

**SMG 1231.20**

**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: December 14, 2018

**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 labeling initiatives and is the Delegate to national and international forums and conferences.
- D. Manages and provides scientific review on issues related to infant formula and medical foods including petitions and notifications, and provides advice to key Agency 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. Food Labeling and Standards Staff (DCEK1)**

- A. Provides policy and regulatory development and management of the conventional food labeling program (other than nutrition labeling), including Nutrition Labeling and Education Act (NLEA), Food Allergen Labeling and Consumer Protection Act (FALCPA) and other Food, Drug and Cosmetic (FD&C)

Act and Fair Packaging and Labeling Act (FPLA) labeling requirements. Also manages the Standards of Identity program.

- B. Provides scientific and technical review and response to petitions and notifications related to all aspects of conventional food labeling.
- C. Determines compliance with existing food standards and common or usual name, regulations, and issuance of temporary marketing permits to allow manufacturers to test market new foods.
- D. Provides scientific and technical review of enforcement and compliance materials for all conventional foods (including infant formula and medical foods), such as inspection reports, analytical reports and other pertinent records and provides policy and enforcement decisions for misbranding charges on for all domestic and import actions, including infant formula and medical food manufacturers.
- E. Provides expert guidance for officials and other FDA units, Federal and State officials, industry and consumers concerning regulatory requirements and compliance policies on conventional food labeling (including infant formula, medical foods and nutrition-related labeling) and reviews proposed enforcement/compliance actions referred by other FDA units.
- F. Provides expert technical advice for participation in international forums.
- G. Reviews food product labeling (including infant formula, medical foods and nutrition labels) for adherence to regulations and appropriateness of:
  - (1) claims and manages the Small Business Nutrition Labeling Exemption, and
  - (2) Notification Program.

### **3. Nutrition Programs Staff (DCEK2)**

- A. Conducts scientific review and analysis of relevant information for making science-based decisions for policies, regulations, research priorities, position papers, and advisory opinions on issues related to nutrition and nutrition labeling, and other nutrition science issues.
- B. Conducts scientific and regulatory review of health claim petitions, qualified health claim petitions, nutrient content claim petitions, Food and Drug Administration Modernization Act (FDAMA) notifications for health claims and nutrient content claims, and for providing regulations for the Nutrition Facts labels.

- C. Provides expert advice and assistance to key officials and coordinates with other domestic and international government agencies and scientific bodies on efforts related to nutrition and health.
- D. Identifies program priorities for, provides content design input to, and analysis of large-scale databases of food consumption, food composition, food ingredients, sales of processed packaged food products and product label information.
- E. Develops methods for monitoring United States populations and special subgroups relative to use and safety of conventional foods.

#### **4. Authority and Effective Date.**

The functional statements for the Office of Nutrition and Food Labeling were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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

Office of  
Nutrition & Food Labeling  
  
Food Labeling & Standards Staff  
Nutrition Programs Staff  
  
(DCEK)

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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 in the immediate office reporting to the Director.

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

- Food Labeling and Standards Staff
- Nutrition Programs Staff