratory.

The firm also collects a sample of (b)(4) 4) and tests for contaminants (total gaseous hydrocarbons, carbon dioxide) and for purity (percent (b)(4) .

The (b)(4) rooms are maintained under positive pressure relative to adjacent rooms (b)(4) (b)(4) . The (b)(4) filters have a (b)(4) . A discussion was held with the firm management about the frequency of monitoring the differential pressure between hygienic zones (see **General Discussion with Management**).

The vacuum in the powder transfer system is maintained by (b)(4) (b)(4) is for the (b)(4) is for the filling

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room. (b)(4) [redacted]

MANUFACTURING CODES

The firm has a written procedure for product coding and traceability titled, "Product Coding and Traceability" (QUAL-4519-SOP). All products made at BlendHouse Portland are labeled with a unique identifying product code that allows the firm to traceback the product code of a finished product to the ingredients and packaging components that were used to manufacture the batch of finished product.

Product Codes/Lot Codes and Use By dates for Cans and Stick Packs
The product code and use by date for cans is laser jet coded onto the can bottoms, and the product code and use by date for stick packs is ink jetted onto the roll stock as it passes through the stick pack machine.

(b)(4) [redacted] rom the date of packaging. Cans are also laser engraved with a time stamp in the format of HH:MM:SS.

REFUSALS

Inspection Refusals
No refusal

There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT

A close out meeting was held on 01/23/26.

The following personnel from the firm were present:

In Person:
· Lori M. Boyd, Director of Quality

· Robert (NMI) Esquer, Plant Manager
· (b) (6), (b) (7)(C) Internal Auditor.

Virtual:
· Devon R. Kuehn, Chief Medical and Chief Scientific Officer, East Coast
· Neil G. Betteridge, Chief Operating Officer, East Coast
· William H. Thomas, Senior Director of Manufacturing, Michigan
· Alan (NMI) Estrella, Quality Performance Director, Indiana
· Niall R. Mullane, Chief Quality Officer, East Coast
· Annie R. Piepenhagen, Senior Director of Quality Compliance and Systems, Pennsylvania
· Katleen E. Whitesell, VP of Quality, Kansas
· Marcus R. Jordan, Vice President of Supply Chain and Manufacturing, East Coast

Discussion Items
There was one discussion item regarding the frequency of monitoring the (b) (4) sensors between hygienic zones. During the inspection, Lori Boyd and Robert Esquer explained that the firm does not conduct monitoring of the (b) (4) sensors to monitor the pressure differential between hygiene zones. The firm later explained to Delanie Browning that the Maintenance Team inspects the (b) (4) sensors (b)(4) as part of their Preventative Maintenance Programs. Ms. Boyd explained that, if the HVAC system went down, the firm would stop operations and that product that was exposed to the environment would discarded as waste (from filler to the seamer due to no (b)(4) flush being possible without the HVAC System) and all sealed products would held until pressure is returned. Ms. Boyd also explained that he HVAC system in those rooms is very audible and the sound cutting out would be the first sign of an issue. She also explained that the HVAC system runs off of a generator, and if the generator were to fail, audible alarms would sound. In addition, if they tried to run in the room with no HVAC, the (b)(4) sensors would cause an alarm to sound, and an evacuation would be needed due to lack of oxygen and an increase in (b)(4) .

Ms. Boyd showed Delanie Browning the (b)(4) preventive maintenance environmental check records for (b)(4) that were reviewed by Delanie Browning without comment. The (b) (4) (b) (4) numbers were noted for the following rooms:

1. (b)(4) room: (b) (4)
2. (b)(4) room: (b) (4)
3. (b)(4) room (b) (4)
4. (b)(4) Room: (b) (4)
5. (b)(4) Room: (b) (4)
6. Clean Room Office: (b) (4)
7. (b)(4) Room: (b) (4)
8. Hygienic Hallway: (b) (4)

During the close out meeting we explained that the firm should be monitoring the (b) (4) sensors between hygiene zone more frequently than (b)(4) . We also explained that the (b)(4) preventive maintenance program appeared to be focused on whether the (b) (4) sensors are working as intended, and not to confirm that the pressure differential between rooms is being continuously maintained during manufacturing. We also explained that, while we understood that a pressure loss would be apparent to operators if the HVAC system were to shut down completely, it may not be apparent in the event that there was a drop in pressure differential between zones not caused by the HVAC system shutting down completely.

The firm was provided with the letter "Electronic Submission of Correspondences" for responding the discussion item. Firm management was provided with instructions for responding to the discussion item, and firm management stated that they would consider the discussion item on the frequency of monitoring the (b) (4) sensors and would provide a written response.

The following statement was read to the firm at the close out meeting, "*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).*"

SAMPLES COLLECTED

Sample Number	**1304819**
Description	Sample 1304819 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot 251261P2. Sample was sent to Arkansas Human and Animal Food Laboratory (ARHAFL) for analysis for C. bot. (b)(4) (b)(4)
Sample Number	**1304820**
Description	Sample 1304820 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot 251131P2. Sample was sent to ARHAFL for analysis for C. bot. (b)(4) (b)(4)
Sample Number	**1304821**
Description	Sample 1304821 was collected at BlendHouse Portland on 11/10/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b) (4) . Sample was sent to ARHAFL for analysis for C. bot. (b)(4)
Sample Number	**1304822**
Description	Sample 1304822 was collected at BlendHouse Portland on 11/17/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b) (4) Sample was sent to ARHAFL for analysis for C. bot. (b)(4)
Sample Number	**1316268**
Description	Sample 1316268 was collected at BlendHouse Portland on 11/24/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b) (4) . Sample was sent to ARHAFL for analysis for C. bot. (b)(4) (b)(4) (b)(4)
Sample Number	**1316269**

Description	Sample 1316269 was collected at BlendHouse Portland on 12/02/25 and consisted of 10 subs of 680-gram cans of ByHeart Whole Nutrition Infant Formula Milk Based Powder with Iron for 0-12 months lot (b)(4) . Sample was sent to ARHAFL for analysis for C. bot. (b)(4)

VOLUNTARY CORRECTIONS

During the previous inspection a discussion was held om 03/25/25 regarding the written procedure titled, "Calibration Procedure" (MAIN-4400-SOP) which states that calibration is the responsibility of the Maintenance Supervisor, and that, Quality Assurance "*is responsible for reviewing calibration forms, frequencies, and tolerances for all calibrated GMP critical devices*" (see previous EIR). I asked Ms. Boyd if the firm maintains a list of critical devices. She explained that the firm does not maintain a list of critical devices. I also explained to Ms. Boyd that the written procedure titled "Investigation and Root Cause Analysis" (QUAL-2532-SOP), *"outlines the guidance and process for conducting effectiveness investigations, identifying root causes, assessing impact and risk, and producing high-quality investigations reports for deviations*" and that the SOP states, in part, that the procedure applies to calibration and validation variations (see previous EIR). I asked Ms. Boyd how Maintenance would know to notify Quality Assurance if a critical device was found to be out of calibration if the firm does not maintain a list of critical devices. On 03/26/25, Ms. Boyd agreed that the calibration procedure was not clear in categorizing equipment that is considered critical and non-critical, and she stated that, based on the discussion on 03/25/25, the firm had already started revising the Calibration Procedure which was not completed during the previous inspection.

During the current inspection, Delanie Browning verified that the firm updated the calibration procedure (MAIN-4400-SOP Calibration Procedure SOP) on 03/25/25 to include the following: Identification of critical equipment; that QA is responsible for reviewing all calibration records for magnets and CCP monitoring equipment; and that QA should be notified of all calibration failures to evaluate the requirement to perform a risk assessment.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	(b) (4) from (b)(4)) Lot (b)(4) . 18 pgs.pdf	18
2	Lactoferrin, (b)(4) to BHP_2.	27
3	Lactoferrin, (b)(4) to BHP_1.	12
4	(b)(4) (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4) 6 pgs.pdf	6
5	(b)(4) (b) (4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4).	5
6	(b)(4) (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4)	6
7	(b)(4) (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4).	8
8	EX. 8 (b)(4) (b) (4) from Allerton (b) (4)	5

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
	Lot (b)(4) totes (b)(4)	
9	(b)(4) (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4).	6
10	(b)(4) to BHP (b) (4) Receipt 23APR2025.	8
11	(b)(4) to BHP (b) (4) Receipt 22APR2025.	7
12	(b)(4) to BHP (b) (4) Receipt 21APR2025.	15
13	(b)(4) to BHP (b) (4) 1 Receipt 23APR2025.	9
14	(b)(4) to BHP (b) (4) Receipt 23APR2025.	5
15	(b)(4) to BHP (b) (4) (b) (4) Receipt 28APR2025.	11
16	Transfer records lot (b)(4) BHP to (b)(4) .	20
17	(b)(4) (b) (4) from (b)(4)) Lot (b)(4)	6
18	(b)(4) (b) (4) from (b)(4) Lot (b)(4)	4
19	(b)(4)(b) (4) from (b)(4)) Lot (b)(4)	3
20	(b)(4) (b) (4) from (b)(4) Lot (b)(4) .	46
21	(b)(4) to BHP (b) (4) 1 Receipt 01MAY2025.	6
22	(b)(4) (b) (4) from Allerton (b) (4) totes (b)(4)	8
23	(b)(4) (b) (4) from Allerton (b) (4) totes (b)(4)	7
24	(b)(4) (b) (4) from Allerton (b) (4) ... Lot (b)(4) totes (b)(4)	8
25	(b)(4) (b) (4) from Allerton (b) (4) Lot (b)(4) totes (b)(4).	6
26	(b)(4) (b) (4) from Allerton (b) (4)) Lot (b)(4) totes (b)(4).	5
27	(b)(4) to BHP (b) (4) Receipt 30APR2025.	6
28	(b)(4) to BHP (b) (4) Receipt 29APR2025.	7
29	BHA to BHP (b) (4) Receipt 01MAY2025.	6
30	(b)(4) BHA To (b)(4)	6
31	(b)(4) to BHP (b) (4) Receipt 30APR2025.	6
32	BHP (b) (4) Allerton (b) (4)) Lot (b)(4) totes (b)(4).	6
33	(b)(4) to BHP (b) (4) Receipt 30APR2025.	8
34	(b)(4) to BHP (b) (4) Receipt 01MAY2025.	6
35	(b)(4) to BHP (b) (4) Receipt 29APR2025.	7
36	(b)(4) to BHP (b) (4) Receipt 30APR2025.	6

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
37	25078Z1 (b)(4) To BHP.	8
38	Transfer records lot (b)(4) BHP to (b)(4)	17
39	(b)(4) (b) (4) from (b)(4) (BOL (b)(4)) Lot (b)(4)	4
40	(b)(4) (b) (4) from (b)(4) (BOL (b)(4)) Lot (b)(4) .	4
41	(b)(4) (b) (4) from (b)(4) (BOL (b)(4) Lot (b)(4) .	4
42	BHP Hygienic Zoning Floor Plan.	1
43	Process Flow Diagram.	2
44	Lot (b)(4) Batch Record.	354
45	Lot (b)(4) Batch Record.	334
46	E 25-080-BHP OOS Seamer.	11
47	E 25-093-BHP Incorrect Expiration Date.	18
48	E 25-094-BHP (b) (4) .	14
49	251261P2 Seam Sorting Rework.	49
50	Heat Mapping Study.	50

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
	Inspection Narrative Report	33
	Coversheet PDF Document for Inspection= 335237	
1	ATT. 1. Form FDA 482 - Notice of Inspection. 11.11.25	3
2	ATT. 2. Form FDA 482 - Notice of Inspection. 11.11.25	3
3	ATT. 3. Form FDA 482 - Notice of Inspection. 12.2.25	3
4	ATT. 4. Form FDA 482 - Notice of Inspection. 01.21.26.	3
5	ATT. 5. Consumer Complaint 193263 Memorandum.	4

SIGNATURE

Gerard D Difiore
Investigator
Signed By: GERARD D. DIFIORE -S
Date Signed: 03-06-2026 09:23:36

Stephen G Mclane
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Date Signed: 03-06-2026 07:48:04