

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Food Chemical Safety, Dietary Supplements, and Innovation

Office of Dietary Supplement Programs

Division of Policy and Regulatory Operations

Effective Date: May 13, 2024

1. Division of Policy and Regulatory Operations (DCRKCA).

- A. Facilitates policy development and strategic management of dietary supplement specific guidelines, regulations, and educational aids.
- B. Supports the development of dietary supplement regulatory compliance policies to ensure a safe, high-quality, properly labeled dietary supplement marketplace.
- C. Directs dietary supplement communication efforts including responding to industry, public and other inquiries; developing dietary supplement education activities in coordination within Food and Drug Administration (FDA) and with external stakeholders; and providing content to support dietary supplement outreach efforts.
- D. Provides expert scientific, technical, and policy review on dietary supplement good manufacturing practice requirements, labeling requirements, FDA's inspections and investigations programs, and compliance and enforcement matters.
- E. Provides expert advice to FDA, other federal entities, United States, and foreign government officials including Congress, and external stakeholders including industry, international and domestic organizations on dietary supplement manufacturing and labeling requirements.

2. Regulatory Operations Branch (DCRKCA1).

- A. Manages, reviews, and coordinates evaluations of dietary supplement cases for scientific, technical and policy consistency regarding the manufacturing of dietary supplements.
- B. Manages, reviews, and coordinates evaluations of dietary supplement cases for scientific, technical and policy consistency regarding the labeling of dietary supplements.
- C. Evaluates and promptly responds to applications for Certificates of Free Sale, following Center and Division policies and procedures.
- D. Provides expert support to FDA legal offices and field units and the Department of Justice in developing legal documents and providing trial or other requested assistance. Assists in preparation for and, as appropriate, represents the Office at enforcement negotiations.
- E. Provides expert support for development and review of regulations, guidance documents, Federal Register notices, and resolution of other policy questions related to dietary supplement manufacturing and labeling.

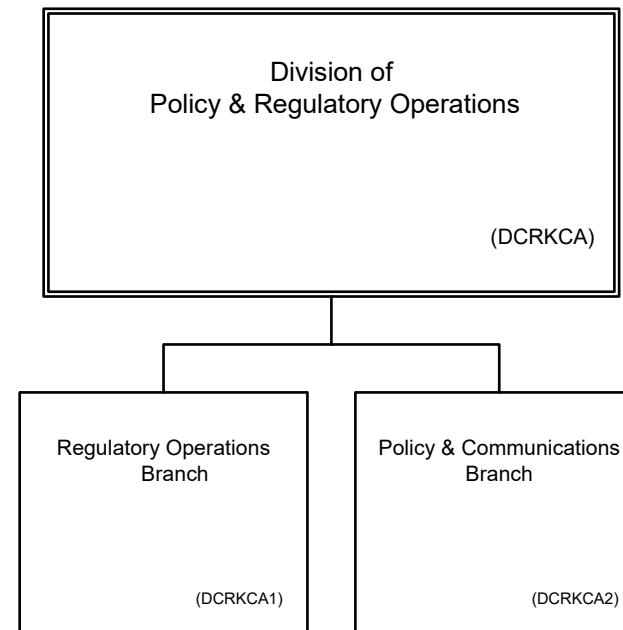
3. Policy and Communications Branch (DCRKCA2).

- A. Resolves policy issues involving dietary supplements in collaboration with the Office Director, other members of the Office leadership team, and subject matter experts.
- B. Develops legislative proposals related to dietary supplements; provides leadership and advice on draft and pending legislation and advises on FDA Legislation and Budget component requests for information and technical assistance.
- C. Serves as the Office's point of contact for enforcement policy and import and domestic inspectional, investigational, and analytical planning.
- D. Works with other Center and FDA units to develop compliance and enforcement strategies to address dietary supplement regulatory issues or emerging compliance challenges. Develops innovative solutions to novel, complex, and precedent-setting regulatory problems.
- E. Responds quickly and accurately to industry, public and others inquires, that are received through phone calls, letters, email, and other media as appropriate.

4. Authority and Effective Date.

The functional statements for the Division of Policy and Regulatory Operations were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Human Foods Program
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Office of Dietary Supplement Programs
Division of Policy and Regulatory Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Office of Dietary Supplement Programs, Division of Policy and Regulatory Operations organization structure depicting all the organizational structures reporting to the Director:

Regulatory Operations Branch (DCRKCA1)

Policy and Communications Branch (DCRKCA2)