

***Clostridium botulinum*/Infant Formula/Jun 2026 - CARA ID 1383**

On 6/10/2026, FDA's Office of Critical Foods (OCF) notified CORE Signals about three cases of infant botulism since April 2026, with all cases reporting exposure to Nara Organics Brand Whole Milk Powdered Infant Formula. Epidemiologic and traceback information determined that the identified Nara Organics powdered infant formula lots linked to illnesses were made with fluid milk supplied by Organic West Milk and spray dried by Dairy Farmers of America. The traceback investigation supported the epidemiological link between exposure to contaminated Nara Organics PIF and infant botulism illnesses. Additionally, it confirmed ingredient supplier commonalities between the June 2026 outbreak investigation and the November 2025 ByHeart Powdered Infant Formula outbreak investigation. *Clostridium botulinum* was detected in an open consumer sample collected from a case patient in WA. Whole genome sequencing (WGS) of one product (WA open consumer sample) and the three clinical [CA (2) and WA] isolates was performed by CDPH. Of those isolates, the two CA clinical isolates and WA open consumer were not closely related to existing isolates in the national database. The WA clinical and WA open consumer PIF isolate were not closely related. However, the WA clinical was closely related to one clinical, one PIF base isolate, and four unopened PIF isolates from the 2025 ByHeart investigation (5 SNPs). On 06/12/2026, Nara Organics, Inc initiated a voluntary recall of all lots of Nara Organics Powdered Infant Formula that were on the market out of an abundance of caution due to the potential risk of *Clostridium botulinum* contamination. On 06/25/2026, (b)(4) was placed on Import Alert 40-05. Although there were commonalities between the two infant formula investigations for the organic whole milk and organic whole milk powder, there was not enough evidence to confirm sources and routes of contamination.