

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 Nutrition and Food Labeling

Division of Food Labeling and Standards

Effective Date: May 13, 2024

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

- A. Provides policy and regulatory development and management of the conventional food labeling program (including specialized topics such as allergen labeling, e-commerce, and menu labeling), including implementation of relevant statutes and requirements including the Federal Food, Drug, and Cosmetic (FD&C) Act and Fair Packaging and Labeling Act (FPLA) and the implementing regulations under Title 21 of the Code of Federal Regulations.
- B. Manages all activities related to reviewing, establishing or amending food standards, determining compliance with existing food standards, and issuance of temporary marketing permits for standardized foods. Develops regulations and policies for, and assesses compliance with, labeling, including the naming of foods.
- C. Provides scientific, technical, and policy review and response to petitions and requests related to all aspects of conventional food labeling from industry, consumers and other stakeholders.
- D. Provides scientific, technical and policy review of all potential misbranding violations for enforcement and compliance materials for conventional foods, by reviewing product labeling, inspection reports, and other pertinent records for all domestic and import labeling enforcement actions.
- E. Provides expert guidance for officials and other Food and Drug Administration (FDA) components, federal and state officials, international

bodies and other stakeholders concerning the implementation of regulatory requirements and compliance policies on conventional food labeling.

2. Labeling Regulations Implementation Branch (DCRLAA1).

- 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 FD&C Act and FPLA.
- B. Provides scientific and technical review of and support to enforcement and compliance materials and actions for all conventional 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 (non-nutritional) 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 (DCRLAA2).

- A. Develops regulations, guidance, and policy for, and management of, the food standards program, under the provisions of the FD&C 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 (DCRLAA3).

A. Develops regulations, guidance, and policy for, and management of, the food standards program, under the provisions of the FD&C 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.

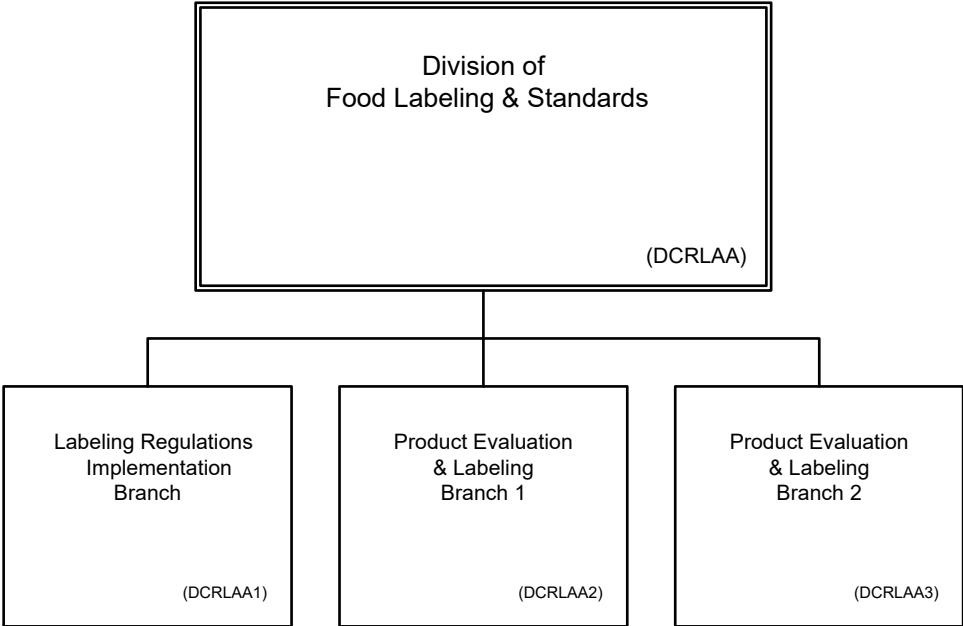
C. Provides scientific and technical review and response to petitions and notifications related to conventional food labeling and food standards of identity.

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 Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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

Labeling Regulations Implementation Branch (DCRLAA1)

Product Evaluation and Labeling Branch 1 (DCRLAA2)

Product Evaluation and Labeling Branch 2 (DCRLAA3)