

***Listeria monocytogenes* / (b)(5) (suspect)/Jun 2025 - CARA ID 1309**

On 6/5/2025, CDC notified CORE Signals they had reopened a *Listeria monocytogenes* cluster investigation, (b)(5), due to five 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. In August 2025, (b)(5) collected (b)(5) samples from (b)(5) distribution centers in (b)(5), (b)(5) based on historical sample analysis, and (b)(5) identified as the supplier for a reported restaurant exposure by a (b)(5) case. Two of the samples collected by (b)(5) tested positive for the outbreak strain, (b)(5). FDA did not conduct an official traceback investigation for this incident. However, a limited distribution analysis was conducted for (b)(5) case that reported purchasing (b)(5) and (b)(5) case that reported purchasing (b)(5). CORE issued a total of six assignments to FDA Office of Emergency Response, Emergency Response Coordinators for record collection. No FDA 483s were issued during these record requests. One import sample was collected by FDA as part of this outbreak investigation; The sample was negative for *Listeria* spp and *Salmonella*. Based on the (b)(4) sample collected by (b)(5) that matched the outbreak strain, (b)(4), the supplier to the distribution center with the outbreak matching (b)(5) sample, recalled specific lots of (b)(4) manufactured by (b)(4). An Import Bulletin for increased screening was issued for (b)(4) from (b)(4) manufacturing facilities in (b)(4). Additionally, all products containing any of the following: (b)(4) from (b)(4) of the (b)(4) manufacturing facilities in (b)(4), were added to Import Alert 99-23, Detention Without Physical Examination of Produce Due to Contamination with Human Pathogens. 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 limited traceback opportunities. Based on positive laboratory findings and related WGS of the (b)(4) linked to (b)(4), (b)(4) remain the suspect vehicle for this outbreak. As of 10/6/2025, a total of 27 cases, with 25 hospitalizations and one death reported, in (b)(5) states (b)(5) were associated with this outbreak.