Clostridium botulinum/Infant Formula/Nov 2025
Executive Incident Summary
CARA # 1350
Date:05/01/2026

EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 11/7/2025, CORE Signals was notified by CDC about a potential link between ByHeart powdered infant formula (PIF) consumption and an increase in infant botulism illnesses reported to the California Department of Public Health's (CDPH) Infant Botulism Treatment and Prevention Program (IBTPP). CORE Signals collaborated over the weekend with CORE Response Team 3, CDC and IBTPP to facilitate rapid flow of information and urgent coordination, and information sharing needs, ensuring protective public health action items (firm notification, voluntary recall, public communications, etc.) could begin as soon as possible. At the time of transfer, the case series included 13 cases from 10 states: AZ (1), CA (2), IL (2), MN (1), NJ (1), OR (1), PA (1), RI (1), TX (2), and WA (1) with suspect or confirmed botulism diagnosis that occurred between August and November 2025 with reported exposure to ByHeart PIF.

Epidemiology Overview & Genomic Analysis

This outbreak included 48 (28 confirmed and 20 probable) infant botulism cases from 17 states : AZ (5), CA (12), ID (2), IL (2), KY (1), MA (2), MI (1) MN (3), NC (2), NJ (1), OR (3), PA (1), RI (1), TX (8), VA (1), WA (2), WI (1). The onset date ranges from 12/24/2023 to 11/29/2025. Case ages ranged from 16-264 days old, and 22 (46%) were female. All cases were hospitalized and treated with Botulism Immune Globulin Intravenous (BabyBIG), none died.

The case definition for this outbreak includes all cases associated with consumption of ByHeart Whole Nutrition PIF with symptom onset between December 2023 and February 2026. Confirmed case is defined as: Laboratory confirmed infant botulism. Probable case is defined as : Completed botulism diagnostic testing of a clinical specimen (negative, inconclusive, or testing unable to be performed) AND Compatible infant botulism clinical presentation and recovery pattern AND Lack of alternate diagnosis.

WGS analysis identified multiple clusters linking clinical isolates with contaminated ByHeart PIF and ingredient samples, including matched isolates from finished product (open and closed cans and Anywhere Pack sticks), organic whole milk powder, and base mix, collectively representing 17

distinct *C. botulinum* strains and providing strong genomic evidence supporting ByHeart formula as the outbreak source.

CDC closed out the investigation on 2/26/2026 with infant formula as the confirmed vehicle.

Field Investigations & Findings

CORE issued 12 assignments during the outbreak investigation. Assignments were issued for record collection, inspections, and sampling. FDA conducted investigations at blending, packaging, and ingredient supplier facilities. An FDA FORM 483 was issued for one out of the 12 assignments issued as described below.

1. BlendHouse Allerton LLC: On 11/10/2025, CORE issued eNSpect Assignment #273337 to OII Critical Foods Investigations Branch for an infant formula inspection, traceback records and information collection, and product sampling at BlendHouse Allerton LLC (Allerton, IA; FEI:1921383). BlendHouse Allerton LLC is ByHeart Inc. manufacturing facility of PIF where (b)(4) at BlendHouse Portland LLC. Investigators collected requested traceback records and documents and collected base powder retains and raw material samples. On 1/22/2026, FDA's OII Critical Foods closed the assignment and FDA Form 483 was issued for not having a qualified individual document corrective actions, not ensuring all food contact surfaces were cleaned and sanitized and not reviewing and evaluating public health significance of process specification deviations.

2. Blendhouse Portland, LLC: On 11/10/2025, CORE issued eNSpect Assignment #273272 to OII Critical Foods Investigations Branch for an infant formula inspection, traceback records and information collection, and product sampling at Blendhouse Portland, LLC (Portland, OR; FEI: 3013670080) where ByHeart finished product PIF is manufactured. Investigators collected traceback documents and PIF samples. The assignment was closed 1/23/2026 and no FDA Form 483 was issued.

3. Dairy Farmers of America, Inc.: On 11/25/2025, CORE issued eNSpect assignment #273902 to Office of Inspections and Investigations (OII), Office of Human Food Inspectorate (OHFI) Central 3 for traceback record collection at Dairy Farmers of America, Inc. (DFA) (Fallon, NV; FEI #3010316948), the supplier of milk powder used to

manufacture base mix for ByHeart PIF. DFA manufactures powdered milk from whole liquid milk, supplied by Organic West Milk, Inc. (OWM). The assignment was closed 12/1/2025.

4. On 11/26/2025, CORE issued eNSpect assignment # 274101 to Human Foods program Office of Microbiological Food Safety, Division of Dairy Safety for a full Preventive Controls (PC) inspection and traceability record collection at Dairy Farmers of America, Inc. (Fallon, NV; FEI #3010316948). The inspection did not find any objectional findings and no FDA 483 was used. The assignment was closed on 12/4/2025.

5. Organic West Milk, Inc.: On 12/30/2025, CORE issued eNSpect assignment #275309 to OII OHFI West 2 for traceback records and information collection at Organic West Milk, Inc. (Ripon, CA; FEI:3031273796). The assignment was closed on 1/27/2026.

6. (b)(4).: On 1/7/2025, CORE issued eNSPECT assignment ID #275595 to OHFI West 2 for traceability record and information collection at (b)(4). The assignment was closed on 1/22/2026.

7. (b)(4): On 1/28/2026, CORE issued eNSPECT Assignment ID# 276429 to OII OHFI East 2 for traceability record and information collection at (b)(4). The assignment was closed on 2/4/2026.

8. (b)(4): On 1/28/2026, CORE issued eNSPECT Assignment ID# 276430 to OII OHFI West 3 for traceability record and information collection at (b)(4). The assignment was closed on 1/28/2026.

9. (b)(4).: On 1/28/2026, CORE issued eNSPECT Assignment ID #276433 to OII OHFI East 1 for traceability record and information collection at (b)(4). The assignment was closed on 2/24/2026.

10. On 1/28/2026, CORE issued eNSPECT Assignment ID# 276415 to OII OHFI Central 3 for traceability record and information collection at (b)(4). The assignment was closed on 1/29/2026.

11. (b)(4) On 1/28/2026, CORE issued eNSPECT Assignment ID#276416 to OII OHFI West 2 for traceability record and information collection at (b)(4). The assignment was closed on 1/29/2026.

12. (b)(4): On 2/3/2026, CORE issued eNSPECT Assignment ID# 276740 to OII OHFI West 3 for traceability record and information collection at (b)(4). The assignment was closed on 2/5/2026.

Laboratory Sample Overview

FDA collected finished products (PIF), components (PIF base mix), and raw ingredient samples (whole milk powder) used to manufacture ByHeart PIF. State partners collected open consumer PIF samples and CDC, and state partners analyzed the samples in response to the outbreak investigation. The outbreak strain was isolated from finished product ByHeart PIF, base powder mix and whole milk powder (ingredient). Whole genome sequencing matched strains in whole milk powder, finished PIF product, and an infant botulism clinical isolate.

FDA samples

A total of 26 FDA samples (PIF, base mix, and ingredients) were collected during the response of the outbreak investigation and two FDA samples (1316851, 1319424) tested positive for *C. botulinum* (toxin type A).

Table 1- List of FDA C. botulinum positive samples analyzed by Arkansas Human and Animal Food Laboratory.

Sample ID	Sample Type	Lot #	Sample Result
1316851	Blendhouse Allerton base mix	(b)(4)	Positive (Toxin type A), WGS strain 1
1319424	Powdered milk retain sample from DFA		Positive (Toxin type A), WGS strain 11

Laboratory Flexible Funding Model for food safety testing (LFFM) laboratories Samples

A total of 5 samples were analyzed under FDA LFFM at The Wadsworth Center; two samples (Table.2) tested positive for *C. botulinum* toxin type A.

Table #2- List of C. botulinum positive samples analyzed under FDA LFFM, The Wadsworth Center

Sample ID	Sample Type	Lot #	Sample Result
IDR2500084760-01-01	Consumer closed PIF collected by state of AZ	251481P2	Positive (Toxin type A), WGS strain 11
IDR2500090013-01-01/ FDA # 1315221	Powdered milk retain sample collected by FDA from DFA	(b)(4)	Positive (Toxin type A), WGS strain 2

State Samples

State partners collected and CDC analyzed a total of 35 ByHeart open Infant formula consumer samples and all reported negative.

On 11/17/2025, California Department of Public Health (CDPH) reported positive (Botulinum toxin Type A) for CA ByHeart open Infant formula sample with lot # 206VABP/251131P2.

Table #3- C. botulinum positive sample analyzed by CDPH

Sample ID	Sample Type	Lot #	Sample Result
N/A	Open Consumer PIF	206VABP/251131P2	Positive (Toxin type A), WGS strain 6

ByHeart Inc. Samples

ByHeart Inc. reported collecting and analyzing several PIF, base powder mix and multiple ingredient samples. A total of 12 *C. botulinum* positive samples were reported.

Table #4 – List of ByHeart Inc. C. botulinum positive samples

Sample ID	Sample Type	Lot #	Result	WGS Strain
W532474 W532496 W532493	Finished product PIF	251131P2	Positive (Toxin A)	Strain 8
W532612	Finished product PIF	251261P2	Positive (Toxin A)	Strain 2
W532646	Base Powder	(b)(4)	Positive (Toxin A)	Strain 8
W532916 W532917	Finished product PIF	252161P2	Positive (Toxin B)	Strain 10
W532952 W533001 W532953	Organic Whole Milk Powder	(b)(4)	Positive (Toxin A & B)	Strain 11
W533098	Finished product PIF	(b)(4)	Positive (Toxin A & B)	Strain 11
W533101 W533103	Finished product PIF	(b)(4)	Positive (Toxin A)	Strain 7 Strain 1

WGS analysis

Human Foods Program (HFP) Signal Detection & Bioinformatics Branch performed WGS analysis on 37 *C. botulinum* isolates for this outbreak investigation (16 clinical isolates and 21 product isolates) and a total of 17 different strains have been found.

Clinical-Product Matches

• **Strain 6:** Clinical isolates PNUSAB000052 (CA), PNUSAB000006 (OR), and PNUSAB000007 (AZ) match opened PIF isolate CA-25-0146 (CA) (mean genetic distance: 7 SNPs).

• **Strain 8:** Clinical isolate PNUSAB000047 (CA) matches ByHeart-provided PIF isolates (W532474, W532493, W532495, and W532496) and one ByHeart provided base powder isolate (W5326460; mean genetic distance: 4SNPs).

• **Strain 11:** FDA1319424-S020-002, FDA1319424-S020-004, W532953/CFSAN145405 (USA 2026 [ByHeart whole milk powder]), W532952/CFSAN145404 (USA 2026 [ByHeart whole milk powder]), W533001/CFSAN145421 (USA: IA 2025-11-26[ByHeart whole milk powder]), W533098/CFSAN145424 (USA:OR 2025-12-29 [ByHeart PIF]), IDR2500084760-01-01 (Wadsworth unopened PIF [AZ], lot 251481P2), PNUSAB000004 (clinical [NJ]), and historical isolate CDC77151H1 2022 Broccoli and cheddar soup match each other (mean 7.5 SNPs).

Product-to-Product Matches

• **Strain 1:** W533103/CFSAN145423 (USA: OR 2025-12-29 [ByHeart PIF]), FDA1316851-S005-001 (USA: IA 2025-12-03 powdered infant formula base), and FDA1316851-S005-002 (USA: IA 2025-12-03 PIF base) match each other (mean 10 SNPs).

• **Strain 2:** ByHeart Inc. provided powdered infant formula isolate W532612 matches isolate IDR2500090013-01-01/FACTS#1315221 which was isolated from a retain sample of powdered milk that was collected from Dairy Farmers of America, Inc. (NV) (genetic distance 8 SNPs).

• **Strain 10:** ByHeart Inc.-provided powdered infant formula isolates W532916/CFSAN145402 and W532917/CFSAN145403 match (genetic distance: 0 SNPs).

Clinical-to-Clinical Matches

• **Strain 9:** Clinical isolates PNUSAB000012 CA-25-0143 (CA) and PNUSAB000013 CA-25-0144 (RI) match each other (genetic distance: 9 SNPs).

Matches with Historical Isolates Only
• **Strain 4:** Clinical isolate PNUSAB000003 (WA) matches historical isolate Aichi2011 from the database (collected in 2011; genetic distance: 1 SNP).

Traceback Abbreviated Summary

This outbreak involved a branded product, limited traceback/trace forward activities and a targeted lot code distribution analysis was conducted. Limited traceback/trace forward activities were focused on mapping the distribution of specific lots of products and ingredients to identify the source of contamination within the supply chain. A targeted distribution analysis was initiated on 11/19/2025, focusing initially on 5 PIF lot codes of greatest interest. FDA identified "lot codes of greatest interest" as those reported by one or more ill cases identified early in the response. FDA consulted with CDC, which provided updated case line listings with reported lot code information as it became available. FDA identified "lot codes of greatest interest" as those reported by one or more ill cases identified early in the response. Because all cases are infants who are typically nutritionally dependent on infant formula and/or human milk, many cases likely consumed multiple lots of the product prior to illness. Lot numbers reported by patients represent lots that were either consumed or on hand at the time of reporting but are not necessarily the specific lot that caused illness.

A total of 12 cases reported exposure to one or more of the 5 lot codes of greatest interest (206VABP/ (b)(4) , 206VABP/251131P2, 206VABP/251261P2, 206VABP/251481P2, and 206VABP/ (b)(4)). These 5 lot codes were traced back to a total of (b)(4) lots of base mix products, (b)(4) lots of organic whole milk powder, and (b)(4) lots of (b)(4) supplied from 22 unique dairies. All PIFs were manufactured at ByHeart Blendhouse (Portland, OR) and all base mixes were manufactured at ByHeart Blendhouse (Allerton, IA). Whole milk powder was supplied by Organic Milk West and processed at facilities at Dairy Farmers of America (Fallon, NV). Liquid milk was supplied by dairies throughout (b)(4) .

Of significance, 7 cases reported exposure to ByHeart PIF lot 206VABP/251261P2 and this lot tested positive for *C. botulinum* Toxin Type A with WGS analysis.

In addition to traceback of lot codes of greatest interest, FDA also traced product and ingredient lot codes that tested positive for *C. botulinum* through sampling conducted by FDA, CDC, state partners, or the firm's third-party laboratory. The purpose of this tracing was to identify where in the supply chain contamination may have happened, identify implicated ingredients, appropriately scope inspections, and inform future sampling or route cause analysis.

At least 17 product samples tested positive or CRO related to this outbreak investigation, including 8 finished product (PIF) samples, 4 base mix samples, and 5 whole milk powder samples.

The comprehensive product distribution analysis conducted by FDA supports the epidemiological link between exposure to contaminated ByHeart PIF and infant botulism illnesses. Sampling results confirmed contamination was present in finished product, base mix, and organic milk powder. The distribution and comingling of ingredients likely contributed to the widespread nature of the contamination. Detailed traceback and product flow diagrams and summary are in the document section of CARA.

Product & Firm Actions

On 11/ 8/2025, ByHeart issued a voluntary recall of two batches of Infant Formula and on 11/11/2025 expanded its voluntary recall to include all ByHeart infant formula products.

On 1/17/2026, ByHeart Inc. issued RFR in response to a sample of the (b)(4) tested PCR positive for *C botulinum* Toxin (B) by ByHeart Inc. on 1/20/2026, (b)(4) . also issued RFR report.

On 1/16/2026, ByHeart Inc. issued RFR in response to the Organic West Milk, Inc. whole milk powder manufactured by Dairy Farmers of America Lot: (b)(4) *C botulinum* positive result.

Communications Overview

On 11/8/ 2025: FDA and CDC issued a public outbreak advisory and Food Safety Alert advising consumers to not use certain lots of ByHeart Whole Nutrition Infant Formula and announcing ByHeart's voluntary recall.

FDA and CDC web posts were updated and reported on investigational updates on 11/ 11/2025, 11/14/2025, 11/19/2025, 11/20/20, 11/26/2025, 12/3/2025, 12/17/2025, 1/ 23/ 2026, 2/2024

On 11/15/2025: FDA reported that recalled formula was still being found on store shelves and released EIRs and Form 483s, Inspectional Observations from inspections completed previously at ByHeart facilities.

On 12/ 15/ 2025: FDA released press announcement addressing recall effectiveness and announcing warning letters issued to retailers that failed to remove recalled ByHeart infant formula from sale.

On 2/ 26/2026, FDA and CDC issued final Outbreak Advisory and close out regarding the outbreak investigation.

Conclusions

Epidemiological, laboratory and traceback evidence indicate that consumption of ByHeart powdered infant formula resulted in this multistate infant botulism outbreak. The outbreak strain was isolated from finished product ByHeart PIF, base powder mix and whole milk powder (ingredient). Whole genome sequencing matched strains in whole milk powder, finished powdered infant formula product, and an infant botulism clinical isolate. Even though there are several hypotheses, investigational findings could not identify the source or root cause of contamination of the powdered infant formula. As of 2/26/2026, this cluster included 48 cases in 17 States: AZ (5), CA (12), ID (2), IL (2), KY (1), MA (2), MI (1) MN (3), NC (2), NJ (1), OR (3), PA (1), RI (1), TX (8), VA (1), WA (2), WI (1).

Acknowledgements

CORE would like to acknowledge the efforts of all our partners engaged in this investigation. Special thanks to Human Foods Program Office of Critical Foods, Office of Laboratory Operations & Applied Science, Arkansas Human and Animal Food Laboratory, Office of Surveillance Strategy and Risk Prioritization, Nutrition Cener of Excellence, Office of Inspections and Investigations, CDC Division of Foodborne, Waterborne, and Environmental

Diseases Enteric Diseases Epidemiology Branch and Enteric Diseases Laboratory Branch. CDPH Infant Botulism Treatment and Prevention Program and Microbial Diseases Laboratory New York State Department of Health and The Wadsworth Center, Maryland Department of Health and Maryland Public Health Laboratory.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:	2. Operational Period #7	
Clostridium botulinum/ Infant Formula/Nov 2025	Date From: 2/17/2026 Time From: 18:00 EST	Date To:3/27/2026 Time To: 18:00 EST

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness

On 11/7/2025, CDC notified CORE Signals of an infant botulism cluster with a strong epidemiologic signal for ByHeart brand powdered infant formula (PIF). As 11/10/2025, the cluster, which was issued a PulseNet code, 1125MLBOT**,** includes 15 cases of suspected or confirmed infant botulism with 10 cases confirmed as Type A. Ill infants are from 12 states including: Arizona, California (2), Illinois (2), Kentucky, Minnesota, North Carolina, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington. Infant ages range from 16-157 days and 7 (50%) are female. State and local public health officials interviewed caregivers about the foods infants were fed in the month before they got sick. Fifteen infant botulism cases have been identified that were fed ByHeart Whole Nutrition powdered infant formula before getting sick. The case definition for this incident is defined as **Confirmed**: Laboratory-confirmed infant botulism in an infant exposed to any ByHeart powdered infant formula, with illness onset dates from 08/1/2025, to the present; **Suspect:** Symptoms consistent with infant botulism in an infant exposed to any ByHeart powdered infant formula who received Baby BIG treatment.

According to information shared by CDPH Infant Botulism Treatment and Prevention Program (IBTPP), from 8/1/2025 through 11/10/ 2025, 84 infants nationwide have received BabyBIG® treatment. Among them, 36 (43%) had any powdered infant formula exposure. Notably, more than 40% (15) of infants who had powdered infant formula exposure consumed ByHeart Whole Nutrition infant formula. This information shows that ByHeart brand formula is disproportionately represented among sick infants in this outbreak, especially given FDA's data that ByHeart represents an estimated 1% of all Powdered Infant formula (PIF) sales in the United States. ByHeart, Inc. is a small niche PIF producer with product distributed throughout the US, and as such, this firm has a low PIF market share compared to other PIF manufacturers. The high number of infant botulism cases reporting this brand is highly unusual and represents a significant epidemiological signal.

ByHeart, Inc., (NY) is the parent company of three manufacturing facilities in Allerton IA (FEI:1921383), in Reading PA (FEI:3015728839), and in Portland, OR (FEI: 303670080). FDA has conducted inspections at these facilities in 2025. The most recent inspection at the Portland, OR facility (3/2025) was classified No Action Indicated (NAI), and the most recent inspection at the Allerton, IA facility (02/2025) was also classified NAI. The Reading, PA, facility is no longer in operation. Founded in 2016, ByHeart, Inc. has developed what it calls "the only infant formula in the U.S. to combine certified organic, grass-fed whole milk and a patented protein blend closest to breast milk." Per the company's website, the Reading facility focuses on small-batch blending, while the Allerton plant primarily handles powder production, and the Portland facility is dedicated to packaging and blending. ByHeart Inc. confirmed the base powder is produced in IA and containers are filled in Portland, OR.

(b)(6), (b)(7)(d)

.

The firm sells 100% of their product as retail and it is available both online and in stores such as Walmart, Target, Amazon, Albertsons, (b)(4) (Whole Foods, Sprouts, and (b)(4)), (b)(4), and Kroger. Several states have collected product samples from case's homes including CA, IL and RI. Testing is pending on samples from an open container of PIF from a CA case at the CDPH lab.

On 11/7/2025, CORE held Firm call #1 with ByHeart, Inc at 8 pm EST to request a voluntary recall of 2 identified lots of Powdered Infant Formula. On 11/8/2025, the CDPH Infant Botulism Treatment and Prevention Program Microbial Diseases Laboratory noted a preliminary positive (Botulinum toxin Type A) for the CA open product sample with lot # 206VABP/251131P2. The remaining samples are currently being analyzed, and results are pending.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:	2. Operational Period #7	
Clostridium botulinum/ Infant Formula/Nov 2025	Date From: 2/17/2026 Time From: 18:00 EST	Date To:3/27/2026 Time To: 18:00 EST

On 11/8/2025, ByHeart, Inc. (FEI: 3022729623) recalled two lots of ByHeart Whole Nutrition Infant Formula with lot numbers 206VABP/251261P2 (Use BY 01DEC2026) and 206VABP/251131P2 (Use By 01DEC2026). On 11/8/2025, both FDA and CDC issued a health advisory warning, aimed at safeguarding the public from consuming potentially contaminated product.
On 11/9/2025, CORE held SPTC #1 to discuss the strategy of retain sample collection at ByHeart, Inc. facilities in Iowa and Oregon. On 11/9/2025, FDA, CDC and CDPH held a firm Call #2 with ByHeart, Inc. to inform the firm of preliminary positive sample findings by CDPH.
On 11/10/2025, the incident was transferred to CORE RT3 for further coordination and CORE held SPTC #2 with CDC, FDA, CDPH, Association of Public Health Laboratories (APHL) and Council of State and Territorial Epidemiologists (CSTE) to discuss alignment in communications and messaging for worried well parents. On 11/10/2025, due to additional lots identified, CORE and CDC held Firm call #3 with ByHeart, Inc. and FDA requested voluntary recall of ALL LOTS of ByHeart Powdered Infant Formula currently within expiry. On 11/10/2025, CORE issued eNSpect/FACTS Assignment #273337 to OII Critical Foods Investigations Branch for an infant formula inspection, traceback records and information collection, and product sampling at Blendhouse Allerton, LLC (Allerton, IA). On 11/10/2025, CORE issued, eNSpect Assignment #273272 to OII Critical Foods Investigations Branch for an infant formula inspection, traceback records and information collection, and product sampling at Blendhouse Portland, LLC (Portland, OR).
On 11/11/2025, ByHeart, Inc. updated their recall notice to include ALL LOTS of ByHeart Powdered Infant Formula currently within expiry. FDA and CDC web posts were also updated with the updated recall notice. The inspection started on 11/11/2025 and CORE RT3 also learned that interior construction on the Allerton facility occurred earlier this year. On 11/11/2025, OII Critical Foods Investigations Branch initiated the inspection and collected 3 samples (FDA Sample# (b)(4)) of retains and finished product at BlendHouse Portland LLC; sample analysis is pending at Arkansas Laboratory (ARKL). On 11/11/2025, CORE sent out sampling guidance stating sample collected for FDA analysis must meet the criteria: Infant received BabyBIG and consumed ByHeart formula, product is unopened and unexpired. On 11/11/2025, FDA received an INFOSAN request regarding international distribution of recalled ByHeart Infant Formula. As of 11/12/2025, no foreign recipients have been identified as receiving products either directly or through a distribution center.
On 11/12/2025, Day 1 Inspectional updates for both ByHeart, Inc. facilities were provided by Critical Foods Branch. Updates were disseminated to SMEs. On 11/12/2025, Association of Public Health Laboratories (APHL) held a 50 States call where FDA ORTS highlighted the importance of samples meeting all three criteria and submission of the FDA Isolate/Sample document. On 11/12/2025, CORE RT3 was notified by Office of Surveillance Strategy and Risk Prioritization that the US Poison Control line has created an emergent code for the ByHeart recall tracking cases in the National Poison Data System (NPDS). On 11/12/2025, CDC informed CORE that 2 new cases were added to the outbreak bringing the total to 17 (added AZ and OR). Additional lot numbers for ByHeart Powdered Infant Formula were also provided.
On 11/13/2025, Critical Foods Branch provided Day 2 updates for both inspections. Updates were shared with SMEs and CDC. A SPTC #3 has been scheduled for Friday 11/14/2025 to discuss FDA sampling strategy, laboratory coordination, and laboratory capacity.

Operational Period #1
On 11/14/2025, Day 3 inspectional updates for both ByHeart, Inc. facilities were provided by Critical Foods Branch. Investigators collected two base power retain samples ((b)(4) from Blendhouse Allerton, LLC (Allerton, IA). On 11/17/2025, CDPH reported positive Clostridium botulinum type A for the CA ByHeart open Infant formula sample with lot # 206VABP/251131P2. WGS analysis is pending.
On 11/18/2025, ByHeart Infant Formula recall information was shared through INFOSAN. On 11/18/2025, Due to laboratory capacity and giving priority to inspection Samples, FDA has engaged analytical support from the Laboratory Flexible Funding Model for food safety testing (LFFM) laboratories to test state unopened ByHeart infant formula samples.
On 11/18/2025, Critical Foods Branch provided Day 4 and 5 updates for both inspections. Finished Product retains (sample number: (b)(4)) were collected at Blendhouse Portland, LLC and sample was shipped to Arkansas Laboratory (ARHAFL) for analysis.
On 11/19/2025, Critical Foods Branch provided Day 6 updates for both inspections. Additional five samples ((b)(4)) of infant formula base were collected from Blendhouse Allerton, LLC as part of the CORE Assignments, analysis pending. The Portland inspection will remain open to review information collected and additional data collection as needed.
On 11/19/2025, CDC hosted a multi-state call and updated their web post with new case count (35 cases in 15 states). On 11/19/2025, Amazon provided a list of 23 countries that ByHeart Inc. PIF was sent. The countries are: Argentina, Brazil, Brunei, Canada, Chile, China, Colombia, Ecuador, Egypt, Guam, Hong Kong, Israel, Jamaica, Japan, Korea, Peru, Philippines, Puerto Rico, Romania, Singapore, South Africa, Thailand, Virgin Islands. On 11/19/2025, ByHeart Inc. informed FDA that 5 of 36 of their own retain samples are PCR-positive for C. botulinum and issued updated web post. with the sample result Information.
As of 11/20/2025, a total of 70 consumer complaints were received by FDA. Consumer complaints will be shared with Division Field Emergency Response coordinators to be shared with their respective state partners.
On 11/20/2025, at the request of ByHeart Inc., FDA and CDC held a firm call with ByHeart Inc. to answer questions related to the outbreak investigation and communication plans. ByHeart Inc. shared their sample analysis update and reported the five positive samples correspond to three lots tested: Lot 206VABP/251261P2, Lot: 206VABP/251131P2, and (b)(4) . The first two lots were in the initial recalled product, the third lot code indicates a 2024 production date (11/15/2024) in the batch code (b)(4)

Operational Period #2
On 11/21/2025, Critical Foods Branch provided Day 7 and 8 inspections updates. Investigators obtained requested traceback records. They also collected base powder information used to make finished product lot (b)(4) , raw material receiving records and COAs associated lots used in the implicated base powder lots 251261P2 and 251131P2. On 11/21/2025, OII critical office branch collected sample #1218194 and #1218195 from Blendhouse Portland, LLC.
On 11/24/2025, OII critical office branch provided Day 9 inspection updates - Finished product retain sample #1316268 (from Lot# (b)(4)) was collected from Blendhouse Portland, LLC.
On 11/24/2025, HFP Office of Critical Foods collected 6 samples of ByHeart infant formula for toxic element testing as part of Operation Stork Speed. On 11/24/2025, CORE shared ByHeart Consumer complaints received to date with FERCs to be shared with their respective states with 20:88 agreement.
On 11/25/2025, CORE issued eNSpect assignment #273902 to OII OHFI West 4 for traceback records and information collection at Dairy Farmers of America, Inc. (Fallon, NV). Traceback records indicate liquid whole milk is supplied by 20 dairies in (b)(4) to Dairy Farmers of America (Fallon, NV) where it is spray dried to produce organic whole milk powder (WMP). Organic Milk West acts as a broker and uses a third-party carrier to deliver WMP from Dairy Farmers of America to Blendhouse Allerton, where it is incorporated into the base mix for ByHeart Infant Formula. On 11/25/2025, The Association of Public Health Laboratories (APHL) hosted 50 states call to discuss the outbreak and laboratory updates.
On 11/26/2025, CORE issued (eNSpect #33600) for a full scope Preventive Controls (PC) inspection at Dairy Farmers of America, Inc. (Fallon, NV). On 11/26/2025, FDA held a meeting with Byheart representatives to facilitate open, direct technical discussions between FDA processing experts and the ByHeart's SMEs regarding the firm's root cause investigation and other infant formula manufacturing issues, following the processes typically used by OCE and HFP experts when engaging with infant formula manufacturers.
On 11/28/2025, CORE received a new consumer complaint - a second death reported FL case - case reported consuming ByHeart formula and passed away August 31st. No medical records / death certificate yet.
On 12/1/2025, Office of Inspections and Investigations Division West 4 closed out Assignment #273902 (eNSpect #336569) for traceback records and information collection at Dairy Farmers of America, Inc. (Fallon, NV; FEI #3010316948).
On 12/3/2025, Critical Foods Branch provided investigational update, sample #1316269 was collected from Blendhouse Portland on 12/02/25 (Lot# (b)(4)) which is the oldest unexpired PIF lot available.
On 12/3/2025, FDA and CDC updated their wed posts to include updated case count and sample update.

Operational Period #3
On 12/5/2025, CDC held states call #6. CDC expanded the case definition of this outbreak back to March 23, 2022. ByHeart Inc. started manufacturing the ByHeart Infant formula on March 23, 2022.
On 12/5/2025, OII DHFI West 4 reported that seven samples (Sample # 1315216- 22) have been collected at Dairy Farmers of America, Inc. (Fallon, NV). The samples are of dried milk retains that would have gone into specific infant formula lots of interest.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:	2. Operational Period #7	
Clostridium botulinum/ Infant Formula/Nov 2025	Date From: 2/17/2026 Time From: 18:00 EST	Date To:3/27/2026 Time To: 18:00 EST

On 12/8/2025, HFP Office of Laboratory Operations and Applied Science reported that AZ closed consumer PIF sample (lot #206VABP/ 251481P2) analyzed by NY Wadsworth laboratory using LFFM is preliminarily positive (Botulinum toxin Type A). WGS analysis is pending.

On 12/8/2025, FDA held a meeting with ByHeart representatives to facilitate open, direct technical discussions between FDA processing experts and the ByHeart's SMEs regarding the firm's root cause investigation and updates. ByHeart Inc. informed FDA their contracted laboratory, The Institute for Environmental Health (IEH) detected 2 PCR positive sample findings that correspond to base mix lots manufactured at Blend House Allerton LLC ((b)(4)). These base mix lots were associated with the finished PIF lots (251261P2 & 251131P2) from the initial recall on 11/8/2025 and are associated with the CDPH positive PIF sample finding.

On 12/10/2025, OII Critical Foods Branch held Pre-Closeout meeting for Inspections at Byheart manufacturing facilities (Blend House Allerton, LLC and Blend House Portland, LLC) to provide updates on both inspections and discuss closeout date.

On 12/10/2025, FDA and CDC updated their public postings to include expanded case definition and case count. Previously, case counts included illnesses from August 1, 2025, onward. With the expanded definition, CDC and state partners identified 10 additional cases that occurred from December 2023 through July 2025. No cases were identified between March 2022 and December 2023. All 10 are confirmed infant botulism cases with documented exposure to ByHeart formula.

On 12/12/2025, FDA sent warning letters to four major retailers for failing to remove recalled ByHeart infant formula from their store shelves despite being notified of the recall.

On 12/16/2025, ByHeart Inc. reported that they received a C. botulinum positive PCR result for lot (b)(4) Base Powder Mix. They reported that they conducted an ingredient level analysis for each of the 3 C. bot positive base powder mixes they have so far ((b)(4)) and they will share their report as well as IEH's COAs for all 3 samples when available.

Operational Period #4

On 12/17/2025, FDA-Office of Laboratory Operations and Applied Science reported that AZ closed consumer PIF sample (lot #206VABP/ 251481P2) is positive (Botulinum toxin Type A). The sample was analyzed by NY Wadsworth laboratory using LFFM funding.

On 12/19/2025, FDA-Office of Laboratory Operations and Applied Science reported that FDA Sample# 1316851 has screened positive by PCR for C. bot Type A. Sample# 1316851 corresponds to Byheart base mix base mix (Lot (b)(4)).

On 12/19/2025, OII DHFI West 4 reported Sample # 1319424, milk powder Lot# (b)(4) collected from Dairy Farmers of America, Inc. (Fallon, NV) and shipped to ARHAFL for C. Bot analysis. This lot is associated with AZ closed consumer PIF sample and C.bot positive base mix lot # (b)(4) .

On 1/6/2026, Sample # 1319424, reported PCR for C. bot Type A.

On 12/30/2025 CORE was notified FDA Sample #1315221, a powdered milk sample collected at Dairy Farmers of America (lot (b)(4)) has screened positive by PCR for C. bot type A. This sample was analyzed by NY Wadsworth laboratory using LFFM funding. WGS analysis is pending.

On 12/30/2025, CORE issued eNSpect assignment #339139 to OII DHFI West 2 for traceback records and information collection at Organic West Milk, Inc. (Ripon, CA).

On 12/31/2025, OII DHFI West 2 provided traceback records and customer list collected from Organic West Milk, Inc. (Ripon, CA).

On 1/2/2026, ByHeart Inc. reported a presumptive PCR positive on an ingredient for C. Bot toxin type B, Whey Protein hydrolysate (Lot# (b)(4)) supplied by (b)(4) (b)(4)). -Lot (b)(4) was delivered to ByHeart Inc. on 1/16/2025 but was not used in production.

On 1/5/2026, Human Foods Program (HFP) Signal Detection & Bioinformatics Branch provided updated WGS report.

Operational Period #5

On 1/6/2026, FDA-Office of Laboratory Operations and Applied Science reported that FDA Sample # 1319424, milk powder Lot# (b)(4) collected from Dairy Farmers of America, Inc. (Fallon, NV) was PCR positive for C. bot Type A. Confirmation and WGS analysis is pending.

On 1/7/2026, CORE issued eNSPECT Assignment ID #275595 to OII Division DHFI West 2 for traceback records collection at (b)(4) ; (b)(4)).

On 1/14/2026, CORE held Special Tactics call #6 to discuss Reportable Food Registry (RFR) request for (b)(4)). On 1/17/2026, Byheart Inc. issued RFR in response to a sample of the (b)(4) tested by Byheart Inc. was PCR positive for Clostridium botulinum Toxin (B). On 1/20/2026, (b)(4) , Inc. also issued RFR report in response to the sample result. On 1/22/2026 traceback eNSPECT Assignment ID #275595 was closed.

On 1/15/2026, Human Foods Program (HFP) Signal Detection & Bioinformatics Branch provided updated WGS report. Sample (IDR2500090013-01-01/FACTS #1315221, (milk powder lot # (b)(4)) isolated from a retain sample collected from Dairy Farmers of America, Inc. (Fallon, NV) matched Byheart Inc. powdered infant formula isolate W532612- Lot 251261P2 (genetic distance 8 SNPs). Sample (IDR2500090013-01-01/FACTS #1315221) was collected from DFA and analyzed by NY Wadsworth laboratory using LFFM funding. On 1/21/2026, HFP Office of Compliance and Enforcement held firm call with Dairy Farmers of America, Inc., Byheart Inc. and Organic West Milk, Inc. to inform the firms about positive sample and whole genome sequence results.

On 1/16/2025, Byheart Inc. reported that Whole Milk Powder Lot#: (b)(4) was PCR positive for C.bot Type A and Type B. This lot was not used by ByHeart Inc. in any Powdered infant formula. On 1/16/2026, Byheart Inc. issued RFR in response to the Organic West Milk, Inc. Whole Milk Powder manufactured by Dairy Farmers of America Lot#: (b)(4) positive results. On 1/21/2026, Byheart Inc. provided WGS analysis of the sample.

On 1/22/2026, Human Foods Program (HFP) Signal Detection & Bioinformatics Branch provided updated WGS report, Byheart Inc. provided whole milk powder isolates W532952 and W532953 match isolate IDR2500084760-01-01/PNUSAB000008 which was isolated from unopened PIF from AZ and a clinical isolate from NJ (PNUSAB000004; mean 8.16 SNPs.

On 1/22/2026, FDA-Office of Laboratory Operations and Applied Science reported that FDA Sample # 1315217 milk powder (Lot # (b)(4)) and Sample #1315219 (milk powder Lot# (b)(4)) collected from Dairy Farmers of America, Inc. (Fallon, NV) reported CRO for Clostridium botulinum analysis.

Operational Period #6

On 1/22/2026, FDA's OII Critical Foods Branch closed eNSpect Assignment #273337 at Blendhouse Allerton, LLC (Allerton, IA). An FDA Form 483 was issued for failure to have a qualified individual document corrective actions, failure to ensure all food contact surfaces were cleaned and sanitized and failure to review and evaluate public health significance of process specification deviations. On 1/23/2026, FDA's OII Critical Foods Branch closed eNSpect Assignment #273272 Blendhouse Portland, LLC (Portland, OR). No FDA Form 483 was issued.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:	2. Operational Period #7	
Clostridium botulinum/ Infant Formula/Nov 2025	Date From: 2/17/2026 Time From: 18:00 EST	Date To:3/27/2026 Time To: 18:00 EST

On 1/23/2026, FDA and CDC updated their wed posts to include sample analysis update.

On 1/28/2026, CORE issued traceability assignments to firms who received Organic West Milk Inc, (Ripon, CA) lots of whole milk powder that tested positive for Clostridium botulinum. The trace forward assignment included a request for all distribution of the whole milk power to infant formula manufacturers in the past two years. None of the firms identified any infant formula manufacturers as customers that were supplied whole milk powder. The assignments issued were as follows:

- **OII OHFI East 1 at (b)(4) (eNSPECT Assignment ID #276433).**
- **OII OHFI East 2 at (b)(4) (eNSPECT Assignment ID# 276429).**
- **OII OHFI West 2 at (b)(4) (eNSPECT Assignment ID #276416).**
- **OII OHFI West 3 at (b)(4) (eNSPECT Assignment ID# 276430).**
- **OII OHFI Central 3 at (b)(4) (eNSPECT Assignment ID# 276415).**

On 2/3/2026, CORE issued eNSPECT Assignment ID# 276740 to OII OHFI West 3 for traceability record and information collection at (b)(4) .

On 2/6/2026, Human Foods Program (HFP) Signal Detection & Bioinformatics Branch provided an updated WGS report. FDA Sample #1319424 (whole milk powder, Lot# (b)(4)), ByHeart tested whole milk powder lot #2 (b)(4) ByHeart tested PIF lot # (b)(4) (Type A and Type B), LFFM NY laboratory tested PIF Lot #251481P2, and NJ Clinical isolate match each other (mean 7.5 SNPs). Please refer strain 11 in the WGS report.

On 2/9/2026, FDA OCE hosted a firm call to share sample result of FDA Sample # 1319424 (whole milk powder, Lot# (b)(4)) with Dairy Farmers of America, Inc. (Fallon, NV) and Organic West Milk, Inc. (Ripon, CA).

5. Site Safety Plan Required? Yes ☐ No ☒
Approved Site Safety Plan(s) Located at:

6. Incident Action Plan (the items checked below are included in this Incident Action Plan):

☐ ICS 203	☐ Map/Chart	Other Attachments:
☐ ICS 204	☐ Weather Forecast/Tides/Currents	c _____
☐ ICS 205		c _____
☐ ICS 206		c _____
☐ ICS 208		c _____

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:	2. Operational Period #7	
Clostridium botulinum/ Infant Formula/Nov 2025	Date From: 2/17/2026 Time From: 18:00 EST	Date To:3/27/2026 Time To: 18:00 EST
7. Prepared by: Name: Angela Fields	Position/Title: Planning Chief	Signature: *Angela Fields*
8. Approved by Incident Commander: Adiam Tesfai Signature: *Adiam Tesfai*		
ICS 202	**IAP Page _____**	Date/Time: 2/19/2026 1400 ET

Updated by FDA 2/2011

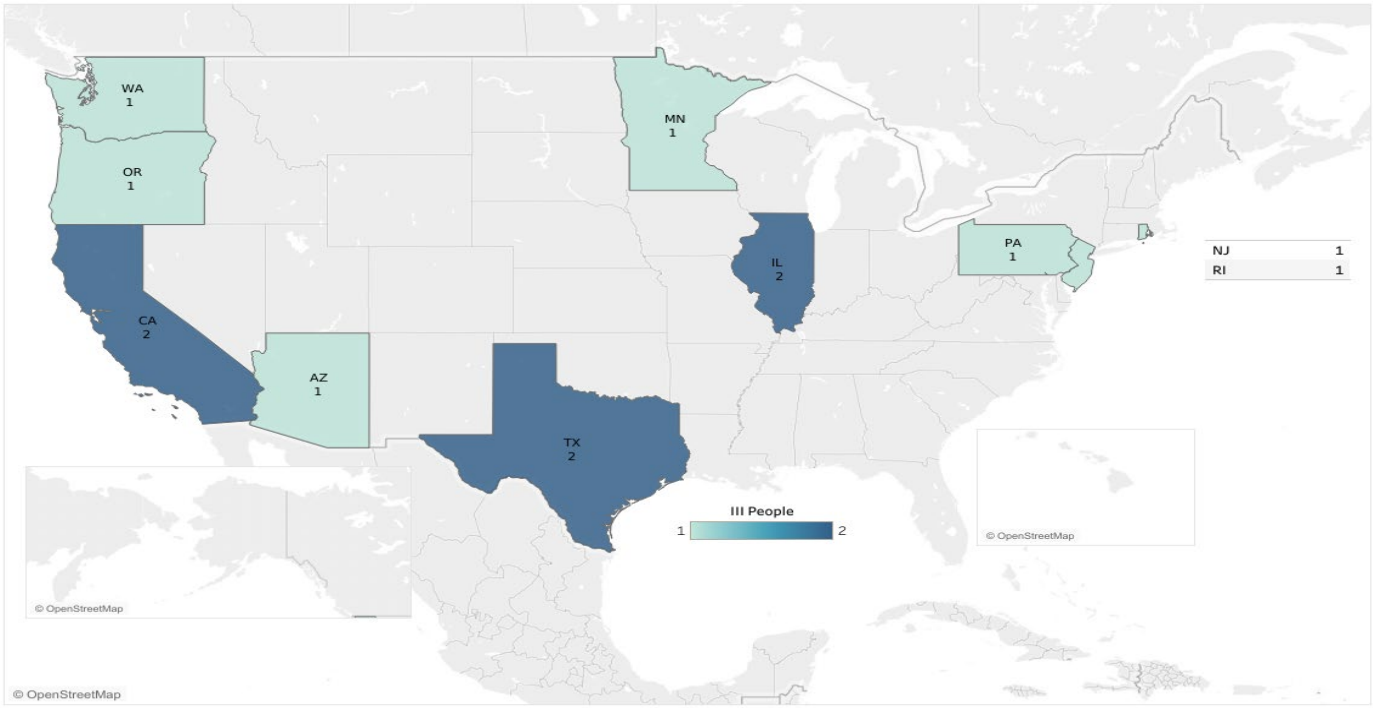
INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

4. Map/Sketch

Date: 11/9/2025

C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025



6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

ICS 201, Page 1 Date/Time: 11/10/2025 11:00 AM EST

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

5. Situation Summary and Health and Safety Briefing

Incident Overview and Early Actions Timeline

On 11/7/2025, CDC notified CORE Signals of an infant botulism case series linked to ByHeart powdered infant formula (PIF). This case series (PulseNet ID: 1125MLBOT) includes 13 cases of suspected or confirmed infant botulism with 8 cases confirmed as Type A with onsets beginning in August 2025. Cases are from 10 states including: AZ (1), CA (2), IL (2), MN (1), NJ (1), OR (1), PA (1), RI (1), TX (2), and WA (1). Infant ages range from 16-157 days. All 13 cases have been hospitalized, and no deaths have been reported. Cases in this series report a combination of feeding practices, including formula fed (only), formula fed + breast fed, and formula fed + solid foods. All cases included in the series were exposed to ByHeart powdered infant formula. According to the California Department of Public Health (CDPH), Infant Botulism Treatment and Prevention Program (IIBTPP) the high number of infant botulism cases reporting this particular brand is unusual and represents a significant epidemiological signal.

The geographic spread of cases is notable. CDC reports in general that botulism cases in the western US are more likely to be caused by botulinum toxin Type A, whereas botulinum toxin Type B is more likely to cause illness in cases in the eastern US. Two cases from this series (RI and PA) are from the eastern portion of the US where Type A is less common. The incidence of toxin Type A associated cases in this cluster is high. Because cases in this series are geographically dispersed, it indicates an atypical distribution of toxin Type A cases. According to FDA HFP SMEs, this is likely due to an ingested exposure rather than an environmental one.

CDC held a states call Friday afternoon, during which time FDA learned about two lots of interest that had been reported by three cases: 206VABP/251261P2 (Use BY 01DEC2026) and 206VABP/251131P2 (Use By 01DEC2026). Additional lot information was pending from the other cases. On the evening of 11/7/2025, FDA and CDC held a firm call with ByHeart representatives to notify them about the ongoing investigation of infant botulism illnesses linked to ByHeart brand PIF and the plan for public communications, and to request a voluntary recall of two lots of ByHeart infant formula reported by cases (206VABP/251261P2 and 206VABP/251131P2).

Prior to FDA learning about these cases, state partners (CA, IL, MN, RI) had already collected samples of ByHeart brand PIF from case-patients homes, and laboratory analyses at multiple labs are in various stages of completion, as described below. As the investigation has unfolded, additional lot information has been obtained for these samples and is described below.

Samples Collected

Open container samples were collected from case-patients home in CA, IL, MN, and RI, and lot information was obtained.

Recalled:

206VABP/251261P2; Use By 01DEC2026 (CA and RI)
206VABP/251131P2; Use By 01DEC2026 (CA)

Not recalled

206VABP/ (b)(4) ; Use by 01SEP2026 (MN)
206VABP/ (b)(4) ; Use By 01JAN2027 (IL)
206VABP/ (b)(4) ; Use By 01NOV2026 (IL)
206VABP (b)(4) ; Use BY 01FEB2027 (IL)
206VABP/ (b)(4) ; Use By 01DEC2026 (IL)
206VABP/ (b)(4) ; Use by 05JUN2026 (IL)

On 11/8/2025, CDPH IBTPP Microbial Diseases Laboratory noted a preliminary positive (Botulinum toxin Type A) for the CA open product sample with lot # 206VABP/251131P2. The remaining samples are currently being analyzed or are still en route to a laboratory, and results are pending.

On 11/8/2025, ByHeart, Inc. (FEI: 3022729623) recalled 2 lots of ByHeart Whole Nutrition Infant Formula with lot numbers 206VABP/251261P2 (Use BY 01DEC2026) and 206VABP/251131P2 (Use By 01DEC2026). This recall decision was made prior to the firm being notified of the preliminary positive sample.

On 11/8/2025, both FDA and CDC issued a health advisory warning, aimed at safeguarding the public from consuming potentially contaminated product. In addition, CDPH issued an alert notification linking the outbreak to ByHeart brand PIF and specifically mentioned the preliminary positive results from an open can of ByHeart PIF.

On 11/9/2025, FDA, CDC and CDPH had a second call with ByHeart representatives to notify them of the preliminary positive sample.

Firm Summary

ByHeart is a small, niche PIF producer with product distributed throughout the US at the following retailers: Target, Amazon, Albertsons, (b)(4) (Whole Foods, Sprouts, and (b)(4) , (b)(4) , and Kroger. Additionally,

customers can purchase the product directly online through the ByHeart website/subscription service. While the ByHeart PIF is distributed nationally, the firm has a low PIF market share compared to other PIF manufacturers.

Founded in 2016, ByHeart has developed what it calls the only infant formula in the U.S. to combine certified organic, grass-fed whole milk and a patented protein blend closest to breast milk.

ByHeart, Inc., (NY) is the parent company of three manufacturing facilities in Allerton, IA (FEI:1921383), in Reading, PA (FEI:3015728839), and in Portland, OR (FEI: 3013670080). These manufacturing locations are referred to as Blendhouse in the firms inspectional history.

Historically, both Blendhouse Allerton (Allerton, IA) and Blendhouse Reading (Reading, PA) manufactured the infant formula base powder and shipped it to their sister facility Blendhouse Portland (Portland, OR) for blending, filling, and packing. However, when this investigation began, Blendhouse Reading was reported as not having been in commercial production since 2023. Blendhouse Allerton was last inspected in February 2025. The inspection was classified as VAI, and a 483 was issued to the firm. Blendhouse Portland was last inspected in March 2025, and the inspection was classified as NAI. More specific information on each BlendHouse location is described next:
BlendHouse Portland LLC (OR; FEI: 3013670080) (b)(4) manufactured by ByHeart. Products manufactured at BlendHouse Portland (b)(4) According to the 2025 EIR, "BlendHouse Portland manufactures a single infant formula product for the firms parent company ByHeart. The product (b)(4). BlendHouse Portland began blending and filling operations for ByHeart in July 2023. BlendHouse Portlands operations consist of receiving base powder from its sister facility located in Allerton, IA, (b)(4)

BlendHouse Allerton, LLC (IA; FEI: 1921383) manufactures infant formula bulk base powder under the brand name ByHeart. (b)(4) by the sister facility in Portland, OR. (b)(4) FDA recently conducted an inspection at the firm in February 2025, which was classified as VAI. A 483 was issued for 3 items which included: (b)(4) used in infant formula base powder that was not held under conditions to prevent adulteration; not taking actions to eliminate all potential harborage areas when issues with rodents arose during the year 2024-2025; and not monitoring the floor conditions adequately at the (b)(4) (b)(4) when there were findings of confirmed Cronobacter sakazakii. Inspections in 2023 and 2024 were NAI, and a 2022 inspection was classified as VAI and cites issues related to insanitary conditions and inadequate written preventive control measures. FDA held a regulatory meeting with the firm in 2022.

(b)(6), (b)(7)(d)

.

BlendHouse Reading LLC (PA; FEI: 3015728839), a previous manufacturer of the base powder, ceased commercial operation in September 2023. FDA conducted an inspection in December 2023 as a follow up to a Warning Letter that was issued to ByHeart in August 2023.
The December 2023 inspection resulted in a 483 and citied issues related to insanitary conditions of the building and food contact surfaces, pest issues, and noting that the firm did not implement a system of production and in-process controls for infant formula and did not minimize the potential for contamination of raw materials using appropriate measures. The inspection was classified OAI, and a 483 was issued, citing several violations including 1) the firm not establishing a system of process controls covering all stages of processing, designed to ensure that the infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment; and 2) the firm did not ensure that equipment used in the manufacturing, processing, packing or holding of an infant formula were of appropriate design to facilitate their intended function. Due to significant GMP issues as well as the previous warning letter, the facility has not been in operation since 9/30/2023. FDAs last inspection of the facility was from 12/2023 to 1/2024 which resulted in a multiple item 483 and was classified OAI. The production facility was not in operation at the time of the inspection, but the observations were concerning enough that a regulatory meeting was held with the firm on in February 2024. ByHeart corporate has committed to notifying FDA before this facility goes back into commercial production but confirmed that would be in 2026.

Blendhouse Lot Code Information and Use-By Date
According to the 2025 BlendHouse Portland EIR, (b)(4)

The Use By Date is (b)(4)

Historical Infant Botulism Outbreaks and Past Investigations of PIF
Although findings of positive product have been rare, it is not outside the realm of possibility that PIF can become contaminated with C. botulinum. There have been at least two reported incidents of C. botulinum linked to PIF.
Infant botulism is the most common form of human botulism in Canada and the US. Of note, infant botulism is caused by an infection. Babies develop infant botulism when the C. botulinum bacteria spores enter into their intestines and make toxin. Foodborne adult botulism is most often caused by intoxication and the ingestion of pre-formed heat-stable toxin with or without the live bacteria. Adults generally do not develop botulism when they consume bacterial spores, if the toxin has not already been formed and consumed as well. However, the immaturity of the infant GI tract renders infants susceptible to invasive disease by C. botulinum, and once it colonizes the intestine, it produces toxin inside the body. Literature reports of botulism cases have confirmed (identified) a variety of sources of C. botulinum exposure, including outdoor soil and indoor dust, commonly ingested such as honey and dry cereals, and PIF. In 2005, a case of infant botulism in the UK was linked to an opened can of PIF. In 2017, a C. botulinum isolate from an opened PIF was genetically linked to an isolate from the enema fluid of an infant botulism patient from China (Harris, 2024, Infant Botulism: In Search of Clostridium botulinum Spores).
In 2022, FDA, CDC, and states investigated a series of infants infected with Cronobacter spp who consumed PIF products manufactured by Abbott Nutritions Sturgis, MI, facility. Although these illnesses were not conclusively linked to Abbott PIF and were not considered an outbreak due to a common source, the investigation revealed important insanitary conditions at the firm, and several brands and varieties of infant formula products were part of a large-scale recall, leading to a subsequent infant formula shortage in 2022. Following this incident, FDA developed a strategy to enhance the safety of PIF to help prevent Cronobacter sakazakii contamination. The strategy seeks to improve oversight of safe production of PIF, and enhance communications and engagement with industry, consumers, federal, state, local, and other public health partners about infant formula safety.
In 2024, FDA underwent a reorganization that brought together components across FDA field offices and laboratories with the Center of Food Safety and Applied Nutrition (CFSAN), combining into a new Human Food Program (HFP). As part of this reorganization, it was determined that HFPs Office of Enforcement, Division of Critical Foods and Dietary Supplement Enforcement, Critical Foods and Labeling Enforcement Branch would coordinate compliance activities related to infant formula investigations.

Rationale

This incident is being transferred from CORE Signals to CORE Response Team 3 based on the following rationale:

ByHeart Whole Nutrition Powdered Infant Formula (PIF), an FDA regulated product, has been named as the confirmed vehicle for this outbreak based on the combined strong epidemiologic and traceback evidence for this branded product and the positive laboratory finding of BotA in an open sample of ByHeart PIF from one of the case patients.

This incident involves severe outcomes in a highly vulnerable population and has been linked to a critical food. As such, this incident has been identified as an agency leadership priority.

Response coordination is needed for additional activities, including epidemiologic scoping, firm follow-up, inspectional coordination, traceback and sampling activities, public communications, and regulatory product actions.

PIF has an extended shelf life and recalled lots may still be available for sale or in consumer homes. This is an incident of significant public health importance and requires prompt product action to remove contaminated product from the market

ByHeart Whole Nutrition Powdered Infant Formula (PIF), an FDA regulated product, has been named as the confirmed vehicle for this outbreak based on the combined strong epidemiologic and traceback evidence for this branded product and the positive laboratory finding of BotA in an open sample of ByHeart PIF from one of the case patients.

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

This incident involves severe outcomes in a highly vulnerable population and has been linked to a critical food. As such, this incident has been identified as an agency leadership priority.

Response coordination is needed for additional activities, including epidemiologic scoping, firm follow-up, inspectional coordination, traceback and sampling activities, public communications, and regulatory product actions.

PIF has an extended shelf life and recalled lots may still be available for sale or in consumer homes. This is an incident of significant public health importance and requires prompt product action to remove contaminated product from the market.

Exposure Table

State	Lot #/Batch #/Product Code	Use By Date	Recall Status	Notes
CA	206VABP/251261P2	01DEC2026	Recalled	
RI	206VABP/251261P2	01DEC2026	Recalled	
MN	206VABP (b)(4)	01SEP2026		
IL	206VABP (b)(4)	01JAN2027		
IL	206VABP (b)(4)	01NOV2026		
IL	206VABP (b)(4)	01FEB2027		
IL	206VABP (b)(4)	01DEC2026		
IL	206VABP (b)(4)	05JUN2026		
CA	206VABP/251261P2	01DEC2026	Recalled	
RI	206VABP/251261P2	01DEC2026	Recalled	
CA	206VABP/251131P2	01DEC2026	Recalled	Preliminary positive for Botulinum toxin Type A
MN	206VABP (b)(4)	01SEP2026	Not Recalled	
IL	206VABP (b)(4)	01JAN2027	Not Recalled	
IL	206VABP (b)(4)	01NOV2026	Not Recalled	
IL	206VABP (b)(4)	01FEB2027	Not Recalled	

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

IL	206VABP (b)(4)	01DEC2026	Not Recalled	
IL	206VABP (b)(4)	05JUN2026	Not Recalled	

6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

ICS 201, Page 2 Date/Time: 11/10/2025 11:00 AM EST

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

7. Current and Planned Objectives:

(b)(5)

8. Current and Planned Actions, Strategies, and Tactics:

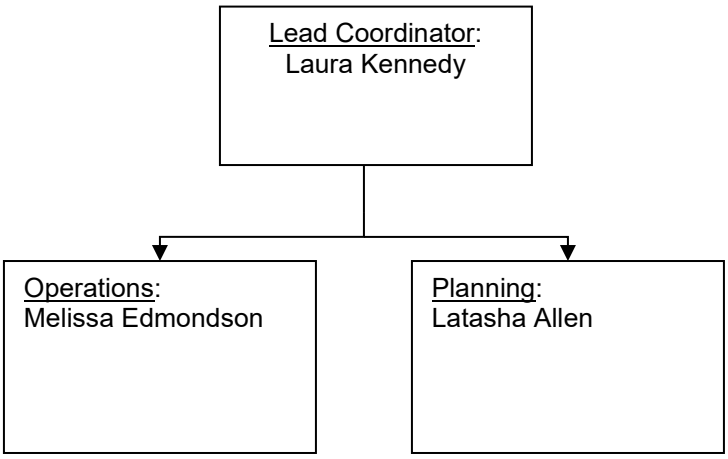
Time:	Actions:

6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

9. Current Organization (fill in additional organization as appropriate)**:**



6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

10. Resource Summary:

Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Nicole Clausen	Office of Human Food Inspectorate				
					OII HF East 1 Recalls listserv
					OII Recalls listserv
Elizabeth Schulz	Nutrition Center of Excellence				Infant Formula SME
OII Critical Foods Listserv					
Infant Product Complaints Email					
OCE Listserv	Office of Compliance and Enforcement				
Steven Grube	Office of Surveillance Strategy & Risk Prioritization				Chief Medical Officer
Latasha Robinson	Nutrition Center of Excellence				Infant Formula SME
Julia Bracken	Nutrition Center of Excellence				Infant Formula SME
Jennifer Hicks	Office of Compliance and Enforcement				OCE POC
Marjorie Davis	Office of Compliance and Enforcement				OCE POC

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

10. Resource Summary:

Leslie Hintz	Office of Compliance and Enforcement				OCE POC
Mouhamed Halwani	Office of Field Operations and Response				Recalls
OII Senior ERCs ListServ					
Byron Beerbower	Office of Human Food Inspectorate				
OII OFOR OER DER Managers Listserv					
Nicole Yuen					HFI West 2 ERC
Steven Galvez					HFI West 2 ERC
Joseph Cooper					HFI Central 1 ERC
Sana Elassar					HFI Central 3 ERC
William Muszynski					HFI East 3 ERC
Kelsey Volkman					HFI West 3 ERC
Bradley Benasutti					HFI East 2 ERC
Erin Dugan					HFI Central 5 ERC
Milan McGorty					HFI East 1 ERC
Herminio Francisco					HFI West 1 ERC
Megin Nichols	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				Director

1. Incident Name: C. botulinum (1125MLBOT)/Powdered Infant Formula/Nov 2025	2. CORE Incident Number: 1350	3. Date/Time Initiated: Date: 11/10/2025 Time: 11:00 AM

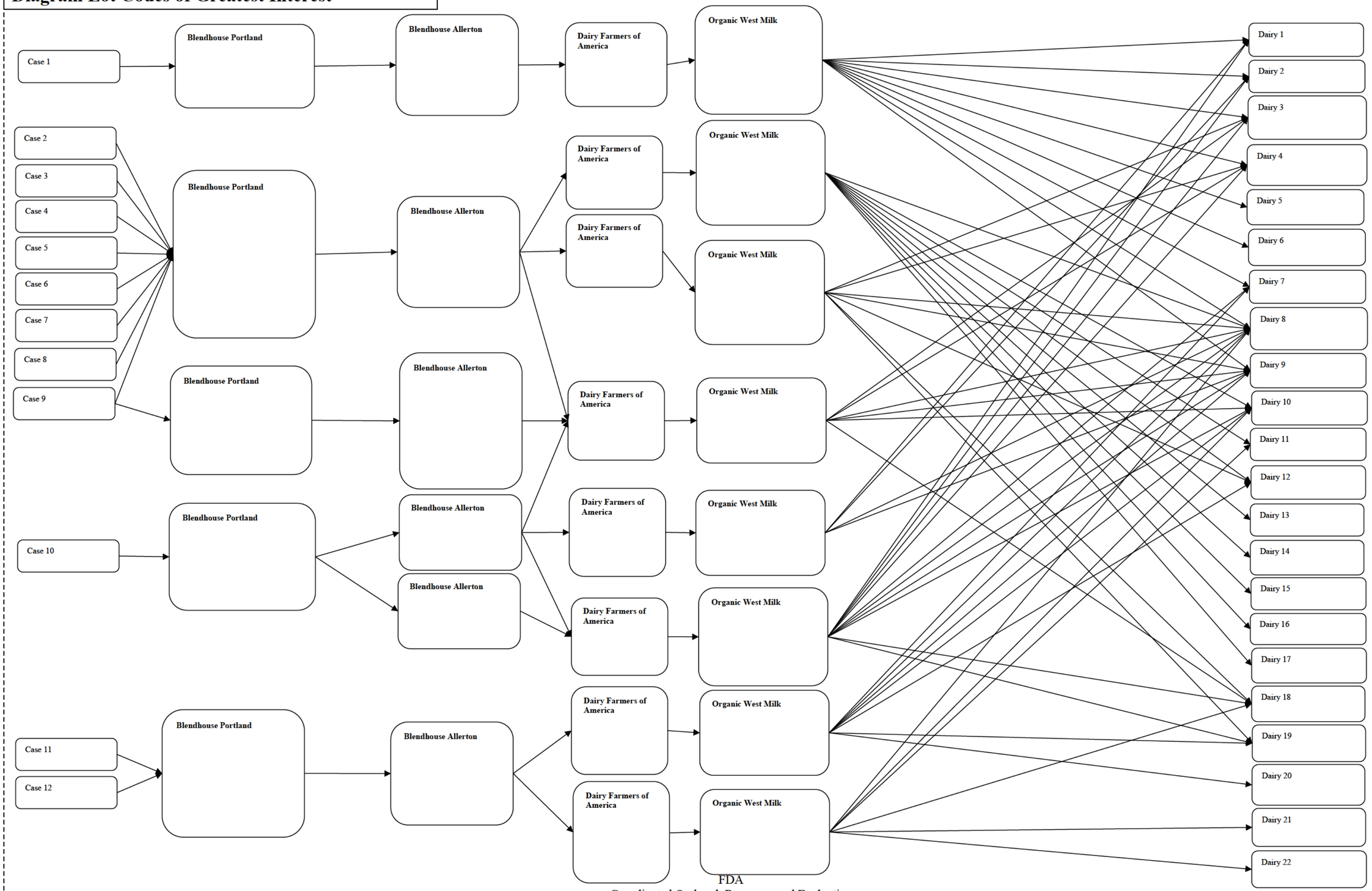
10. Resource Summary:

Jennifer Cope	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				Botulism Team
Ethel Taylor	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				Botulism Team
Laura Gieraltowski	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Amanda Conrad	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Carolina Luquez	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				Comms
Laura Whitlock	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				Comms

6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

Clostridium botulinum– Infant Formula
Multi-state Outbreak Nov 2025
LOT CODE ANALYSIS FLOW DIAGRAM

Exhibit 1: Master Targeted Distribution Analysis Diagram Lot Codes of Greatest Interest



Human Foods Program Signal Detection and Bioinformatics Branch WGS Analysis Report

This document may contain non-public information, including information for which public disclosure is prohibited by law, such as confidential commercial information (CCI). The information in this report must not be further disclosed without written permission by the FDA.

Report Title: WGS-Report-ByHeart-260224

Firm Name: ByHeart

Pathogen: Clostridium botulinum

Date Generated: `24 February, 2026`

Sample or Facts IDs:

WGS Discussion:

Whole genome sequence analysis was performed for nine *Clostridium botulinum*.

The isolates represent four strains (labelled clust1-clust4 below):

- clust1 includes PNUSAB000008/IDR2500084760-01-01 (isolated from unopened powdered infant formula in November 2025; blue label in phylogenetic tree below). It is part of a group of matching *C. botulinum* that were isolated from dry powdered milk/whole milk powder, powdered infant formula, and one clinical sample (red label; mean 7.22 SNPs).
- clust2 includes FDA1316851-S005-001 and FDA1316851-S005-002 (isolated from powdered infant formula base in December 2025; blue labels in phylogenetic tree below). They match CFSAN145423/W533103 (isolated from powdered infant formula; 15 SNPs) and they are inconclusive matches to a cluster of historical isolates collected in 2015 (mean 7.2 SNPs).
- clust3 includes PNUSAB000014/CA-25-0146 (isolated from opened powdered infant formula in 2025; blue label in phylogenetic tree below). It matches three clinical isolates (red labels; mean 5.64 SNPs).
- clust4 includes CFSAN145335, CFSAN145336, CFSAN145337, and CFSAN145338 (isolated from powdered infant formula in 2025) and CFSAN145340 (isolated from powdered infant formula base in 2025). They match one clinical isolate (red label; mean 4.13 SNPs).

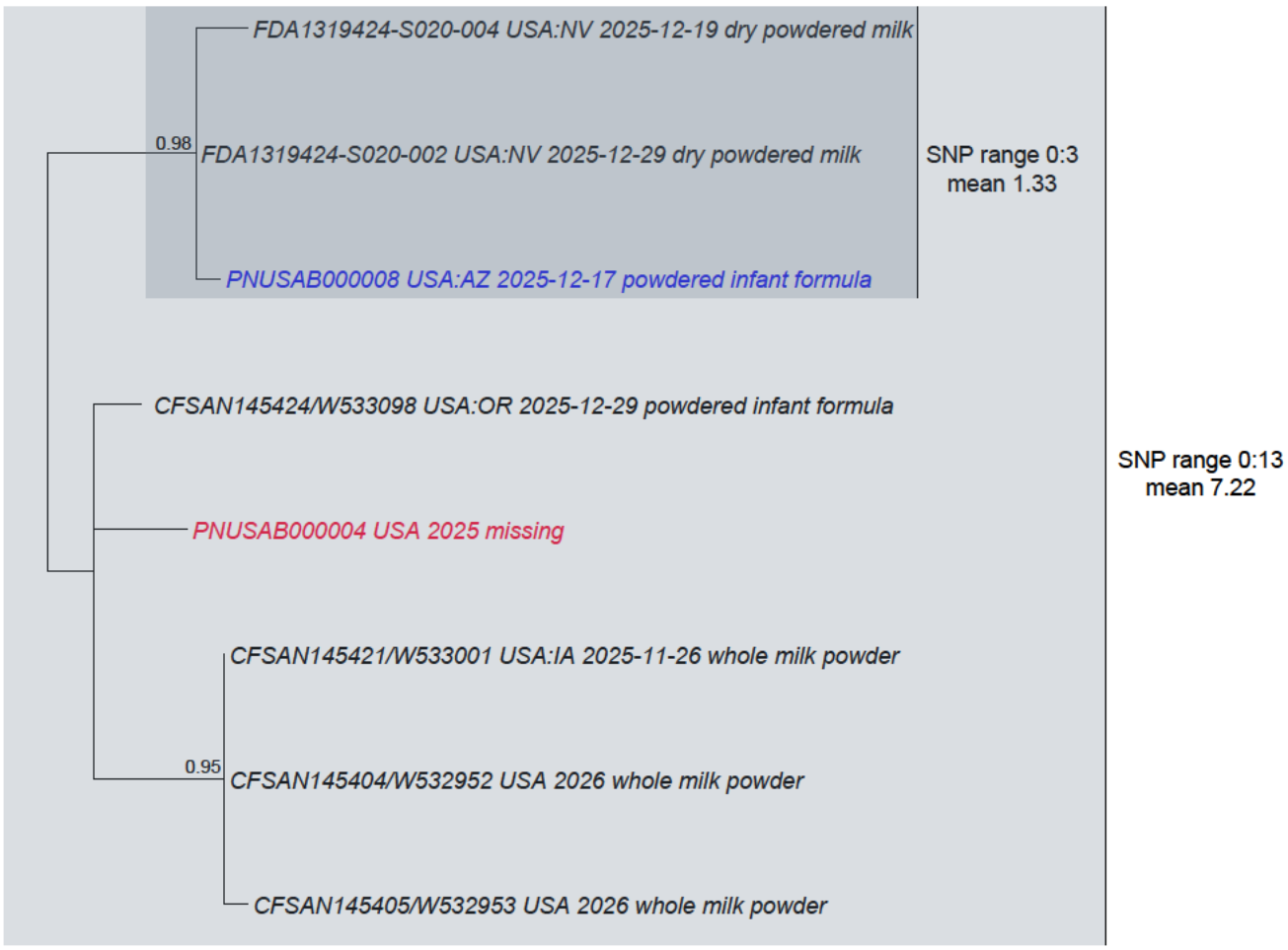
CFSAN SNP Pipeline Version: `v2.2.1.`

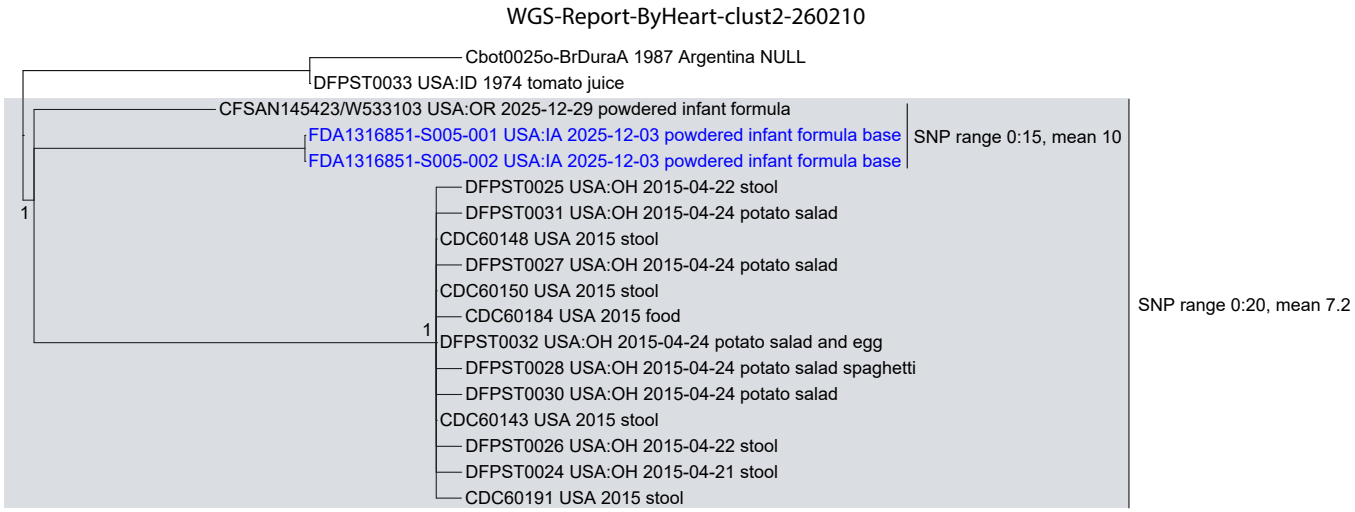
See below for phylogenetic clusters (if they were generated).

References

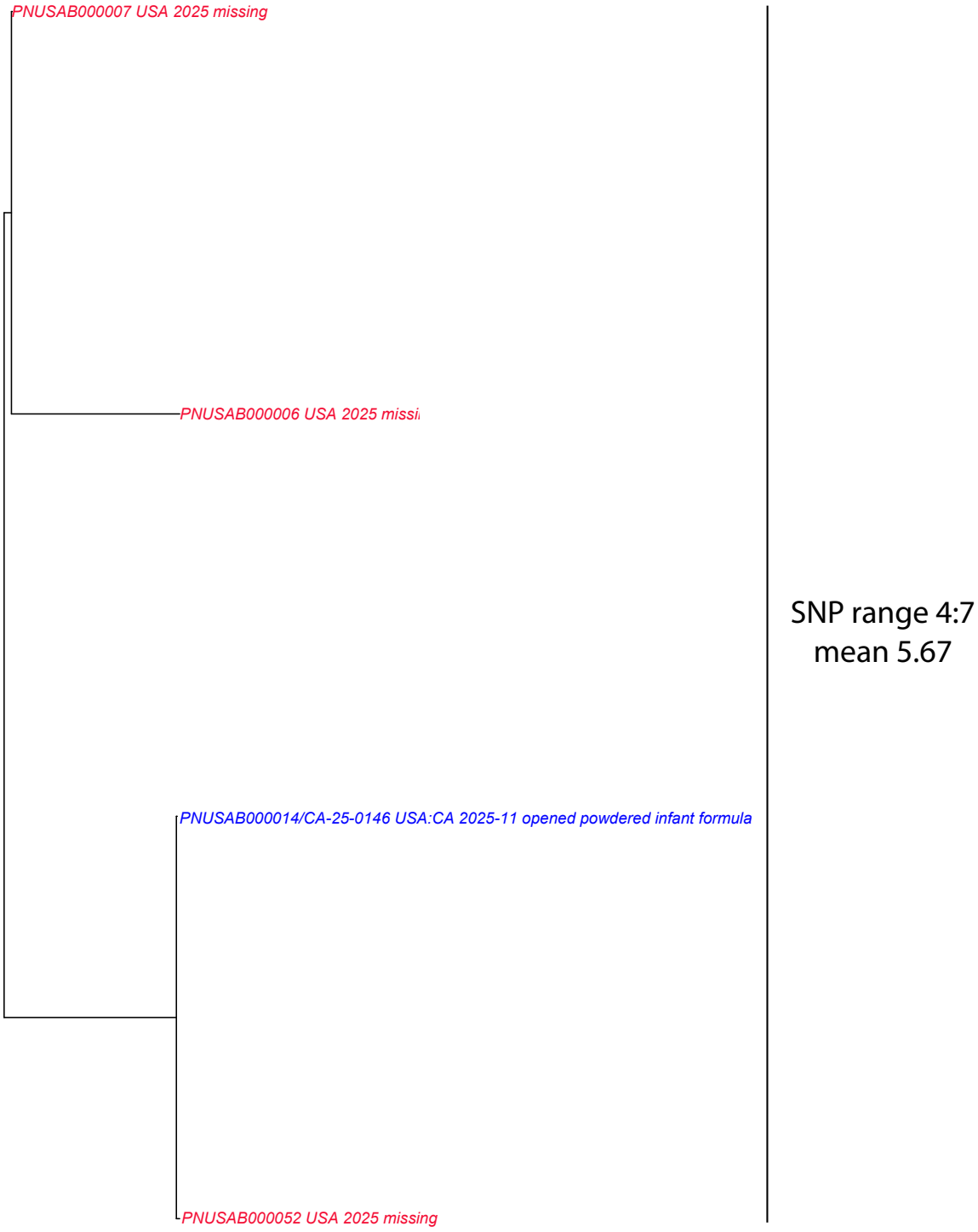
- Information about the CFSAN SNP Pipeline can be found https://peerj.com/articles/cs-20/.
- Information on the interpretation of SNP distances and those clusters can be found https://www.frontiersin.org/articles/10.3389/fmicb.2018.01482/full.

WGS-Report-ByHeart-clust1-260210




WGS-Report-ByHeart-clust2-260210
Cbot0025o-BrDuraA 1987 Argentina NULL
DFPST0033 USA:ID 1974 tomato juice
CFSAN145423/W533103 USA:OR 2025-12-29 powdered infant formula
FDA1316851-S005-001 USA:IA 2025-12-03 powdered infant formula base
FDA1316851-S005-002 USA:IA 2025-12-03 powdered infant formula base
SNP range 0:15, mean 10
1
DFPST0025 USA:OH 2015-04-22 stool
DFPST0031 USA:OH 2015-04-24 potato salad
CDC60148 USA 2015 stool
DFPST0027 USA:OH 2015-04-24 potato salad
CDC60150 USA 2015 stool
CDC60184 USA 2015 food
1
DFPST0032 USA:OH 2015-04-24 potato salad and egg
DFPST0028 USA:OH 2015-04-24 potato salad spaghetti
DFPST0030 USA:OH 2015-04-24 potato salad
CDC60143 USA 2015 stool
DFPST0026 USA:OH 2015-04-22 stool
DFPST0024 USA:OH 2015-04-21 stool
CDC60191 USA 2015 stool
SNP range 0:20, mean 7.2

WGS-Report-ByHeart-clust3-260224



WGS-Report-ByHeart-clust4-260224

HUMAN FOODS PROGRAM HEALTH HAZARD EVALUATION

HHE # 11418 **RES# 97959 Date Sent: 12/2/2025**

Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)

1. ByHeart Whole Nutrition Infant Formula cans 24 OZ 680 grams; Cans sold in 1 pack, 2 packs, 4 packs, or 6 packs 2. ByHeart Whole Nutrition Infant Formula Anywhere Packs Single Serve Packet 17 grams in packages containing 14 Single Serve Packets

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic or foreign.)

ByHeart, INC.
131 Varick St
New York, NY 10013-1410 US

3. SOURCE OF PROBLEM

☐**Undeclared allergen:**
☐**Presence of contaminant or impurities (specify):**
☒**Microbial contamination (specify):** ***Clostridium botulinum***
☐**Presence of foreign bodies:**
☐**Other:**

4. NATURE OF PROBLEM (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

On November 8, 2025, the FDA and Centers for Disease Control (CDC), were alerted by California Department of Public Health (CDPH) Infant Botulism Treatment and Prevention Program (IBTPP), of a multistate outbreak of 13 cases of infant botulism from 10 states. The CDPH IBTPP reported an increase in number of botulism type A infections among infants consuming ByHeart powdered infant formula from August 2025 to November 2025. All 13 cases included in the initial outbreak cluster reported consuming ByHeart brand powdered infant formula. FDA recommended that the firm conduct a voluntary recall due to the large number of cases, severity of illness, and the strong epidemiological signal. On 11/8/2025, ByHeart, Inc. agreed to initiate a recall of two lots of ByHeart Whole Nutrition Infant formula that were initially reported to have been consumed by the infants. On 11/11/25, after a recommendation by the FDA, the firm expanded the voluntary recall to include all product and lots due to additional cases with exposure to lots not covered under the more limited recall and preliminary testing results from CDPH. Testing by the CDPH laboratory recovered *C. botulinum* from an open

container of infant formula obtained from an ill infant's home. ByHeart's independent third-party testing of 36 unopened cans found *Clostridium botulinum* in five samples, spanning three different product lots. Based on these findings, the company stated publicly it could not rule out the risk of contamination across all its product lots. On 11/19/25, due to firm-sponsored testing revealing the presence of the causative pathogen, they amended their recall press to remove exculpatory statements regarding sampling.

5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

☐No ☒Yes: Currently 39 illnesses

6. PRECEDENT HHEs (Using the HFP HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

HHE #	Date Signed	Hazard Identified
None		

Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

Infant botulism is a potentially life-threatening neuroparalytic disorder affecting children younger than 12 months of age. It is caused by ingestion of *Clostridium botulinum* spores that germinate and colonize the infant's large intestine, producing botulinum neurotoxin in situ.[i] Once absorbed, the neurotoxin irreversibly binds to acetylcholine receptors at neuromuscular junctions, blocking neurotransmitter release and causing progressive flaccid paralysis.[ii] This condition represents a unique infectious process termed intestinal toxemia, which is distinct from foodborne botulism where preformed toxin is ingested. The affected population consists primarily of infants younger aged than 6 months, with a median age at onset of 16.8 weeks globally. However, outpatient cases often present slightly older at a median age of 20 weeks.[iii]

The clinical spectrum of infant botulism ranges from mild outpatient illness accounting for less than 1% of cases to severe disease requiring hospitalization and mechanical ventilation.[iv] Most infants experience moderate or severe illness necessitating inpatient medical management, treatment with Human Botulism Immune Globulin (BabyBIG) administration, and pediatric intensive care support.[v] Without BabyBIG, mortality can reach 5–15%. With modern supportive care and BabyBIG treatment, mortality in the U.S. as fallen to less than 1%.[vi]

Clinical presentation typically begins with constipation, followed by progressive bulbar palsy manifesting as weak cry, poor feeding, decreased head control, ptosis, and poor suck. [vii]The descending bilateral symmetric paralysis can ultimately involve respiratory and diaphragmatic

muscles, leading to respiratory failure requiring intubation and mechanical ventilation in approximately 21% of U.S. cases and 50% of cases elsewhere.[viii]
The disease can progress rapidly from initial symptoms to respiratory compromise to death, and the toxin is most effective very early in the disease course. Preventing severe disease and adverse outcomes requires that clinicians have a high index of clinical suspicion that results in early treatment.

The primary health hazards include progressive paralysis that can lead to respiratory failure requiring mechanical ventilation, as well as prolonged hospitalization (median 12 days in the U.S., 27 days globally) While not all infants will require mechanical ventilation, most hospitalized cases require intensive care unit admission. [ix] Even after treatment BabyBIG, some infants require temporary outpatient tube feeding and may have persistent hypotonia following recovery.[x]
Permanent neurologic sequelae are rare with appropriate treatment, and spontaneous recovery occurs as new motor endplates regenerate.

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

☐No – the general population is at risk
☒Yes – check all that apply

- ☒Infants
- ☒Children: **Limited to very young children still consuming infant formula.**
- ☐Pregnant women, nursing women, or women of childbearing age
- ☐Elderly consumers
- ☐Individuals with allergy/intolerance to (food/product)
- ☐Immunosuppressed individuals
- ☐Medical conditions (e.g., diabetes, celiac disease)
- ☐Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

☒No ☐Yes

10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

☒Life-threatening (death has or could occur): **Respiratory failure requiring mechanical ventilation.**

☐Results in permanent impairment of a body function or permanent damage to a body structure
☒Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function: **Most cases require hospitalization, critical care support, and immunoglobulin treatment**
☒Temporary or reversible (without medical intervention): **A rare minority of cases remain outpatient with self-resolving symptoms.**
☐Limited (transient, minor impairment or complaints)
☐No adverse health consequences
☐Hazard cannot be assessed with the data currently available

11. **What is the probability of each adverse event occurring, as specified in Item 10?** (If more than one item is selected below, specify the corresponding health hazard.)

☐Highly likely to occur (every time the product is used)
☒Likely to occur (reasonable probability of occurrence)
☐Might occur (remote probability of occurrence)
☐Unlikely to occur
☐Unknown (please explain):
☐Not applicable

Conclusion:

Contamination of ByHeart powdered infant formula with *Clostridium botulinum* presents a severe health hazard to infants consuming this product as it can cause infant botulism, a potentially life-threatening neuroparalytic disease. This condition almost always requires medical intervention, with most affected infants needing hospitalization and many requiring intensive care or mechanical ventilation due to the risk of rapid respiratory failure or death. These hazards are likely to occur in infants consuming the implicated ByHeart powdered infant formula given the vulnerability of this population's immature gastrointestinal and immune system.

SIGNATURES

Requested By:
Leonora Darlington
Consumer Safety Officer

Julia M. Bracken -S
Digitally signed by Julia M. Bracken -S
Date: 2025.12.05 08:24:01 -06'00'

Julia Bracken, MD
Health Hazard Evaluation Board Member

STEVEN M. GRUBE -S
Digitally signed by STEVEN M. GRUBE -S
Date: 2025.12.05 10:56:09 -05'00'

CAPT Steven M. Grube, MD MPH
Chief Medical Officer and HHE Board Chair
Human Foods Program
Food and Drug Administration

[i] Antonucci L, Locci C, Schettini L, Clemente MG, Antonucci R. Infant botulism: an underestimated threat. Infect Dis (Lond). 2021 Sep;53(9):647-660. doi: 10.1080/23744235.2021.1919753. Epub 2021 May 8. PMID: 33966588.
[ii] Arnon S, Schechter R, Maslanka SE, Jewell NP, Hatheway CL. Human Botulism Immune Golbulin for the Treatment of Infant Botulism. The New England Journal of Medicine. 2006;354(5):462-71.
[iii] Dabritz HA, Chung CH, Read JS, Khouri JM. Global Occurrence of Infant Botulism: 2007-2021. Pediatrics. 2025 Apr 1;155(4):e2024068791. doi: 10.1542/peds.2024-068791.
[iv] Antonucci L, Locci C, Schettini L, Clemente MG, Antonucci R. Infant botulism: an underestimated threat. Infect Dis (Lond). 2021 Sep;53(9):647-660. doi: 10.1080/23744235.2021.1919753. Epub 2021 May 8. PMID: 33966588.
[v] Khouri JM, Dabritz HA, Payne JR, Read JS, Chung CH. Outpatient Infant Botulism in the United States, 1976-2021. J Pediatr. 2025 Jan;276:114365. doi: 10.1016/j.jpeds.2024.114365. Epub 2024 Oct 18. PMID: 39428092.
[vi] Centers for Disease Control and Prevention (CDC). Botulism in the United States, 1899–1996: Handbook for Epidemiologists, Clinicians, and Laboratory Workers. Atlanta, GA: U.S. Department of Health & Human Services, CDC; 1998.
[vii] Antonucci L, Locci C, Schettini L, Clemente MG, Antonucci R. Infant botulism: an underestimated threat. Infect Dis (Lond). 2021 Sep;53(9):647-660. doi: 10.1080/23744235.2021.1919753. Epub 2021 May 8. PMID: 33966588.
[viii] Dabritz HA, Chung CH, Read JS, Khouri JM. Global Occurrence of Infant Botulism: 2007-2021. Pediatrics. 2025 Apr 1;155(4):e2024068791. doi: 10.1542/peds.2024-068791.
[ix] Antonucci L, Locci C, Schettini L, Clemente MG, Antonucci R. Infant botulism: an underestimated threat. Infect Dis (Lond). 2021 Sep;53(9):647-660. doi: 10.1080/23744235.2021.1919753. Epub 2021 May 8. PMID: 33966588.
[x] Cox N, Hinkle R. Infant botulism. Am Fam Physician. 2002 Apr 1;65(7):1388-92. PMID: 11996423.