

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Nutrition and Food Labeling

Effective Date: October 9, 2020

1. Office of Nutrition and Food Labeling (DCEK).

- A. Provides policy development and management of food and nutrition labeling, conventional foods, special nutritionals (including infant formula and medical foods), and associated educational initiatives.
- B. Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions for matters within the scope of the responsibility of the Office.
- C. Provides expert advice to the Center Director, other key officials, and directs major Food and Drug Administration (FDA) and Department nutrition and food labeling initiatives.
- D. Manages and provides scientific review on issues related to infant formula and medical foods including petitions and notifications and provides advice to key FDA components as well as international bodies.
- E. Provides clinical and scientific expertise on the design and conduct of clinical trials, risk assessment, adverse event reports, and educational initiatives related to infant formula and medical foods.

2. Infant Formula and Medical Foods Staff (DCEK3).

- A. Provides technical knowledge and expertise in composition, nutrition, and safety of infant formulas set forth under the Infant Formula Act of 1980, and subsequent amendments.
- B. Manages and provides scientific review and analysis of infant formula submissions, petition dossiers, and inspection records as they are submitted

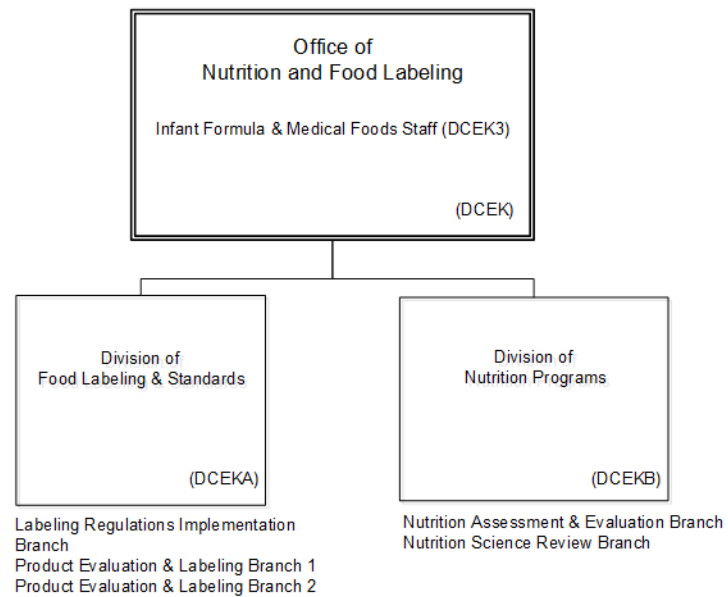
in order to determine if the quality factor requirements for infant formula (21 CFR 106.96 and 21 CFR 106.121) have been met.

- C. Develops regulations, compliance policy, position papers, regulatory guidelines, guidances, and advisory opinions for matters within the scope of infant formula and medical foods.
- D. Provides expert advice to the Office Director, Center Director, other key officials and national and international bodies on infant formula and medical foods initiatives and issues.
- E. Provides clinical and scientific expertise on the design and conduct of clinical trials for stakeholders, risk assessment, and adverse event reports. Provides training for, and feedback to FDA Field investigators in order to strengthen FDA's oversight on issues related to infant formula and medical foods.

3. Authority and Effective Date.

The functional statements for the Office of Nutrition and Food Labeling were approved by the Commissioner of Food and Drugs, FDA effective on October 9, 2020.

**Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutrition and Food Labeling**



Staff Manual Guide 1231.20
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling, organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Nutrition and Food Labeling (DCEK):

Infant Formula and Medical Foods Staff (DCEK3)

Division of Food Labeling and Standards (DCEKA)

Division of Nutrition Programs (DCEKB)

These organizations report to the Division of Food Labeling and Standards (DCEKA):

Labeling Regulations Implementation Branch (DCEKA1)

Product Evaluation and Labeling Branch 1 (DCEKA2)

Product Evaluation and Labeling Branch 2 (DCEKA3)

These organizations report to the Division of Nutrition Programs (DCEKB):

Nutrition Assessment and Evaluation Branch (DCEKB1)

Nutrition Science Review Branch (DCEKB2)