***Listeria monocytogenes*/(b)(5) (suspect)/Aug 2025 - CARA ID 1334**

On 8/21/2025, FDA/CORE was notified by CDC of a new multistate cluster of *Listeria monocytogenes* illness. On 9/12/2025, CORE Signals and CDC named (b)(5) as the leading hypothesis for this outbreak based on preliminary epidemiologic data. FDA initiated a traceback investigation on (b)(5) cases, both of whom had purchased and consumed (b)(5) prior to illness onset. (b)(5) were supplied to the (b)(5) points of services by (b)(4)) during the specified timeframe of interest for the cases. However, traceback could not conclusively implicate the firm or any specific (b)(5) variety, lot, or growing field. Based on the analysis of the limited traceback data, a comprehensive inspection was conducted at (b)(4) by FDA Office of Inspections and Investigations, Division of Produce Safety. During the inspection, environmental samples were collected throughout the processing environment and product samples were also collected. *Listeria monocytogenes* was identified from environmental and (b)(5) product samples during the inspection, but these samples did not match the outbreak strain. The inspection at (b)(4) resulted in the issuance of FDA Form 4056, Produce Farm Inspection Observations, citing concerns related to equipment and tools as well as inaccurate sanitation recordkeeping. Other than the inspectional findings at (b)(4) , there were no indicators to formulate a hypothesis as to sources or routes of contamination for this outbreak. (b)(4) . The recall was initiated based on the firm's internal root cause analysis conducted following FDA's inspection and *Listeria monocytogenes* laboratory findings. With the lack of sufficient traceback, and limited laboratory evidence, (b)(5) remained the suspect vehicle for this outbreak investigation based on epidemiologic evidence. As of 11/3/2025, this cluster included 8 cases in (b)(5) states (b)(5) .