***Listeria monocytogenes*/(b) (5) (Suspect)/Jun 2025**

DRAFT Executive Incident Summary
CARA # 1309
Date: 1/29/2026
CORE Response Team 1

EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 6/5/2025, CDC notified CORE Signals they had reopened *Listeria monocytogenes* cluster investigation, (b) (5), due to 5 additional clinical illnesses added since December 2024. This cluster had been previously investigated by CDC and CORE Signals in April and August of 2024. Both investigations closed in CORE Signals with an unknown vehicle. Given investigation details gathered during the previous investigations and non-clinical isolates genetically associated to the outbreak isolates (b) (5)) and several FSIS-regulated (b) (5) products), CDC began to utilize a supplemental questionnaire focusing on (b) (5). In August 2025, the (b) (5) collected samples of (b) (5) from a restaurant (b) (5) supplier identified by a case patient associated with the outbreak. Samples collected from (b) (4) and (b) (4) tested positive for *Listeria monocytogenes*, matching the outbreak strain. At the time of transfer, on 8/29/2025, the cluster included 38 isolates, with 13 food isolates and 25 clinical isolates from (b)(6) states, including (b) (5)

Epidemiology Overview & Genomic Analysis

On June 4, 2025, PulseNet reopened this investigation after five new cases of Listeria monocytogenes were identified from 5 states: (b) (5), and (b) (5) with specimen collection dates ranging from December 1, 2024, to May 21, 2025. Of these five, only one was identified in 2024. The remaining four had specimen collection dates from January 2025 to May 2025. All isolates were related within 0-29 alleles by wgMLST

By investigation closure, there were 27 clinical cases from (b)(6) states: (b) (5) and (b) (5) Specimen collection dates ranged from August 16, 2013 to October 30, 2025. Ages ranged from <1 to 97 years (median: 72 years), and 13/27 (48%) of cases were female. Of 25 patients with outcome information, 25 (100%) were hospitalized and there was one death attributed to Lm infection. All isolates were related at 0–37 alleles by wgMLST.

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This outbreak also included 13 non-clinical isolates, seven of which had already been identified across the last two outbreak investigations of this strain, and three newly identified isolates that resulted from the course of this 2025 investigation:

- (b) (5) collected on 6/15/2016
- (b) (5) collected on 7/5/2016 and 7/6/2016
- (b) (5) 8/20/2022
- (b) (5) collected on 7/17/2024
- (b) (5) collected on 7/17/2024
- (b) (5) collected on 8/4/2025

CDC deployed a supplemental questionnaire on June 9, 2025, with questions related to (b) (5) and (b) (5) and (b) (5) food products, (b) (5), and (b) (5). Two questionnaires were completed and returned to CDC. Additionally, a total of 25 LI forms were returned and analyzed. One patient in (b) (5) reported consuming (b) (5) from a local grocer prior to illness onset. A (b) (5) patient reported consuming (b) (5) A patient in (b) (5) reported (b) (5) eaten at a social event. Lastly, a patient in (b) (5) reported (b) (5) and (b) (5) from a local restaurant.

Field Investigations & Findings

CORE issued a total of six assignments to FDA Office of Emergency Response, Emergency Response Coordinators for record collection at (b) (4) No FDA 483s were issued during these record requests.

Laboratory Sample Overview

Based on a USDA historical sample of (b) (5) with (b) (5) supplied by (b) (4), and one 2024 clinical case with exposure at a POS in (b) (5), supplied by (b) (4), (b) (5) collected (b) (5) samples from these (b)(5) distribution centers in (b) (5). On 8/4/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4), and on 8/5/2025, they collected records and (b)(5) (b) (5) samples at (b) (4). On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for *Lm*: (b) (4), and (b) (5) and (b) (5) (b) (4)). On 8/20/2025, Office of Emergency Response PHI ERC notified HFP Office of Compliance and Enforcement of the positive samples and possible connection to clinical cases associated with outbreak cluster (b) (5). On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) (b) (5) matched the outbreak strain by WGS. The (b) (5) collected at (b) (4) were not a match to the outbreak strain, (b) (4) returned the (b) (5) to the manufacturer in (b) (5).

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One sample (FACTS 1316125) was collected by FDA DNEI (Division of Northeast Imports) on 11/6/2025, under IB 99-B54, sample was negative for *Salmonella* spp. and *Listeria* spp. See sample summary for more details about historical samples that were collected by USDA and FDA prior to this outbreak investigation.

Traceback Abbreviated Summary

FDA did not conduct an official traceback investigation for this incident. However, a limited distribution analysis was conducted for two cases, one in [redacted] that reported purchasing [redacted] at a [redacted] on 4/23/2024, and one in [redacted] that purchased [redacted] and [redacted] on 5/19/2025. The [redacted] at [redacted] were supplied by [redacted] located in [redacted]. The [redacted] case purchased [redacted] brand [redacted] the [redacted] were supplied by two domestic firms, [redacted] and [redacted]; the [redacted] were supplied by [redacted]. Since these were the only cases with exposure information to trace, the source of the outbreak could not be determined by traceback analysis.

Traceback records were also analyzed for the [redacted] incorporated in a USDA [redacted] sample in 2024 that tested positive for the outbreak strain. [redacted] were sourced from multiple countries, the [redacted] were supplied by [redacted] via a broker in the U.S., [redacted].

Product & Firm Actions

On 9/2/2025, [redacted]) voluntarily recalled two lots of [redacted]; 335 cases of [redacted] (Production Date 06/11/2025, Best Before End 06/10/2027) and 280 cases of [redacted] (Production Date 06/17/2025, Best Before End 06/16/2025). Both [redacted] products were labeled Product of [redacted].

On 9/15/2025 FDA added [redacted] manufacturing facility in [redacted] and [redacted] the Yellow List under the CORE IB 99-B54 to collect [redacted] and [redacted]

On 9/24/2025, CORE facilitated a firm call with [redacted], FDA, CDC, and PDA. The firm invited a consulting firm [redacted] and their importer [redacted] to the meeting. This was a call to share and answer questions about the WGS analysis of the [redacted] product samples collected by [redacted] Dep of Ag which matched the outbreak strain.

On 9/25/2025, CORE facilitated a firm call with [redacted], their [redacted] FDA, CDC and [redacted]. FDA shared the WGS analysis of the outbreak, and CDC provided an

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overview of the epi using the slides attached. (b) (4) provided a brief overview of their manufacturing processes.

On 9/29/2025, CORE requested DIO add (b) (4) manufacturing facility in ash (b) (4) to the Yellow List under the CORE IB 99-B54 for the collection of (b) (5) and (b) (5) .

On 9/30/2025, all products containing any of the following: (b) (5) or (b) (5) from (b) (5) FEI's (b) (4)) were added to Import Alert 99-23, Detention Without Physical Examination of Produce Due to Contamination With Human Pathogens.

On 10/22/2025, the supplier to (b) (4) was placed on Import Alert 99-23 on 10/22/2025; therefore, the (b) (5) that were returned to the manufacturer in (b) (5) would be subject to Detention Without Physical Examination under IA 99-23.

Communications Overview

There were no federal or state public safety alert communications related to this outbreak. This incident was added to the CORE Investigation Table on 9/4/2025, and the investigation status is scheduled to close on 12/17/2025.

On 9/4/2025, FDA published the (b) (4) . recall to FDA's Recalls, Market Withdraws, & Safety Alerts website.

Conclusions

We were unable to confirm (b) (5) as the vehicle in this outbreak due to a lack of exposure data linking (b) (5) to ill people included in the outbreak and therefore limiting our traceback opportunities. Based on positive laboratory findings and related WGS of the (b) (5) linked to (b) (4) , (b) (5) remain the suspect vehicle for this outbreak.

Acknowledgements

CORE would like to acknowledge the efforts of our state and federal partners who worked collaboratively to identify and remove the implicated product from the market. Specifically, (b) (5) for collecting and analyzing (b) (5) samples based on historical evidence and finding the outbreak strain in those (b) (5) samples.

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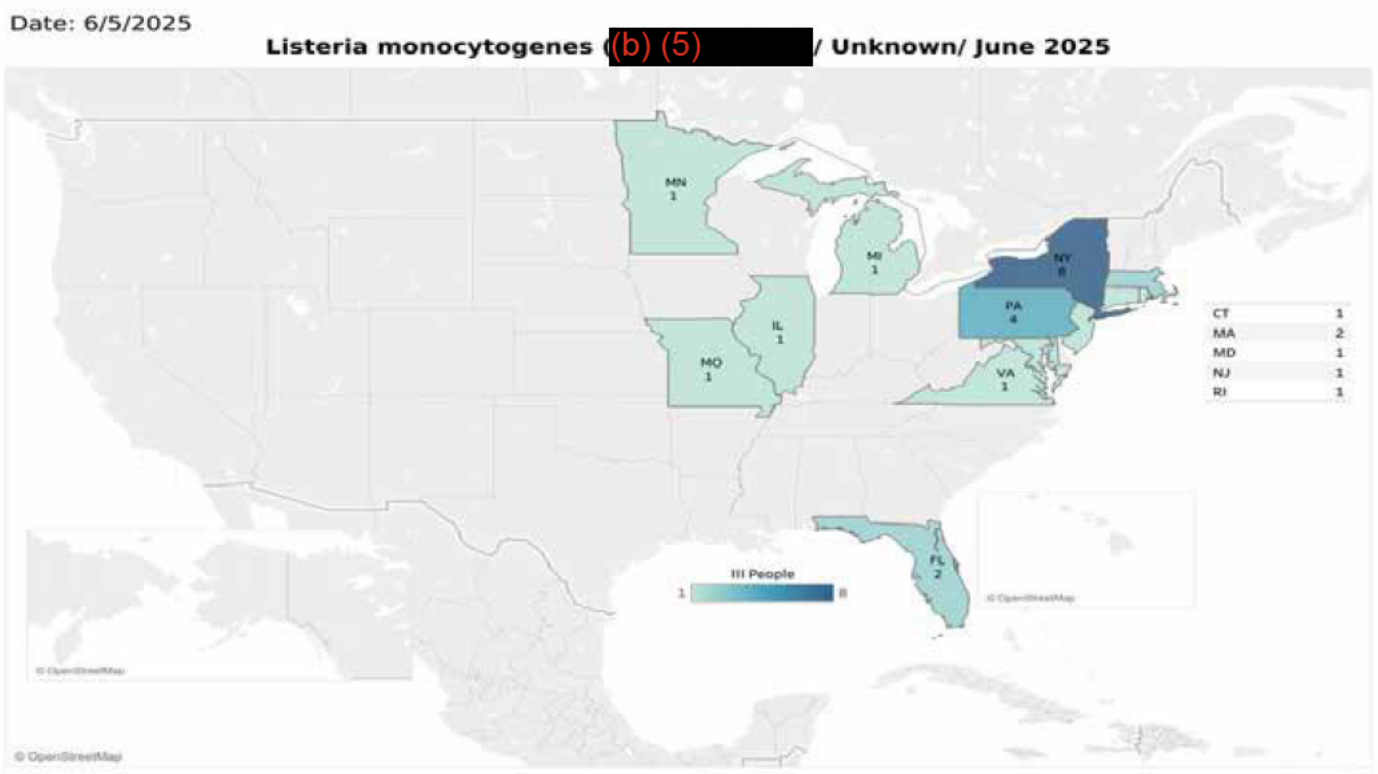
INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b) (5) / Unknown/ June 2025	2. CORE Incident Number: 1309	3. Date/Time Initiated: Date: 8/29/2025 Time: 9:30 AM

4. Map/Sketch



https://www.ncbi.nlm.nih.gov/pathogens/tree#Listeria/PDG000000001.4301/PDS000024708.163?key=l9kSEu1wKAR7ThviGi5NjltfMmBA21KiatwatXv4ILJi_Sy9TP0

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

ICS 201, Page 1 Date/Time: 8/29/2025 9:30 AM EDT

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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Listeria monocytogenes (b) (5) / Unknown/ June 2025		Date: 8/29/2025 Time: 9:30 AM

5. Situation Summary and Health and Safety Briefing

Listeria monocytogenes ([redacted])([redacted]) (suspect)/Jun 2025

Background and Epidemiology
On 6/5/2025, CDC and FDA reopened the investigation of Listeria monocytogenes (Lm) cluster, [redacted]. This is the third time this cluster has been investigated. This cluster was previously investigated in [redacted]; both times the incident was closed with an unknown vehicle.

Currently, this cluster consists of 38 isolates, with 13 food isolates and 25 clinical isolates from [redacted] states, including [redacted]. Isolation dates range from 8/16/2013 to 5/21/2025, with 5 illnesses with onsets in 2025. Cases are 44% female and range in age from 0 to 97, with a median age of 72 years. 95% of cases have been hospitalized; one death has been reported; and there have been two pregnancy associated cases associated with this outbreak.
As of June 2025, CDC stated there were no [redacted] matches to the US clinical or food isolates.

Exposure Information
Exposure data is extremely limited and does not indicate a strong signal for any specific food ([redacted] or otherwise).

Information was collected for 14 cases; of which 1 case explicitly states exposure to [redacted], CT_1293543001). [redacted] case [redacted] provided shopper records for [redacted], which shows the purchase receipt of [redacted] 16 oz on 4/23/2024. Onset for this case is noted as 7/22/2024 [redacted] case [redacted] reports eating [redacted] at a potluck; however, the source of the [redacted] is unknown.

It should be noted that while questions about [redacted] are now included as part of the supplemental questionnaire, they were not included on the initial Listeria Initiative form. As such, epidemiologic information collected for this investigation, as it relates to [redacted] exposures, is challenged by the epidemiological tools used in the early part of the investigation. In addition, poor recall (particularly as it pertains to products like [redacted], which may be included as ingredients in prepared meals) is another significant challenge for this type of investigation.

Genomic analysis
All isolates in the cluster are related within 0-33 SNPs (average 17) by WGS in NCBI and 0-37 alleles by wgMLST. Clinical isolates are related within 0-29 alleles by wgMLST. Included in NCBI tree are 13 food isolates collected since 2016.

Food Samples
The 13 food sample isolates associated with this outbreak were collected by FDA (4), USDA/FSIS (3), and [redacted] (6).

FDA_[redacted] (3; 2016) collected from the processor, [redacted]. The brand is noted as [redacted], and the manufacturer is noted as [redacted]. In 2016, [redacted] issued an RFR for IQF [redacted]. According to the report, two finished products were found to have been manufactured with the affected [redacted]. These products were recalled once positive Lm results were confirmed.

FDA_[redacted] (2022) collected at import. The product is listed as [redacted] and is noted to have been imported to the US and sold to [redacted] for further processing and distribution. In August 2022, during routine testing [redacted] detected the presence of Lm in finished product. The manufacturer is noted as [redacted] and is a product of [redacted].

FSIS_[redacted] (2016) collected at the processor [redacted]. [redacted] used were noted as [redacted] brand.

FSIS_[redacted]; 2024) noted as imported from [redacted].

FSIS_[redacted] product ([redacted]; 2024) collected from the processor [redacted]. [redacted] used the [redacted] were supplied by [redacted].

[redacted] ([redacted]; 8/2025) and [redacted] and [redacted] ([redacted]; 8/2025) collected from distributor [redacted]

(b) (4) . Brand is noted as (b) (4) for both products.

On 7/16/2025, CDC, CORE Signals, and (b) (5) state partners met to discuss the investigation and determine next steps. During the call, it was decided the (b) (5) Department of Agriculture ((b) (5)) would follow up with (b)(5) firms associated with case exposure information. On 7/31/2025, CORE Signals provided a sampling request to PDA (via CDC) for (b) (4) and (b) (4)). Case exposure information from (b) (5) who dined at (b) (4)), provided an opportunity to follow-up at the restaurant to determine supplier information. (b) (5) noted the restaurant made several dishes with (b) (5) . The supplier for (b) (4) was noted as (b) (4) . Information obtained from USDA FSIS regarding the 2024 (b) (5) sample indicated (b) (5) were sourced from (b) (4) .

On 8/4/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/5/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for Lm (b) (4)

On 8/20/2025, OII PHI DO ERC notified HFP OCE of the positive samples and possible connection to clinical cases associated with outbreak cluster (b)(5) .

On 8/21/25, (b) (5) notified (b)(5) firms of the positive Lm findings. (b) (5) requested invoices and records to show where the products were purchased, for the firms to file an RFR with FDA, and for the firms to notify their suppliers of the results. (b) (4) is a warehouse that receives product from a domestic supplier; the firm identified the supplier of the (b) (5) and (b) (5) and (b) (5) as (b) (4)).

On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) ((b) (5)) matched the outbreak strain by WGS. Enumeration has been completed, and the final data packs have been submitted to FDA. OLOAS ORTS reviewed the Lm enumeration worksheets for (b) (4)) and concurred with the findings of 46 MPN/g of Lm in the product. OLOAS ORTS also reviewed the Lm enumeration worksheets for (b) (4) and concurred with the findings of 9.3 MPN/g of Lm in the product.

Firm Information

(b) (4) was inspected by FDA/NYS in 2023 as part of a state contract inspection. This firm is noted to operate as a warehouse/wholesale distributor of an assorted variety of prepackaged, (b) (5) and (b) (5) . 100% of sales are sold wholesale, and 40% are sold outside of (b) (5) . Products (b)(5)

2024, FDA completed a comprehensive inspection of (b) (4) . related to the Foreign Supplier Verification Program (FSVP). (b) (4) is noted as the FSVP Importer for several foreign manufacturers. The importer does not engage in the manufacturing, manipulation, processing, packaging, or labeling of any goods for human or animal consumption at their facility. (b) (4) . acts as a warehouse for (b) (5) and refrigerated products. The firm has a history of one consumer complaint (5/2013) for (b) (5) (b) (5) . The firm has not been subject to any regulatory actions and has no past violative samples. In addition, there have been no relevant recalls for the firm. No major discrepancies were observed during this inspection.

(b) (4)
(b) (4) ; olives) and (b) (4) ; (b) (5)) are not the same firm; however, they are related. As of August 2025, (b) (4) has merged FEIs with (b) (4)

(b) (4) is a joint venture between (b) (4) and (b) (4) . (b) (4) is also a subsidiary of (b) (4) and (b) (4) . (b) (4) distributes internationally, including to the (b) (5) .

(b) (4) is a joint-stock company between (b) (4) and (b) (4) . (b) (4) is noted as a member of the (b) (4) . (b) (4) was established in 2004 as a food-producing company that offers a wide range of products, including (b) (5) and (b) (5) , with international distribution. (b) (4) and (b) (4) operate as separate entities within the larger (b) (4) organization.

(b) (4) , primarily produces and distributes (b) (5) . Import lines show frequent entry dates (b)(5))

of (b) (5) (most common), as well as (b) (5) , (b) (5) and (b) (5) . The Importer of Record for most shipments into the US is listed as (b) (4)) however, (b) (4) is also listed. The Importer of Record for most shipments into the US is listed as (b) (4)), and they ship to (b) (4) (a cold storage facility in (b)(5)).

Information provided by FDAs Food Defense Team in July 2025 indicates, while there is no additional evidence to indicate the (b)(5) firms share the same manufacturing facility, there is evidence to suggest (b)(5) FEIs have used the same filer in the past and have shipped products to the same importer or consignee. FDAs Food Defense Team also noted a Remote Regulatory Assessment (RRA) for (b) (4) that received an Official Action Indicated (OAI) rating. The assessment noted that the firms food safety plan does not appear to effectively control biological and chemical hazards.The full report is available in OSAR under the title: (b) (4) .pdf

Historical Outbreaks
There have not been many Listeria outbreaks linked to (b) (5) ; however, with the use of WGS, connections between illness and firms/food have been identified. In 2016 CORE investigated an outbreak linked to (b)(5) separate firms: a processor of (b) (5) and a manufacturer of (b) (5) (Listeria monocytogenes, (b) (5) /Mar 2016 - CARA ID 553; Madad, et al., 2023. Investigation of a Multistate Outbreak of Listeria monocytogenes Infections Linked to (b) (5) Produced at Individually (b) (4) Manufacturing Facilities. (b) (4) . (b)(4) . This was the first reported multistate outbreak of Lm illnesses associated with (b) (5) in the US. Similar to this current outbreak, WGS links to the firm was the strongest piece of information connecting the firm/food to cases. Additionally, a separate Listeria outbreak was investigated between 2015-2018 across several (b) (5) countries. The outbreak was ultimately linked to a (b) (5) plant. Similar to the current domestic US outbreak, WGS aided the connection between the (b) (5) illnesses and (b) (5) .

(b)(5) , such as (b) (5) , may be thawed and held refrigerated before consumption, and some people may eat them without cooking or heating. In both the domestic 2016 outbreak investigation, and the 2015-2018 (b) (5) investigation, this observation was noted. Because (b) (5) may be consumed without cooking, control of Listeria in (b) (5) production environments is an important component of preventing potential product contamination.

This incident is being transferred from CORE Signals to CORE Response Team 1 based on the following rationale:

This is an ongoing outbreak of Listeria monocytogenes in which (b) (5) , an FDA-regulated product, has been identified as the suspect vehicle. (b) (5) have an extended shelf life, and contaminated product may still be in consumer homes.

CORE Response coordination is needed product tracing activities, to coordinate product actions, and support import activities.

This is a repeat hazard/commodity pair. (b) (5) are an established vehicle for Listeria monocytogenes. This investigation may illuminate ongoing contamination issues at the manufacturer, including the possibility of a resident stain, thereby allowing for the opportunity to identify future prevention efforts.

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Exposure Table

No Exposure Table Available

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

ICS 201, Page 2 Date/Time: 8/29/2025 9:30 AM EDT

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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Listeria monocytogenes (b) (5))/ Unknown/ June 2025		Date: 8/29/2025 Time: 9:30 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:

ICS 201, Page 3 Date/Time: 8/29/2025 9:30 AM EDT

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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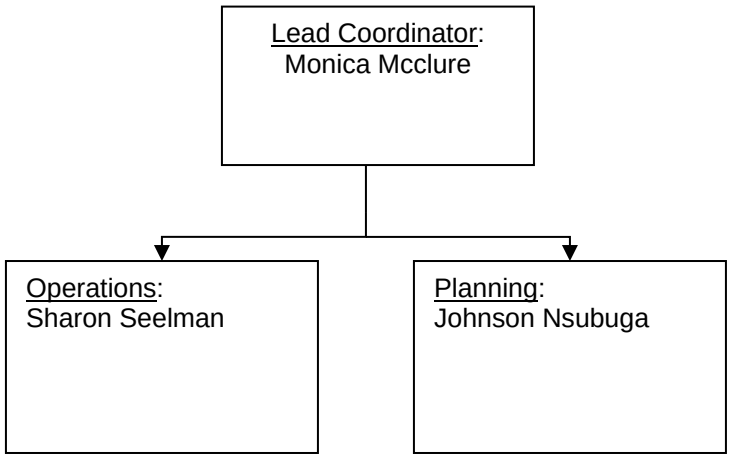
9. Current Organization (fill in additional organization as appropriate)**:**



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

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10. Resource Summary:

Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Joseph Baugher	Office of Surveillance Strategy & Risk Prioritization				
OCE email distro list	Office of Compliance and Enforcement				
Vickery Brewer	Office of Compliance and Enforcement				
Shannon Ballou (Hall)	Office of Compliance and Enforcement				
Katie Arnold	Office of Compliance and Enforcement				
Marilyn Santiago	Office of Compliance and Enforcement				Corresponding CMS Work Activities (WA) 683749, 683783 & 683790
Reeba Roy	Office of Compliance and Enforcement				
Arma White	Office of Compliance and Enforcement				
	Office of Microbiological Food Safety				
Courtney Mickiewicz	Office of Microbiological Food Safety				Backup POC

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10. Resource Summary:

Grace Tung	Office of Microbiological Food Safety				Primary POC
Robin Rivers	Office of Compliance and Enforcement				
Lauren Yeung	Office of Laboratory Operations & Applied Science				
Serajus Salaheen	Office of Import Operations				
Kimberly Langello					
Robert Literman	Office of Surveillance Strategy & Risk Prioritization				
Byron Beerbower	Office of Human Food Inspectorate				
Nicole Clausen	Office of Human Food Inspectorate				
	Office of Field Operations and Response				
Bradley Benasutti					
Milan McGorty					
Erin Dugan					
Sana Elassar					

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10. Resource Summary:

Marlon Turner					
William Muszynski					
Joseph Cooper					
Nelson Venerio					
Michael Vasser	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Laura Gieraltowski	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Allie Busbee	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Amanda Conrad	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Jennifer Freiman	Food Safety and Inspection Service (FSIS)				
Doug Noveroske	Food Safety and Inspection Service (FSIS)				

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

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10. Resource Summary:		
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Updated by FDA 2/2011

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/3/2025 Date To: 9/11/2025 Time From: 3:00 PM Time To: 3:00 PM

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period 1: As of 9/3/2025, this cluster consists of 38 isolates, with 13 food isolates and 25 clinical isolates from (b) (5) states, including (b) (5) Isolation dates range from 8/16/2013 to 5/21/2025, with 5 illnesses with onsets in 2025. Cases are 44% female and range in age from 0 to 97, with a median age of 72 years. 95% of cases have been hospitalized; one death has been reported; and there have been two pregnancy associated cases associated with this outbreak. On 6/5/2025, CDC and FDA reopened the investigation of Listeria monocytogenes (Lm) cluster, (b)(5) . This is the third time this cluster has been investigated. This cluster was previously investigated in (b)(5) . Both times the incident was closed with an unknown vehicle. Exposure data is limited and does not indicate a strong signal for any specific food ((b) (5) or otherwise). CDCs sequencing analysis indicates all isolates in the cluster are related within 0-33 SNPs (average 17) by WGS in NCBI and 0-37 alleles by wgMLST. Clinical isolates are related within 0-29 alleles by wgMLST. Included in NCBI tree are 13 food isolates collected since 2016. On 7/16/2025, CDC, CORE Signals, and (b) (5) state partners met to discuss the investigation and determine next steps. During the call, it was decided the (b) (5) Department of Agriculture (b) (5) would follow up with (b)(5) firms associated with case exposure information. On 7/31/2025, CORE Signals provided a sampling request to (b) (5) (via CDC) for (b) (4)). Case exposure information from a (b) (5) case who dined at (b) (4)), provided an opportunity to follow-up at the restaurant to determine supplier information. (b) (5) noted the restaurant made several dishes with (b) (5) . The supplier for (b) (4) was noted as (b) (4) . Information obtained from USDA FSIS regarding the 2024 (b) (5) sample indicated (b) (5) were sourced from (b) (4) . On 8/4/2025, PDA collected records

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/3/2025 Date To: 9/11/2025 Time From: 3:00 PM Time To: 3:00 PM

and (b)(5) (b) (5) samples at (b) (4). On 8/5/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4). On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for Lm: (b) (4), (b) (4), and (b) (4). (b)(5) of the (b) (5) product samples match the outbreak strain; (b) (5) and (b) (5). On 8/21/25, (b) (5) notified both firms of the positive Lm findings. (b) (5) requested invoices and records to show where the products were purchased, for the firms to file an RFR with FDA, and for the firms to notify their suppliers of the results. On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) (b) (5) (b) (5)) matched the outbreak strain by WGS. On 8/29/2025, CORE facilitated a call with HFP, OII and (b) (5) Department of Agriculture to discuss firm notification of (b) (5) positive (b) (5) samples collected at (b) (4) The (b) (5) were supplied by (b) (4)). An OII Division Recall Coordinator (DRC) notified and shared sample results with (b) (4) on 8/29/2025. On 9/2/2025, OII HFI East 1 DRC provided COA's from (b)(4) showing (b) (5) were supplied by The (b) (4)

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
☐	ICS 204	☐	Weather Forecast/Tides/Currents
☐	ICS 205		
☐	ICS 206		
☐	ICS 208		

Other Attachments:
☐ _____
☐ _____
☐ _____
☐ _____

7. Prepared by: Name: Johnson Nsubuga Position/Title: Planning Signature: _____

8. Approved by Incident Commander: Name: Monica Mcclure Signature:

ICS 202	IAP Page _____	Date/Time: 9/3/2025 3:20 PM EDT

Updated by FDA 2/2011

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/12/2025 Date To: 9/25/2025 Time From: 3:00 PM Time To: 3:00 PM

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period 1: As of 9/3/2025, this cluster consists of 38 isolates, with 13 food isolates and 25 clinical isolates from (b)(5) states, including (b) (5) Isolation dates range from 8/16/2013 to 5/21/2025, with 5 illnesses with onsets in 2025. Cases are 44% female and range in age from 0 to 97, with a median age of 72 years. 95% of cases have been hospitalized; one death has been reported; and there have been two pregnancy associated cases associated with this outbreak. On 6/5/2025, CDC and FDA reopened the investigation of Listeria monocytogenes (Lm) cluster, (b) (5) This is the third time this cluster has been investigated. This cluster was previously investigated in (b)(5). Both times the incident was closed with an unknown vehicle. Exposure data is limited and does not indicate a strong signal for any specific food ((b) (5) or otherwise). CDCs sequencing analysis indicates all isolates in the cluster are related within 0-33 SNPs (average 17) by WGS in NCBI and 0-37 alleles by wgMLST. Clinical isolates are related within 0-29 alleles by wgMLST. Included in NCBI tree are 13 food isolates collected since 2016. On 7/16/2025, CDC, CORE Signals, and (b) (5) state partners met to discuss the investigation and determine next steps. During the call, it was decided the (b) (5) Department of Agriculture (b) (5)) would follow up with (b)(5) firms associated with case exposure information. On 7/31/2025, CORE Signals provided a sampling request to (b) (5) (via CDC) for (b) (4)). Case exposure information from a (b) (5) case who dined at (b) (4)), provided an opportunity to follow-up at the restaurant to determine supplier information. (b) (4) noted the restaurant made several dishes with (b) (5). The supplier for (b) (4) was noted as (b) (4). Information obtained from USDA FSIS regarding the 2024 (b) (5) sample indicated (b) (5) were sourced from (b) (4). On 8/4/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4). On 8/5/2025, (b) (5) collected records and (b) (5) samples at (b) (4). On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for Lm: (b) (4) . (b)(5) of the (b) (5) product samples match the outbreak strain; (b) (5) and (b) (5). On 8/21/25, (b) (5) notified both firms of the positive Lm findings. (b) (5) requested invoices and records to show where the products were purchased, for the firms to file an RFR with FDA, and for the firms to notify

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/12/2025 Date To: 9/25/2025 Time From: 3:00 PM Time To: 3:00 PM

their suppliers of the results. On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) (b) (5)) matched the outbreak strain by WGS. On 8/29/2025, CORE facilitated a call with HFP, OII and PA Department of Agriculture to discuss firm notification of (b)(5) positive (b) (5) samples collected at (b) (4)). The (b) (5) were supplied by (b) (4) An OII Division Recall Coordinator (DRC) notified and shared sample results with (b) (4) on 8/29/2025. On 9/2/2025, OII HFI East 1 DRC provided COA's from (b) (4) showing (b) (5) were supplied by The (b) (4) .

Operational Period 2: As of 9/12/2025, there are 25 clinical isolates from (b)(5) states, including (b) (5) . On 9/3/2025, OII HF East 1 DRC provided additional records and information from (b) (4) . verifying (b) (5) were supplied by (b) (4) . (b) (4) also provided a customer list showing (b) (5) were supplied to retail establishments. On 9/3/2025, OII East 1 DRC provided (b) (4) press release. The recall was posted on the FDA website on 9/4/2025. On 9/4/2025, CRT1 issued an assignment to OER and PHI FERC (eNSpect #267791; FACTS Assignment ID: 12452678; Operation ID 333988; External op ID 324038) for traceback records and information collection at (b) (4) ; (b) (4) . On 9/4/2025, CRT1 issued an assignment to OER and NWE FERC (eNSpect #267787; FACTS Assignment ID 1245270; Op ID 334192; External Op ID 324025) for traceback records and information collection at (b) (4) On 9/5/2025, PHI FERC provided traceback records related to the positive sample collected by (b)(5) state partners. On 9/8/2025, NWE FERC provided traceback records from (b) (4) , this is related to a case that reported consuming (b) (5) from this location in 2024. (b) (5) were sourced from (b) (5) On 9/8/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. (b) (5) were sourced from (b) (5) and (b) (5) . On 9/8/2025, CMS Case 716238 was created to add (b) (4) and (b) (4) to the Yellow List of IB 99-B54. This was removed on 9/9/2025 due to pending regulatory actions. On 9/9/2025, CORE requested PHI FERC collect additional traceback information for (b) (5) from (b) (4) , related to the 2024 (b) (5) sample ingredients (PHI FERC (eNSpect #267791). On 9/10/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. The (b) (5) were sourced from (b) (4) in Egypt. On 9/11/2025, CMS Case 716521 was created to add (b) (4) , to the Yellow List of IB 99-B54.

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	☐ _____	
☐ ICS 205		☐ _____	
☐ ICS 206		☐ _____	
☐ ICS 208		☐ _____	

7. Prepared by: Name: Johnson Nsubuga Position/Title: Planning Signature: _____

8. Approved by Incident Commander: Name: Monica Mcclure Signature:

ICS 202	IAP Page _____	Date/Time: 9/12/2025 1:43 PM EDT

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/29/2025 Date To: 10/15/2025 Time From: 3:00 PM Time To: 3:00 PM

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period 1: As of 9/3/2025, this cluster consists of 38 isolates, with 13 food isolates and 25 clinical isolates from (b)(5) states, including (b) (5)
Isolation dates range from 8/16/2013 to 5/21/2025, with 5 illnesses with onsets in 2025. Cases are 44% female and range in age from 0 to 97, with a median age of 72 years. 95% of cases have been hospitalized; one death has been reported; and there have been two pregnancy associated cases associated with this outbreak. On 6/5/2025, CDC and FDA reopened the investigation of Listeria monocytogenes (Lm) cluster, (b) (5) . This is the third time this cluster has been investigated. This cluster was previously investigated in (b)(5) . Both times the incident was closed with an unknown vehicle. Exposure data is limited and does not indicate a strong signal for any specific food ((b) (5) or otherwise). CDCs sequencing analysis indicates all isolates in the cluster are related within 0-33 SNPs (average 17) by WGS in NCBI and 0-37 alleles by wgMLST. Clinical isolates are related within 0-29 alleles by wgMLST. Included in NCBI tree are 13 food isolates collected since 2016. On 7/16/2025, CDC, CORE Signals, and (b) (5) state partners met to discuss the investigation and determine next steps. During the call, it was decided the [redacted] Department of Agriculture (PDA) would follow up with (b)(5) firms associated with case exposure information. On 7/31/2025, CORE Signals provided a sampling request to (b) (5) (via CDC) for (b) (4) . Case exposure information from a [redacted] case who dined at (b) (4) provided an opportunity to follow-up at the restaurant to determine supplier information. [redacted] noted the restaurant made several dishes with (b) (5) . The supplier for (b) (4) was noted as (b) (4) . Information obtained from USDA FSIS regarding the 2024 (b) (5) sample indicated (b) (5) were sourced from (b) (4) . On 8/4/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/5/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for Lm: (b) (4)

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/29/2025 Date To: 10/15/2025 Time From: 3:00 PM Time To: 3:00 PM

(b) (4) (b)(5) of the (b) (5) product samples match the outbreak strain; (b) (5) and (b) (5). On 8/21/25, (b) (5) notified both firms of the positive Lm findings. (b) (5) requested invoices and records to show where the products were purchased, for the firms to file an RFR with FDA, and for the firms to notify their suppliers of the results. On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) (b) (5)) matched the outbreak strain by WGS. On 8/29/2025, CORE facilitated a call with HFP, OII and (b) (5) Department of Agriculture to discuss firm notification of (b) (5) positive (b) (5) samples collected at (b) (4). The (b) (5) were supplied by (b) (4)). An OII Division Recall Coordinator (DRC) notified and shared sample results with (b) (4) on 8/29/2025. On 9/2/2025, OII HFI East 1 DRC provided COA's from (b) (4) showing (b) (5) were supplied by The (b) (4).

Operational Period 2: As of 9/12/2025, there are 25 clinical isolates from (b)(5) states, including (b) (5). On 9/3/2025, OII HF East 1 DRC provided additional records and information from (b) (4). verifying (b) (5) were supplied by (b) (4). (b) (4) also provided a customer list showing (b) (5) were supplied to retail establishments. On 9/3/2025, OII East 1 DRC provided (b) (4) press release. The recall was posted on the FDA website on 9/4/2025. On 9/4/2025, CRT1 issued an assignment to OER and PHI FERC (eNSpect #267791; FACTS Assignment ID: 12452678; Operation ID 333988; External op ID 324038) for traceback records and information collection at (b) (4); (b) (4). On 9/4/2025, CRT1 issued an assignment to OER and NWE FERC (eNSpect #267787; FACTS Assignment ID 1245270; Op ID 334192; External Op ID 324025) for traceback records and information collection at (b) (4). On 9/5/2025, PHI FERC provided traceback records related to the positive sample collected by (b) (5) state partners. On 9/8/2025, NWE FERC provided traceback records from (b) (4), this is related to a case that reported consuming (b) (5) from this location in 2024. (b) (5) were sourced from (b) (5). On 9/8/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. (b) (5) were sourced from (b) (5) and (b) (5) from (b) (5). On 9/8/2025, CMS Case 716238 was created to add (b) (4) and (b) (4) to the Yellow List of IB 99-B54. This was removed on 9/9/2025 due to pending regulatory actions. On 9/9/2025, CORE requested PHI FERC collect additional traceback information for (b) (5) from (b) (4), related to the 2024 (b) (5) sample ingredients (PHI FERC (eNSpect #267791). On 9/10/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. The (b) (5) were sourced from (b) (4). On 9/11/2025, CMS Case 716521 was created to add (b) (4), to the Yellow List of IB 99-B54.

Operational Period 3: As of 9/29/2025, there are 26 clinical isolates from (b)(5) states, including (b) (4). On 9/16/2025, PHI FERC provided traceback records from (b) (4)), for (b) (5) supplied to (b) (4), the POS a (b) (5) case reported eating at prior to illness. Based on the records, we could not determine if (b) (4) brand (b) (5) would have been served to the case in 2024. On 9/16/2025, CORE RT1 held a SPTC with incident partners to discuss firm calls with (b) (4). It was decided to proceed with holding a firm call with (b) (4) to share WGS analysis. On 9/16/2025, CDC notified CORE of a new (b) (5) case with an isolation date of 8/31/2025. On 9/16/2025, HFI East 1 DRC reported that the division witnessed destruction of remaining recalled (b) (5) at (b) (4) on 9/11/2025. On 9/18/2025, CORE RT1 held an (b) (4)) pre-call to discuss the information to be shared with the firm during the call. On 9/18/2025, HFI EAST 1 DRC provided CORE with (b) (4) report. On 9/19/2025, CORE shared the WGS report with HFI East 1 DRC to share with (b) (4). On 9/24/2025, CORE facilitated a firm call with (b) (4), FDA, CDC, and (b) (5) Department of Agriculture. The firm invited a consulting firm (b) (4) and their importer (b) (4) to the meeting. This was a call to share and answer questions about the WGS analysis of the two product samples collected by (b) (5) Dep of Ag which matched the outbreak strain. The recall is ongoing and no additional requests were made to (b) (4). On 9/24/2025, CORE facilitated a pre-call to a firm call with (b) (4). On 9/25/2025, CORE facilitated a firm call with (b) (4). On 9/25/2025, (b) (4) provided documents and information regarding their production and cleaning and sanitization. CORE shared the records with HFP and OII incident partners. On 9/26/2025, HFP/OCE/EIB notified CORE that a recommendation to add (b) (4) to Import Alert #99-23 had been forwarded to OII DIO for processing. The case (CMS Case: 716733) is pending review.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 9/29/2025 Date To: 10/15/2025 Time From: 3:00 PM Time To: 3:00 PM

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 _____

7. Prepared by: Name: Johnson Nsubuga Position/Title: Planning Signature: _____

8. Approved by Incident Commander: Name: Monica Mcclure Signature:

ICS 202	IAP Page _____	Date/Time: 9/29/2025 12:58 PM EDT

Updated by FDA 2/2011

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 10/16/2025 Date To: 11/13/2025 Time From: 3:00 PM Time To: 5:00 PM

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period 1: As of 9/3/2025, this cluster consists of 38 isolates, with 13 food isolates and 25 clinical isolates from (b)(5) states, including (b) (5) Isolation dates range from 8/16/2013 to 5/21/2025, with 5 illnesses with onsets in 2025. Cases are 44% female and range in age from 0 to 97, with a median age of 72 years. 95% of cases have been hospitalized; one death has been reported; and there have been two pregnancy associated cases associated with this outbreak. On 6/5/2025, CDC and FDA reopened the investigation of Listeria monocytogenes (Lm) cluster, (b) (5) . This is the third time this cluster has been investigated. This cluster was previously investigated in (b)(5) . Both times the incident was closed with an unknown vehicle. Exposure data is limited and does not indicate a strong signal for any specific food ((b) (5) or otherwise). CDCs sequencing analysis indicates all isolates in the cluster are related within 0-33 SNPs (average 17) by WGS in NCBI and 0-37 alleles by wgMLST. Clinical isolates are related within 0-29 alleles by wgMLST. Included in NCBI tree are 13 food isolates collected since 2016. On 7/16/2025, CDC, CORE Signals, and (b) (5) state partners met to discuss the investigation and determine next steps. During the call, it was decided the (b) (5) Department of Agriculture ((b) (5)) would follow up with (b)(5) firms associated with case exposure information. On 7/31/2025, CORE Signals provided a sampling request to (b) (5) (via CDC) for (b) (4) . Case exposure information from a (b) (5) case who dined at (b) (4)), provided an opportunity to follow-up at the restaurant to determine supplier information. (b) (5) noted the restaurant made several dishes with (b) (5) . The supplier for (b) (4) was noted as (b) (4) . Information obtained from USDA FSIS regarding the 2024 (b) (5) sample indicated (b) (5) were sourced from (b) (4) . On 8/4/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/5/2025, (b) (5) collected records and (b)(5) (b) (5) samples at (b) (4) . On 8/18/2025, (b) (5) notified CDC and FDA that the following samples tested positive for Lm: (b) (4) . (b)(5) of the (b) (5) product samples match the outbreak strain; (b) (5) and (b) (5) . On 8/21/25, (b) (5) notified both firms of the positive Lm findings. (b) (5) requested invoices and records to show where the products were purchased, for the firms to file an RFR with FDA, and for the firms to notify their suppliers of the results. On 8/28/2025, CDC notified FDA that the samples collected from (b) (4) (b) (5)) matched the outbreak strain by WGS. On 8/29/2025, CORE facilitated a call with HFP, OII and (b) (5) Department of Agriculture to discuss firm notification of (b) (5) positive (b) (5) e samples collected at (b) (4)). The (b) (5) were supplied by (b) (4)). An OII Division Recall Coordinator (DRC) notified and shared sample results with (b) (4) on 8/29/2025. On 9/2/2025, OII HFI East 1 DRC provided COA's from (b) (4) showing (b) (5) were supplied by The (b) (4) .

Operational Period 2: As of 9/12/2025, there are 25 clinical isolates from (b)(5) states, including (b) (5) On 9/3/2025, OII HF East 1 DRC provided additional records and information from (b) (4) . verifying (b) (5) were supplied by (b) (4) . (b) (4) also provided a customer list showing (b) (5) were supplied to retail establishments. On 9/3/2025, OII East 1 DRC provided (b) (4) press release. The recall was posted on the FDA website on 9/4/2025. On 9/4/2025, CRT1 issued an assignment to

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Listeria monocytogenes/(b) (5) (suspect)/Jun 2025	2. Operational Period: Date From: 10/16/2025 Date To: 11/13/2025 Time From: 3:00 PM Time To: 5:00 PM

OER and PHI FERC (eNSpect #267791; FACTS Assignment ID: 12452678; Operation ID 333988; External op ID 324038) for traceback records and information collection at (b) (4) . On 9/4/2025, CRT1 issued an assignment to OER and NWE FERC (eNSpect #267787; FACTS Assignment ID 1245270; Op ID 334192; External Op ID 324025) for traceback records and information collection at (b) (4) . On 9/5/2025, PHI FERC provided traceback records related to the positive sample collected by (b) (5) state partners. On 9/8/2025, NWE FERC provided traceback records from (b) (4) , this is related to a case that reported consuming (b) (5) from this location in 2024. (b) (5) were sourced from (b) (5). On 9/8/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. (b) (5) were sourced from (b) (5) and (b) (5) from (b) (5). On 9/8/2025, CMS Case 716238 was created to add (b) (4) and (b) (4) to the Yellow List of IB 99-B54. This was removed on 9/9/2025 due to pending regulatory actions. On 9/9/2025, CORE requested PHI FERC collect additional traceback information for (b) (5) from (b) (4) , related to the 2024 (b) (5) sample ingredients (PHI FERC (eNSpect #267791). On 9/10/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) and (b) (5) used to manufacture (b) (5) at (b) (4) in 2024. The (b) (5) were sourced from (b) (4) . On 9/11/2025, CMS Case 716521 was created to add (b) (4) , to the Yellow List of IB 99-B54.

Operational Period 3: As of 9/29/2025, there are 26 clinical isolates from (b)(5) states, including (b) (5) . On 9/16/2025, PHI FERC provided traceback records from (b) (4) for (b) (5) supplied to (b) (4) , the POS a (b) (5) case reported eating at prior to illness. Based on the records, we could not determine if (b) (4) brand (b) (5) would have been served to the case in 2024. On 9/16/2025, CORE RT1 held a SPTC with incident partners to discuss firm calls with (b) (4) . It was decided to proceed with holding a firm call with (b) (4) to share WGS analysis. On 9/16/2025, CDC notified CORE of a new (b) (5) case with an isolation date of 8/31/2025. On 9/16/2025, HFI East 1 DRC reported that the division witnessed destruction of remaining recalled (b) (5) at (b) (4) on 9/11/2025. On 9/18/2025, CORE RT1 held an (b) (4)) pre-call to discuss the information to be shared with the firm during the call. On 9/18/2025, HFI EAST 1 DRC provided CORE with (b) (5) CAPA report. On 9/19/2025, CORE shared the WGS report with HFI East 1 DRC to share with (b) (4). On 9/24/2025, CORE facilitated a firm call with (b) (4) FDA, CDC, and (b) (5) Department of Agriculture. The firm invited a consulting firm (b) (4)) and their importer (b) (4) to the meeting. This was a call to share and answer questions about the WGS analysis of the two product samples collected by (b) (5) Dep of Ag which matched the outbreak strain. The recall is ongoing and no additional requests were made to (b) (4) . On 9/24/2025, CORE facilitated a pre-call to a firm call with (b) (4). On 9/25/2025, CORE facilitated a firm call with (b) (4) . On 9/25/2025, (b) (4) provided documents and information regarding their production and cleaning and sanitization. CORE shared the records with HFP and OII incident partners. On 9/26/2025, HFP/OCE/EIB notified CORE that a recommendation to add (b) (4) to Import Alert #99-23 had been forwarded to OII DIO for processing. The case (CMS Case: 716733) is pending review.

Operational Period 4: As of 10/xx/2025, there are 25 clinical isolates from (b)(5) states, including (b) (5) . On 9/29/2025, DIO added (b)(5) FEI's (b)(5) manufacturing facility and headquarters address) to the red list screening criteria of IA #99-23. (b)(5) (b) (5) products were included in the IA. On 9/29/2025, CORE requested DIO add (b) (4) manufacturing facility), (b) (4) , to the Yellow List of IB 99-B54. On 9/29/2025, CORE CRT1 issued an assignment to OER and PHI FERC (eNSpect #270047; FACTS Op ID 346908; External Op ID 329446) for traceback records and information collection at (b) (4) . On 9/30/2025, CORE RT1 held a SPTC with HFP and OII incident partners to discuss next steps regarding additional (b) (5) (b) (4) imported to the US that contained a common lot of (b) (5) also used to manufacture products that tested positive for Lm. On 9/30/2025, PHI FERC provided records and information from (b) (4) showing the (b) (5) manufactured by (b) (4), using the common lot of (b) (5) also used to manufacture products that tested positive for Lm, were (b) (4) brand and were shipped directly to (b) (4) on 6/22/2025 and 6/28/2025. On 10/1/2025, DIO add (b)(4) (b) (4) ((b) (4) manufacturing facility), (b) (4) , to the Yellow List of IB 99-B54. On 10/1/2025, CORE RT1 submitted questions to (b) (4) FERC for (b) (4). The questions included a request for information related to their processing, cleaning and sanitizing, and labeled cooking instructions of (b) (5) .

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

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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 _____

7. Prepared by: Name: Monica Mcclure Position/Title: Planning Signature: _____

8. Approved by Incident Commander: Name: Monica Mcclure Signature:

ICS 202	**IAP Page** _____	Date/Time: 10/14/2025 10:19 AM EDT

Updated by FDA 2/2011