

***Clostridium botulinum*/Infant Formula/Nov 2025 - CARA ID 1350**

On 11/7/2025, CDC alerted FDA CORE of a multistate cluster of 13 infant botulism cases linked to ByHeart infant powdered formula (PIF). On 11/7/2025, FDA, CDC, and CDPH held a firm call with ByHeart Inc. and recommended voluntary recall. On 11/8/2025 ByHeart initiated a voluntary recall of two lots of ByHeart powdered infant formula reported by cases and FDA and CDC issued consumer health advisories. On 11/11/2025, the recall was expanded to all ByHeart Whole Nutrition infant formula products within expiry. CDC's case definition of this outbreak includes all cases with ByHeart powdered infant formula exposure from March 23, 2022. ByHeart Inc. started manufacturing the ByHeart Infant formula on March 23, 2022. CDC and state partners collected open consumer infant formula samples from case patient homes. FDA conducted investigations at blending, packaging, and raw ingredient supplier facilities and collected finished product and raw ingredient samples used to manufacture ByHeart powdered infant formula. A total of 26 FDA samples were collected. Multiple strains of *C. botulinum* were isolated from finished product, base mix, and whole milk powder (ingredient). Whole genome sequencing revealed genetic commonalities in strains found in whole milk powder, finished powdered infant formula product, and an infant botulism clinical isolate. Traceback activities were initiated on 11/19/2025. All cases reported exposure to ByHeart PIF. Traceback efforts focused on tracing product lots back through the manufacturing process to identify common ingredient lots prioritized for targeted sampling. Based on the lot code distribution analysis, five reported PIF lots were traced through the supply chain and were consumed by 12 cases in the investigation. The five lots were manufactured with 14 base mixes and 8 whole milk lot powders. Additionally, FDA traced PIF products and ingredients that tested positive for *C. botulinum* by FDA, CDC, state partners, or the firm's third-party laboratory. Eight whole milk lot powders were traced to 33 fluid milk lots from (b)(5) located in (b)(5). Epidemiological, laboratory and traceback activity findings indicate that consumption of ByHeart powdered infant formula resulted in this multistate infant botulism outbreak. Even though there are several hypotheses, investigational findings could not identify the source or root cause of contamination of the powdered infant formula. As of 2/26/2026, this cluster included 48 cases in 17 States: AZ (5), CA (12), ID(2), IL (2), KY (1), MA (2), MI (1), MN(3), NC (2), NJ (1), OR (3), PA (1), RI (1), TX (8), VA (1), WA (2), WI (1). CDC declared the outbreak over on 2/26/2026.