

**Listeria monocytogenes/Ice cream (suspect)/ML/May 2017**

**EON # 315180**

**Incident Summary Report**

**9/28/2017**

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## **ABSTRACT**

On 5/12/17, after receiving notification from CDC, FDA CORE Signals began evaluating a multistate cluster of *Listeria monocytogenes* illnesses. Epidemiologic information collected indicated ice cream as the suspect vehicle. Based on exposure and brand information reported by case patients, potential common ice cream manufacturers were identified. On 5/24/17, FDA Division of Human and Animal Food 2 West initiated inspections at the North and South facilities of (b)(4). On 6/13/2017 and 7/10/2017, FDA Division of Human and Animal Food 1 East initiated an inspection at (b)(4). On 7/17/2017, FDA Division of Human and Animal Food 2 East initiated an inspection at (b)(4). On 9/5/17, FDA Division of Human and Animal Food 2 West initiated an inspection at (b)(4). The outbreak strain of *Listeria monocytogenes* was not recovered from any environmental samples or product samples collected as part of the inspections. Informational traceback was inconclusive as all ice cream brands identified by ill people could have been manufactured (b)(4). Due to the absence of additional traceback or laboratory evidence, ice cream could only be identified as the suspect vehicle of this outbreak. At the conclusion of the CORE Response phase, a total of 11 cases (with 10 hospitalizations including 2 deaths attributed to listeriosis) in 9 states were associated with this outbreak.

## **SIGNALS AND SURVEILLANCE ACTIVITIES**

On 5/12/17, CORE Signals began evaluating a cluster of *Listeria monocytogenes* (cluster code 1702MLGX6-1; PFGE pattern GX6A16.0140/GX6A12.2167) after receiving notification from CDC that ice cream was a product of interest. As of 5/16/17, there were 8 cases from 6 states [AZ (1), CO (1), GA (1), NM (1), OH (1), and TX (3)]. Isolation dates ranged from 10/24/2015 to 3/29/2017. Patients ranged in age from <1-84 years (median 45 years) and four (50%) were female. All 8 patients had been hospitalized and 1 death was reported (TX). There were 3 pregnancy-associated illnesses and all of the infants survived. Many of the cases had other underlying health conditions. All 8 clinical *L. monocytogenes* isolates were analyzed by WGS and were highly related (within 1-12 alleles). The PFGE 2-enzyme pattern combination was rare and had only been seen twice prior to this outbreak. Ice cream and/or other frozen novelty products were the leading hypothesis for the cause of illnesses based on the available epidemiologic information and ice cream production facility information.

CDC indicated that all 8 patients or a surrogate had been interviewed. Six (75%) of the eight patients reported consuming ice cream, although this was not statistically significantly higher than expected based on case-case analysis. Among the six patients who consumed ice cream, three (50%) of the six patients also reported eating ice cream bars/novelty. Specific types/flavors were available for four patients, two reported (b)(4) (Neapolitan and chocolate/vanilla) and two reported (b)(4) (strawberry and novelty “crunch” bar/ice cream sandwiches). Two additional cases reported ice cream from (b)(4) with

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unknown brand information. The CO patient reported “don’t know” during interviews because she was unsure about the last time she had ice cream; however, she did report that it would have been Neapolitan ice cream sandwiches and Neapolitan ice cream purchased at (b)(4). A shopper card request was submitted for the (b)(4) shopper to obtain brand/type information. Other food vehicles were examined but patients reported different types or brands or unknown brand information and therefore seemed to be less likely sources. Case-patients also reported (b)(4) brands and (b)(4) ice cream products, although cases reporting these brands also consumed the other brands of interest.

Four (67%) of the six patients specifically reported (b)(4) ice cream products. Additionally, two patients purchased ice cream products (brands unknown) from (b)(4) ice cream products. The exposure information combined with the firm’s manufacturing history suggests that the incident could potentially be linked to a single ice cream manufacturing facility.

Firm research compiled by CORE Signals indicated (b)(4) operates a (b)(4)

(b)(4)

FDA inspected the facility on 3/8/17. No objectionable conditions were noted, and environmental swabs collected were negative for *Listeria monocytogenes* and *Salmonella*. According to the EIR, the firm has approximately (b)(4) products. This location includes a (b)(4) sq. foot production facility, as well as (b)(4) facilities. The facility produces approximately (b)(4) of ice cream (b)(4). The firm conducts routine environmental monitoring and product testing. CORE Signals shared the available manufacturing processes and environmental monitoring program information with CFSAN SMEs for evaluation. Some of the firm’s top customers include: (b)(4). The facility produces ice cream products under numerous brand names. In 2016, the firm (b)(4) ice cream related to *L. monocytogenes* in cookie dough from a 3rd party supplier; the firm was able to recover 97.9% of this product in response to their recall.

(b)(4)

FDA inspected the facility in March 2016. No FDA Form 483 was issued and no samples were collected. The EIR indicates that the firm conducts environmental testing for *Listeria* and *Salmonella*. The firm informed investigators that they have not had a *Listeria* positive on any food contact surfaces. Previous inspectional history indicates the facility manufactures ice cream and frozen novelties under numerous brand names. Products manufactured by the firm at the (b)(4) are sent to the (b)(4) to be distributed in interstate commerce.

(b)(4) brands of ice cream products appeared to be manufactured primarily at (b)(4) own ice cream manufacturing facility in (b)(4). (b)(4)

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((b)(4)) manufactured (b)(4) ice cream products, and information collected during a 2016 inspection also described (b)(4) products.

On 5/17/17, CORE Signals transferred this incident to CORE Response Team 3 for further coordination. The rationale for transfer is as follows: 1) This is a multistate outbreak of *Listeria monocytogenes*, with an FDA-regulated product, ice cream, identified as the suspect vehicle. The outbreak involves severe illnesses over an extended period of time, including pregnancy-associated cases, 8/8 case-patients have been hospitalized, and there has been 1 death. 2) Additional coordination is needed related to (b)(4)

3) Product actions including (b)(4)  
4) This incident has a high level of FDA interest due to the historical multistate outbreak of listeriosis in 2015 linked to ice cream products. 5) Communications relative to this outbreak may be needed.

## **RESPONSE**

### **Epidemiology**

A confirmed case was defined as an ill person infected with *Listeria monocytogenes* matching the PFGE pattern GX6A16.0140/GX6A12.2167, is highly related by whole genome sequencing and with an isolation date ranging from 10/24/15 – 8/11/17.

As of 9/18/17, eleven cases infected with the outbreak strain of *Listeria monocytogenes* were reported from nine states: AL, AR, AZ, CO, GA, NM, OH, OK and TX (3). Patients range in age from <1-104 years (median 61); seven (63%) were female. Ten patients were hospitalized and two patients died. Both deaths were attributable to listeriosis. Three cases were pregnancy associated. Nine out of ten cases reported consuming ice-cream and 5 (50%) report Neapolitan flavor. All clinical *Listeria monocytogenes* isolates (including two suspect cases from 2011) were analyzed by whole genome sequencing and were found to be closely related genetically to one another by a median of 4 alleles (range 0-12).

The CDC line list is available in the Attachments Section in EON.

### **Laboratory**

A total of 72 samples were collected by FDA and state partners during the response to this incident. FDA collected 11 samples and 61 state samples were collected from retail and consumers' homes. Of these samples, 5 FDA samples were positive for *Listeria monocytogenes*. The outbreak strain of *Listeria monocytogenes* was not recovered from any of the FDA positive samples.

### **FDA Samples**

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Office of Regulatory Affairs Human and Animal Foods Division 2 West (HAF 2W) collected 4 of the FDA samples, the Office of Regulatory Affairs Human and Animal Foods Division 1 East (HAF 1E) collected 6 samples and the Office of Regulatory Affairs Human and Animal Foods Division 2 East (HAF 2E) collected 1 sample.

On 5/24/17, HAF 2W collected 1 sample (FACTS# 1009759) consisting of 100 environmental swabs from (b)(4) Facility) and on 5/25/17, they collected 2 samples (FACTS#1009760 and #1009761) consisting of 102 and 5 environmental swabs, respectively from (b)(4) Facility). The samples were analyzed by Arkansas Laboratory (ARKL) and were negative for *Listeria monocytogenes*.

On 6/13/17, HAF 1E collected 1 sample (FACTS#983463) consisting of 100 environmental swabs from (b)(4). The sample was analyzed by Northeast Food and Feed Laboratory (NFFL) and on 6/21/17, 3 swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 5 swabs.

On 6/14/17, HAF 1E collected 1 sample (FACTS#983464) consisting of 101 environmental swabs from (b)(4). The sample was analyzed by NFFL and 12 swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 11 swabs, *Enterococcus faecalis* was detected in 2 swabs and *Lactococcus garvieae* was detected in 1 swab.

On 6/15/17, HAF 1E collected 1 sample (FACTS #983465) consisting 58 environmental swabs from (b)(4). The sample was analyzed by NFFL and 3 swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 3 swabs.

On 7/10/17, HAF 1E collected 1 sample (FACTS # 1004832) consisting of 100 environmental swabs from (b)(4). The sample was analyzed by NFFL and 3 swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 5 swabs.

On 7/11/17, HAF 1E collected 1 sample (FACTS # 1004833) consisting of 26 environmental swabs from (b)(4). The sample was analyzed by NFFL and no *Listeria monocytogenes* was detected. *Listeria innocua* was detected in 1 swab.

On 7/13/17, HAF 1E collected 1 sample (FACTS # 990451) consisting of 10 unopened boxes of 12 individually wrapped ice cream sandwiches from (b)(4). The sample was analyzed by NFFL and no *Listeria monocytogenes* was detected.

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On 7/17/17, HAF 2E collected 1 sample (FACTS #962008) consisting of 127 environmental swabs from (b)(4). The sample was analyzed by NFFL and 2 swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 2 swabs.

On 8/1/17, CFSAN Office of Analytics and Outreach provided the WGS analysis report for the 23 *Listeria monocytogenes* isolates obtained from environmental swab samples FACTS # 983463, 983464, 983465, 962008, and 1004832. The isolates were not closely related to any other food, environmental, or clinical isolate in the database.

On 9/6/17, HAF 2W collected 1 sample (FACTS# 1017099) consisting of 145 environmental swabs from (b)(4). The samples were analyzed by Arkansas Laboratory (ARKL) and no *Listeria monocytogenes* was detected in 143 swabs. *Listeria innocua* was detected in 2 swabs.

#### State Samples

State partners in Alabama, Colorado, Georgia, New York, Ohio, and Texas collected a total of 61 retail and consumer samples. All product samples collected by state partners were negative for *Listeria monocytogenes*. One sample of (b)(4) Neapolitan ice cream collected by the Alabama Department of Health was reported positive for *Microbacterium trichothecenolyticum*.

Additional details on state samples can be found in the attachments section of EON.

#### **Traceback**

Due to the lack of lot information at the consumer level, point of service clusters, and exposure dates, the scope of the informational traceback could not be narrowed and therefore, no regulatory traceback was conducted.

A list of ice cream manufacturers was collected, by the appropriate FDA Divisions, from (b)(4) corporate headquarters. Dates for these manufacturer lists ranged from approximately October 2015 through June 2017. Customer lists were collected from (b)(4) manufacturers of interest, (b)(4) to describe distribution patterns.

(b)(4) manufacturers of interest, (b)(4) manufacture all the ice cream brands of interest mentioned by case patients. However, without confirmed exposure information and verification by point of service locations of product availability during the timeframe of interest, no specific conclusions can be drawn from the informational traceback.

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## **Establishment Inspections and Investigations**

### ORA HAF Division 2W (Kansas District Office)

On 5/22/2017, CORE issued an assignment (FACTS# 11742788) to HAF 2W for an inspection, record collection, and environmental sampling at (b)(4). The inspections included both the (b)(4) facilities and were initiated on 5/24/2017 and 5/25/2017, respectively. The investigation was initiated based on 6 out of 6 case patients reporting exposure to an ice cream product that could have been manufactured by (b)(4). Three environmental samples, consisting of a total of 207 swabs, were collected from the facilities. All environmental samples were negative for *Listeria monocytogenes*. The inspection was closed out on 6/7/2017 and a FDA Form 483 was issued for the (b)(4) facility. The FDA Form 483 is available in the Attachments Section in EON.

On 8/31/17, CORE issued an assignment (FACTS #11767807) to HAF 2W for record collection, inspection and environmental sampling at (b)(4). The inspection was initiated on 9/5/17. One environmental sample, consisting of 145 swabs, was collected on 9/6/17. No *Listeria monocytogenes* was detected in 143 swabs. *Listeria innocua* was detected in 2 swabs. The inspection was closed out on 9/7/2017 and a FDA Form 483 was not issued.

### ORA HAF Division 1E (New York District Office):

On 6/9/17, CORE issued an assignment (FACTS# 11747218) to HAF 1E for an inspection, record collection, and environmental sampling at (b)(4). The inspection was initiated on 06/13/2017 as a joint inspection between New York District Office and the New York Department of Agriculture and Markets (NYSDAM). The investigation was initiated based on 6 out of 6 case patients reporting exposure to an ice cream product that could have been manufactured by (b)(4). Three environmental samples, consisting of a total of 259 swabs, were collected from the facility. Six swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 19 swabs. *Enterococcus faecalis* was detected in 2 swabs and *Lactococcus garvieae* was detected in 1 swab. All other swabs were negative. During the inspection, NYSDAM collected 20 finished product samples at the (b)(4) facility and 20 finished product samples from a (b)(4). All product samples were negative. The inspection was closed out on 7/12/2017 and a FDA Form 483 was issued. The FDA Form 483 and Establishment Inspections Report (EIR) are available in the Attachments Section in EON.

On 07/10/2017 HAF1 E initiated a Preventative Controls Inspection, record collection, and environmental sampling at (b)(4).

This inspection was initiated as a Preventative Control inspection. Record collection and environmental sampling were also conducted. Two environmental samples, consisting of 125 swabs and 1 product sample were collected from the facility. *Listeria innocua* was detected in 1

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swab and all product samples were negative. The inspection was closed on 8/11/17 and an FDA Form 483 was issued. The FDA Form 483 and Establishment Inspection Report is available in the Attachments Section in EON.

#### ORA HAF Division 2E (New Jersey District Office)

On 7/13/2017, CORE issued an assignment (FACTS# 11755493) to HAF 2E for a Preventative Control Inspection, record collection, and environmental sampling at (b)(4)

The inspection was initiated on 07/17/2017. This investigation was initiated based on findings at the (b)(4) facility. One environmental sample, consisting of 127 swabs, was collected from the facility. Two swabs were reported positive for *Listeria monocytogenes*. Additionally, *Listeria innocua* was detected in 2 swabs. The inspection was closed out on 07/20/2017 and no FDA Form 483 was issued. The Establishments Inspections Report (EIR) is available in the Attachments section of EON.

### **Product/Firm Actions/Firm Events**

There was no product and firm action associated with this incident.

### **Communications**

No public communication was issued during incident activities.

### **CONCLUSION**

Epidemiologic information identified ice cream as the suspect vehicle, although the source of the contamination was not identified through investigational activities. Environmental sampling at the facilities of three manufacturers of interest and product sampling did not yield the outbreak strain of *Listeria monocytogenes*.

### **ACKNOWLEDGEMENTS**

FDA/CORE would like to acknowledge the work of the HAF Division 2W (KAN-DO), HAF Division 2E (NWJ-DO) and HAF Division 1E (NYK-DO) during the outbreak. CORE also would like to extend thanks to the state partners that assisted in firm inspection, sample and record collection. Acknowledgements are extended to all FDA, CDC, and state partners that provided assistance and expertise throughout this investigation. Additionally, the contributions and guidance provided by subject matter experts from FDA's Center for Food Safety and Applied Nutrition and Office of Regulatory Affairs were also appreciated.

### **INCIDENT COORDINATION GROUP**

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**Listeria monocytogenes/Ice Cream (suspect)/ML/May 2017**

Date(s):

Type of Incident: CORE Response      Product Centers: CFSAN  
 Districts Involved: ATL-DO, CIN-DO,  
 DAL-DO, DEN-DO, KAN-DO, LOS-DO, NWJ-DO  
 RRT Involved: NY

Qualifier: Outbreak

Notification Source: CDC

**Description**

On 5/12/17, FDA's Coordinated Outbreak Response and Evaluation (CORE) network was notified by the Centers for Disease Control and Prevention (CDC) that ice cream was a food of interest for a cluster of cases infected by *Listeria monocytogenes*. Patients range in age from <1-84 years (median 45 years) and four (50%) are female. There were 3 pregnancy-associated illnesses and all of the infants have survived. All 8 clinical *L. monocytogenes* isolates have been analyzed by Whole Genome Sequencing and are highly related.

Ice cream and/or other frozen novelty products are the leading hypothesis for the cause of illnesses based on the available epidemiologic information combined with production facility manufacturing information. Seven (88%) of the eight patients reported consuming ice cream, and six (86%) of the seven patients specifically report (b)(4) ice cream products. (b)(4)

, (b)(4), as well as numerous other brands, suggesting the incident could be related to a single manufacturing facility. In addition to (b)(4), a second potential common manufacturer, (b)(4), has been identified and FDA is discussing follow up at this firm.

On 5/19/17, Colorado state partners collected the first ice cream retail samples of the investigation. On 5/22/2017, Colorado state partners reported the ice cream samples are negative for *Listeria*. Since then, sampling of ice cream products of interest has been done by officials from the Georgia Department of Agriculture, the Texas Department of State Health Services, Colorado Department of Public Health, and Ohio Department of Agriculture. They have collected several brands of interest from several retail stores. All completed samples have been negative for *Listeria*. Several samples from Georgia are still pending.

On 5/24/17, FDA Kansas City District Office began an investigation at (b)(4) and closed the investigation on 6/8/2017. The focus of the investigation was to collect samples of the production environment there. As the investigation began, FDA and CDC held a call with the leadership at (b)(4) in order to share epidemiological information and discuss the status of the investigation.

FDA has collected three samples consisting 207 environmental swabs from (b)(4) different production facilities at the site. All swabs are negative for *Listeria monocytogenes*.

On 6/8/17, Kansas City District Office reported that the inspection at (b)(4) was closed and a two item FDA form 483 was issued for the (b)(4) Facility.

On 5/26/17, Georgia Department of Agriculture collected (b)(4) (b)(4) Neapolitan ice-cream from (b)(4). On 6/12/17, the samples were reported negative for *Listeria* spp.

On 5/31/17, TX Department of State Health Services reported that three consumer samples of (b)(4) popsicles were negative for *Listeria* spp. On 6/5/17, TX Department of State Health Services reported that six retail ice-cream samples ((b)(4) Neapolitan and (b)(4) Neapolitan) were negative for *Listeria* spp.

On 6/1/17, Colorado Department of Public Health reported collecting (b)(4) Neapolitan ice-cream samples from (b)(4). On 6/6/17 all samples reported as negative for *Listeria* spp.

On 6/5/17, the New York District office provided (b)(4) ice cream manufacturer and distribution information. On 6/9/17, CORE issued an assignment (FACTS# 11747218) to New York District Office for the inspection and environmental sampling at (b)(4).

On 6/13/17, New York District office (NYK-DO) and New York Department of Agriculture and Markets initiated a joint inspection and sampling assignment at (b)(4) NYK-DO collected

one sample (#983463) consisting 100 environmental swab samples from (b)(4) and shipped to Northeast Regional Laboratory for analysis.

On 6/15/17, NYK-DO reported that 20 product samples collected by New York Department of Agriculture and Markets during the inspection of (b)(4) . were negative for *Listeria* spp.

On 6/16/17, Sample # 983463 out of 100 sub samples individually analyzed; 8 sub samples reported *Listeria* spp. CRO. On 6/21/17, out of the 8 CRO sub samples, 3 sub samples were reported positive for *Listeria* monocytogenes.

On 6/17/17, Sample # 983464 out of 101 sub samples individually analyzed; 23 sub sample reported as CRO for *Listeria* spp. On 6/22/17, out of the 23 CRO sub samples, 9 sub samples were reported positive for *Listeria* monocytogenes. On 6/23/17, three additional sub samples were reported positive for *Listeria* monocytogenes.

On 6/18/17, Sample # 983465 out of 58 sub samples individually analyzed; 7 sub samples reported as CRO for *Listeria* spp. On 6/23/17, out of the 7 CRO sub samples, 3 sub samples were reported positive for *Listeria* monocytogenes.

On 6/19/17, NYK-DO reported that New York Department of Agriculture and Markets collected 20 finished product samples from (b)(4) storage warehouse in (b)(4) . On 6/21/17, all the samples were reported negative for *Listeria* Spp.

On 6/28/17, Office Regulatory Affairs/Office of Regulatory Science reported the final results for the remaining sub samples of sample 983464. No additional *Listeria* monocytogenes was reported, however *Listeria* innocua was detected in eleven sub samples, *Enterococcus faecalis* was detected in two sub samples, and *Lactococcus garvieae* was detected in one subsample.

On 7/3/17, CFSAN Office of Analytics and Outreach provided WGS analysis report for the 18 *Listeria* monocytogenes isolates obtained from environmental swab samples FACTS # 983463, 983464, and 983465. The isolates are not closely related to any other food, environmental, or clinical isolate in the database.

On 8/7/17, CDC reported a new Oklahoma case. The case was a 104 y/o female with an isolation date of 7/21 /2017. The patient was hospitalized and died on 7/26/2017. Her daughter was her caretaker and reported exposure to (b)(4) Neapolitan ice cream, (b)(4) sherbet, and (b)(4) vanilla ice cream. All products were purchased from (b)(4) within the last 6 months.

Follow up at (b)(4) by OK state partners, determined that the (b)(4) Neapolitan ice cream currently available in the store is manufactured at (b)(4) facility. This (b)(4) facility also manufacturers select sizes of (b)(4) ice cream (which was reported by other case patients).

Based on informational traceback, (b)(4) could explain 3 out of 11 cases (2 (b)(4) exposures, 1 (b)(4) exposure) including one case from 2011 that is not included in the case count but is a WGS match to the clinical isolates.

On 8/28/17, CDC reported a new case from Arkansas. The case is an 83 y/o female, with an isolation date of 8 /11/2017. She did not report ice cream but does shop at (b)(4) . AR is following up to get more information and shopper card information.

#### Surveillance Information / Epidemiology

Pathogen/Contaminant:	Biological - Bacteria / <i>Listeria</i> mono.		Serotype:			
<b>Total Cases:</b>	10	<b>Confirmed:</b>		<b>Hospitalized:</b>	9	<b>Deaths:</b> 1
Location/Number of Cases:	AL(1),AZ (1), CO, (1), GA (1), NM (1), OH (1), TX (3),(OK)					

Surveillance Information / Epidemiology			
Age Range:	<1 to 84	% Female:	56
Median Age:	58	Animal/Human:	Human cases
Date of First Exposure:		Date of Last Exposure:	
Date of First Onset:		Date of Last Onset:	
Date of First Isolation:	10/24/2015	Date of Last Isolation:	06/10/2017
PFGE Pattern ID:	GX6A16. 0140\GX6A12. 2167	PulseNet Cluster ID:	1702MLGX6-1
PFGE Pattern Frequency:	Rare	Serotype Frequency:	
MLVA pattern/Frequency:		Historical Pattern Information:	The pulsed-field gel electrophoresis (PFGE) 2-enzyme pattern combination is rare and has only been seen twice prior to this outbreak.
<b>Complaint #</b>		<b>Complaint Details</b>	
Pet Food Reports?		MedWatch Reports?	

Vehicle / Product	
Product Category:	
Product Name:	Ice cream (suspect)
Product Description:	
Food Safety Code:	
Vehicle Status:	Suspected
Product Actions:	
Product Origin:	

Laboratory Information							
Total Number of Samples:	10	Number of Positive Samples:	5	Number of Pending/CRO Samples:		Number of Negative Samples:	5
Positive Sample Number	Date of Collection	Sample Source	Sample Type	Sample Collected By	Sample Analyzed By		
983463	06/13/2017	(b)(4)	Environmental	New York District office	Northeast Regional Laboratory		
Laboratory Conclusion		Sample Description					
Listeria monocytogenes type 4 detected in Sub 65, 66 and 69.		One sample containing 100 environmental sub-samples to be analyzed for Listeria. Closed controls included are subs a-f.					
Positive Sample Number	Date of Collection	Sample Source	Sample Type	Sample Collected By	Sample Analyzed By		
983464	06/14/2017	(b)(4)	Environmental	New York District office	Northeast Regional Laboratory		
Laboratory Conclusion		Sample Description					
Listeria monocytogenes type 1 detected in subs # 130, 135, 151, 157, 168, 170, 171, 180, 184, 185, 186, and 201		One sample containing 101 environmental sub-samples to be analyzed for Listeria. Closed controls included are subs g-h.					
Positive Sample Number	Date of Collection	Sample Source	Sample Type	Sample Collected By	Sample Analyzed By		



983465	06/14/2017	(b)(4)	Environmental	New York District office	Northeast Regional Laboratory
Laboratory Conclusion		Sample Description			
Listeria monocytogenes type 1 detected in Subs 207, 220, and 248.		One sample containing 58 environmental sub-samples to be analyzed for Listeria.			
Positive Sample Number	Date of Collection	Sample Source	Sample Type	Sample Collected By	Sample Analyzed By
1004832	07/10/2017	(b)(4)	Environmental	New York District office	Northeast Regional Laboratory
Laboratory Conclusion		Sample Description			
Listeria monocytogenes detected in sub # 50, 91, 95.		One sample containing 100 environmental subsamples to be analyzed for Listeria. 100 Environmental swabs taken during EI of ice cream manufacturer. Please note that swabs are numbered 1-101. Subsample #98 is void due to it breaking off the sponge stick and falling onto the ground. Controls are labeled as INV1004832, sub a, b, c			
Positive Sample Number	Date of Collection	Sample Source	Sample Type	Sample Collected By	Sample Analyzed By
962008	07/17/2017	(b)(4)	Environmental	New Jersey District Office	Northeast Regional Laboratory
Laboratory Conclusion		Sample Description			
Listeria monocytogenes type 1 detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs #18 and 75).		Listeria monocytogenes type 1 detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs #18 and 75). Listeria innocua detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs # 14 and 83). The remaining one-hundred and twenty-three (123) subs are negative for Listeria spp.			

Investigations / Inspections					
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)		(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11742788	05/24/2017	06/08 /2017	No	Record collection , inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)		(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11742788	05/24/2017	06/08 /2017	Yes	Record collection, inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)		(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11747218	06/13/2017	07/12 /2017	Yes	Record collection, inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)		(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11755493	07/17/2017	07/20 /2017	No	PC inspection and sampling	

Investigations / Inspections					
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)		(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
	07/10/2017	08/11/2017	No	PC inspection and sampling	

<b>Traceback Investigations</b>
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Communications	
FDA Communication Dates:	N/A
Firm Press Release Dates:	
Release Dates - Other Sources:	
Situation Report Dates:	

Other Information	
Signals Evaluation:	Yes
Signals Evaluation Description:	<p>The rationale for transfer of the <i>Listeria monocytogenes</i> (1702MLGX6-1)/Ice Cream (suspect)/ML/May 2017 incident is as follows: 1) This is a multistate outbreak of <i>Listeria monocytogenes</i>, with an FDA-regulated product, ice cream, identified as the suspect vehicle. The outbreak involves severe illnesses over an extended period of time, including pregnancy-associated cases, 8/8 case-patients have been hospitalized, and there has been 1 death. 2) Additional coordination is needed related to (b)(5)</p> <p>3) Product actions including (b)(5)</p> <p>4) This incident has a high level of FDA interest due to the historical multistate outbreak of listeriosis in 2015 linked to ice cream products.</p> <p>5) Communications relative to this outbreak may be needed.</p>
Response Start Date:	05/17/2017
Response End Date:	
FDA End Date:	
Post-Response Activity:	
Post-Response Activities Description:	

# **Listeria monocytogenes/Ice Cream (suspect)/ML/May 2017**

Date(s):

Type of Incident: CORE Response      Product Centers: CFSAN  
 Districts Involved: ATL-DO, CIN-DO,  
 DAL-DO, DEN-DO, KAN-DO, LOS-DO, NWJ-DO      RRT Involved: NY

Qualifier: Outbreak

Notification Source: CDC

## **Description**

On 5/12/17, after receiving notification from CDC, FDA CORE Signals began evaluating a multistate cluster of *Listeria monocytogenes* illnesses. Epidemiologic information collected indicated ice cream as the suspect vehicle. Based on exposure and brand information reported by case patients, potential common ice cream manufacturers were identified. On 5/24/17, FDA Division of Human and Animal Food 2 West initiated inspections at the (b)(4) facilities of (b)(4). On 6/13/2017 and 7/10/2017, FDA Division of Human and Animal Food 1 East initiated an inspection at (b)(4). On 7/17/2017, FDA Division of Human and Animal Food 2 East initiated an inspection at (b)(4). On 9/5/17, FDA Division of Human and Animal Food 2 West initiated an inspection at (b)(4). The outbreak strain of *Listeria monocytogenes* was not recovered from any environmental samples or product samples collected as part of the inspections. Informational traceback was inconclusive as all ice cream brands identified by ill people could have been manufactured by (b)(4). Due to the absence of additional traceback or laboratory evidence, ice cream could only be identified as the suspect vehicle of this outbreak. At the conclusion of the CORE Response phase, a total of 11 cases (with 10 hospitalizations including 2 deaths attributed to listeriosis) in 9 states were associated with this outbreak.

## **Surveillance Information / Epidemiology**

Pathogen/Contaminant:	Biological - Bacteria / Listeria mono.			Serotype:					
<b>Total Cases:</b>	11	<b>Confirmed:</b>		<b>Hospitalized:</b>	10	<b>Deaths:</b>	2		
Location/Number of Cases:		AL(1), AR(1), AZ(1), CO(1), GA(1), NM(1), OH(1), OK(1), TX (3)							
Age Range:		<1-104		% Female:		63			
Median Age:		61		Animal/Human:		Human cases			
Date of First Exposure:				Date of Last Exposure:					
Date of First Onset:				Date of Last Onset:					
Date of First Isolation:		10/24/2015		Date of Last Isolation:		08/11/2017			
PFGE Pattern ID:		GX6A16. 0140\GX6A12. 2167		PulseNet Cluster ID:		1702MLGX6-1			
PFGE Pattern Frequency:		Rare		Serotype Frequency:					
MLVA pattern/Frequency:				Historical Pattern Information:		The pulsed-field gel electrophoresis (PFGE) 2-enzyme pattern combination is rare and has only been seen twice prior to this outbreak.			
<b>Complaint #</b>		<b>Complaint Details</b>							
Pet Food Reports?				MedWatch Reports?					

## **Vehicle / Product**

Product Category:	
Product Name:	Ice cream (suspect)
Product Description:	

Vehicle / Product	
Food Safety Code:	
Vehicle Status:	Suspected
Product Actions:	
Product Origin:	

Laboratory Information											
Total Number of Samples:		11	Number of Positive Samples:		5	Number of Pending/CRO Samples:			Number of Negative Samples:		6
Positive Sample Number		Date of Collection		Sample Source		Sample Type		Sample Collected By		Sample Analyzed By	
983463		06/13/2017		(b)(4)		Environmental		New York District office		Northeast Regional Laboratory	
Laboratory Conclusion				Sample Description							
Listeria monocytogenes type 4 detected in Sub 65, 66 and 69.				One sample containing 100 environmental sub-samples to be analyzed for Listeria. Closed controls included are subs a-f.							
Positive Sample Number		Date of Collection		Sample Source		Sample Type		Sample Collected By		Sample Analyzed By	
983464		06/14/2017		(b)(4)		Environmental		New York District office		Northeast Regional Laboratory	
Laboratory Conclusion				Sample Description							
Listeria monocytogenes type 1 detected in subs # 130, 135, 151, 157, 168, 170, 171, 180, 184, 185, 186, and 201				One sample containing 101 environmental sub-samples to be analyzed for Listeria. Closed controls included are subs g-h.							
Positive Sample Number		Date of Collection		Sample Source		Sample Type		Sample Collected By		Sample Analyzed By	
983465		06/14/2017		(b)(4)		Environmental		New York District office		Northeast Regional Laboratory	
Laboratory Conclusion				Sample Description							
Listeria monocytogenes type 1 detected in Subs 207, 220, and 248.				One sample containing 58 environmental sub-samples to be analyzed for Listeria.							
Positive Sample Number		Date of Collection		Sample Source		Sample Type		Sample Collected By		Sample Analyzed By	
1004832		07/10/2017		(b)(4)		Environmental		New York District office		Northeast Regional Laboratory	
Laboratory Conclusion				Sample Description							
Listeria monocytogenes detected in sub # 50, 91, 95.				One sample containing 100 environmental subsamples to be analyzed for Listeria.100 Environmental swabs taken during EI of ice cream manufacturer. Please note that swabs are numbered 1-101. Subsample #98 is void due to it breaking off the sponge stick and falling onto the ground. Controls are labeled as INV1004832, sub a, b, c							
Positive Sample Number		Date of Collection		Sample Source		Sample Type		Sample Collected By		Sample Analyzed By	

962008	07/17/2017	(b)(4)	Environmental	New Jersey District Office	Northeast Regional Laboratory
Laboratory Conclusion		Sample Description			
Listeria monocytogenes type 1 detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs #18 and 75).		Listeria monocytogenes type 1 detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs #18 and 75). Listeria innocua detected in two (2) of one hundred and twenty-seven (127) subs tested (Subs # 14 and 83). The remaining one-hundred and twenty-three (123) subs are negative for Listeria spp.			

Investigations / Inspections					
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11742788	05/24/2017	06/08 /2017	No	Record collection, inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11742788	05/24/2017	06/08 /2017	Yes	Record collection, inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11747218	06/13/2017	07/12 /2017	Yes	Record collection,inspection and enviromental sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11755493	07/17/2017	07/20 /2017	No	PC inspection and sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
	07/10/2017	08/11 /2017	Yes	PC inspection and sampling	
Firm Name	City	State	Country	FEI	Type
(b)(4)	(b)(4)	(b)(4)	UNITED STATES	(b)(4)	Manufacturer
FACTS No	Start Date	End Date	483	Activity	
11767807	09/05/2017	09/07 /2017	No	Record collection, inspection and enviromental sampling	



**Traceback Investigations****Communications**

FDA Communication Dates:	N/A
Firm Press Release Dates:	
Release Dates - Other Sources:	
Situation Report Dates:	

**Other Information**

Signals Evaluation:	Yes
Signals Evaluation Description:	<p>The rationale for transfer of the Listeria monocytogenes (1702MLGX6-1)/Ice Cream (suspect)/ML/May 2017 incident is as follows: 1)This is a multistate outbreak of Listeria monocytogenes, with an FDA-regulated product, ice cream, identified as the suspect vehicle. The outbreak involves severe illnesses over an extended period of time, including pregnancy-associated cases, 8/8 case-patients have been hospitalized, and there has been 1 death. 2) Additional coordination is needed related to (b)(5)</p> <p>. 3)Product actions including (b)(5)</p> <p>. 4) This incident has a high level of FDA interest due to the historical multistate outbreak of listeriosis in 2015 linked to ice cream products. 5) Communications relative to this outbreak may be needed.</p>
Response Start Date:	05/17/2017
Response End Date:	
FDA End Date:	
Post-Response Activity:	
Post-Response Activities Description:	