

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Human Foods Program**

**Nutrition Center of Excellence**

**Office of Critical Foods**

Effective Date: May 13, 2024

**1. Office of Critical Foods (DCRLB).**

- A. Directs strategic planning, policy development, and management, oversight, coordination, and facilitation in the area of critical foods.
- B. Develops policy, regulations, guidance, and similar documents for matters within the scope of the responsibility of the Office.
- C. Provides expert advice to the Nutrition Center of Excellence leadership, other key officials, and directs major Food and Drug Administration (FDA) initiatives for critical foods as well as provides expertise in the area of critical foods to federal and state partners as well as international bodies.
- D. Collaborates on monitoring the supply of critical foods in the United States (U.S.) to help assure adequate supply and to address and alert on potential interruptions.
- E. Provides technical and regulatory support as well as medical, nutritional, and other scientific expertise for critical foods facility inspections, compliance and enforcement actions, and recalls. Provides medical, nutrition, and other scientific consultations (e.g., food safety, food packaging) for adverse event reports related to critical foods.
- F. Promotes and advances the science related to critical foods, including topics of nutrition, bioactive ingredients, and environmental and processing contaminants.

## **2. Infant Formula Pre-Market Review Staff (DCRLB1).**

- A. Develops regulations and policies for matters within the scope of infant formula.
- B. Provides technical knowledge and expertise in composition, nutrition and safety of infant formulas set forth under the Food, Drug, and Cosmetic Act, its subsequent amendments, and associated regulations.
- C. Manages and provides scientific review and analysis of premarket infant formula submissions, including data and information submitted to demonstrate that the quality factor requirements for infant formula have been met. Provides nutrition expertise for the safety evaluation of infant formula ingredients.
- D. Provides expert advice to the Office Director, senior leadership, other key officials, and national and international bodies on infant formula initiatives and issues.
- E. Provides clinical, scientific, and statistical feedback on the design, conduct and evaluation of preclinical and clinical infant formula studies for stakeholders.

## **3. Authority and Effective Date.**

The functional statements for the Office of Critical Foods were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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Office of  
Critical Foods

Infant Formula Pre-Market Review Staff

(DCRLB)

Staff Manual Guide 1232A.32  
Organizations and Functions  
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Nutrition Center Excellence, Office of Critical Foods organization structure depicting all the organizational structures reporting to the Director:

Infant Formula Pre-Market Review Staff (DCRLB1)