U.S. FOOD & DRUG ADMINISTRATION

FDA Sends Call to Action to Infant Formula Industry

Call to Action	Description
Evaluate and ensure that appropriate controls are implemented	• Evaluate all stages of production and in-process control (from receipt of raw materials and ingredients through distribution) • Ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at every step
Ensure full compliance with all relevant regulations	• Infant Formula requirements pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 106); and • Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117);
Consider the concerns shared in this letter	• Control water in dry production areas • Verify the effectiveness of controls through environmental monitoring • Implement appropriate corrective actions • Implement effective supply-chain controls for biological hazards • Identify all relevant biological hazards
Ensure adherence to the notification requirement of an adulterated infant formula	• In accordance with 21 CFR 106.150, infant formula manufacturers are required to notify FDA of an adulterated or misbranded infant formula any time product has left the facility.
Additionally, we ask that firms voluntarily notify FDA any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed.	