

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

Division of Food Labeling and Standards

Effective Date: October 9, 2020

1. Division of Food Labeling and Standards (DCEKA).

- A. Provides policy and regulatory development and management of the conventional food labeling program (other than nutrition labeling policy), including implementation of the requirements under the Nutrition Labeling and Education Act (NLEA), Food Allergen Labeling and Consumer Protection Act (FALCPA) and other labeling requirements under the Federal Food, Drug and Cosmetic (FD&C) Act and Fair Packaging and Labeling Act (FPLA). 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 foods with standardized names that deviate from an established food standard.
- D. Provides scientific and technical review of enforcement and compliance materials for all conventional foods (including infant formula and medical foods), such as product labeling, inspection reports, analytical reports and other pertinent records, and also provides policy and enforcement decisions for misbranding charges for all domestic and import actions.
- E. Provides expert guidance for officials and other Food and Drug Administration (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. Also provides expert advice for representatives to national and international forums.

2. Labeling Regulations Implementation Branch (DCEKA1)

- A. Provides interpretation and implementation of regulations and policy under the conventional food labeling program, including labeling requirements under the Nutrition Labeling and Education Act (NLEA), Patient Protection and Affordable Care Act of 2010, Food Allergen Labeling and Consumer Protection Act (FALCPA) and other labeling requirements under the Federal Food, Drug and Cosmetic (FD&C) Act and Fair Packaging and Labeling Act (FPLA).
- B. Provides scientific and technical review of and support to enforcement and compliance materials and actions for all conventional foods (including infant formula and medical foods), such as inspection reports, analytical reports and other pertinent records and also provides policy and enforcement decisions for misbranding charges on for all domestic and import actions.
- C. 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.
- D. Provides policy, regulations, guidance documents, and enforcement strategies governing all aspects of food labeling including warning statements and safe handling practices, and food standards.
- E. Initiates special field assignments, as appropriate, and conducts establishment inspection report (EIR) reviews, provides technical review of food labels, supports the issuance of warning letters, provides technical input on legal actions, and participates in foreign inspections of infant formula manufacturers.

3. Product Evaluation and Labeling Branch 1 (DCEKA2).

- A. Develops regulations, guidance, and policy for, and management of, the food standards program, under the provisions of the Federal Food, Drug and Cosmetic Act.
- B. Provides expert advice for officials and other FDA units, Federal and State officials, industry and consumers concerning regulations and policies on conventional food labeling. Participates in, and provides support to other FDA representatives to national and international forums on food labeling.

- C. Provides scientific and technical review and response to petitions and notifications related to conventional food labeling and food standards of identity.
- D. Determines compliance with existing food standards and common or usual name, regulations, and issues temporary marketing permits to allow manufacturers to test market foods with standardized names that deviate from an established food standard.

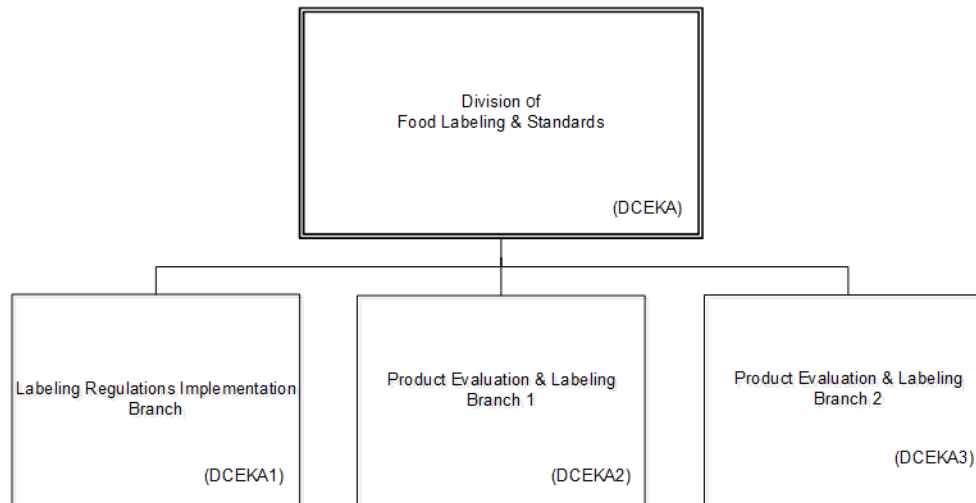
4. Product Evaluation and Labeling Branch 2 (DCEKA3).

- A. Develops regulations, guidance, and policy for, and management of, the food standards program, under the provisions of the Federal Food, Drug and Cosmetic Act.
- B. Provides expert advice for officials and other FDA units, Federal and State officials, industry and consumers concerning regulations and policies on conventional food labeling. Participates in, and provides support to other FDA representatives to national and international forums on food labeling.
- C. Provides scientific and technical review and response to petitions and notifications related to conventional food labeling and food standards of identity.
- D. Determines compliance with existing food standards and common or usual name, regulations, and issues temporary marketing permits to allow manufacturers to test market foods with standardized names that deviate from an established food standard.

5. Authority and Effective Date.

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

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Division of Food Labeling & Standards**



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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, Division of Food Labeling and Standards, organization structure depicting all the organizational structures reporting to the Director:

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)