

**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 Dietary Supplement Programs**

**Division of Policy and Regulations Implementation**

Effective Date: October 9, 2020

**1. Division of Policy and Regulations Implementation (DCELB).**

- A. Serves as the primary contact between the Office and the Compliance program and Food and Drug Administration (FDA) field organization.
- B. Provides subject matter expertise for dietary supplement specific guidelines, regulations, position papers, and educational aids.
- C. Directs the Office's activities in responding to industry, public and other inquiries on topics that fall under Center for Food Safety and Applied Nutrition's (CFSAN) purview
- D. Provides expert advice for official and other FDA units on good manufacturing practices, field programs, compliance and enforcement issues, and provides assistance to Federal and State agencies and industry concerning regulatory requirements and compliance policies.
- E. Directs the Office's consumer education activities in coordination with other CFSAN and FDA components, including identifying areas where education is needed and providing content to support outreach.

**2. Regulations Implementation Branch (DCELB1).**

- 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.

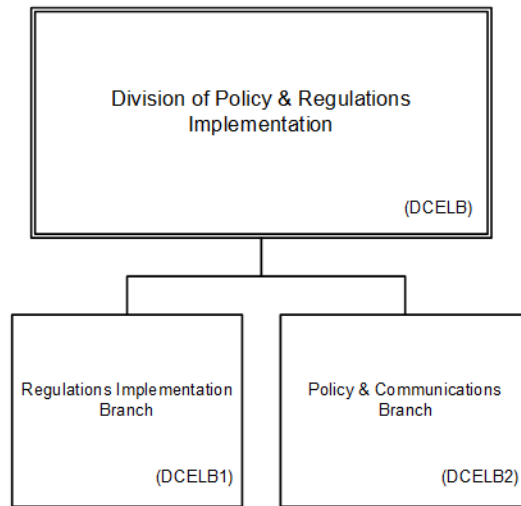
### **3. Policy and Communications Branch (DCELB2).**

- A. Coordinates the development of all Office regulations and guidance documents, and works with Office subject matter experts to draft regulations, guidance documents, and Federal Register notices related to dietary supplements.
- B. Resolves policy issues involving dietary supplements in collaboration with the Office Director, other members of the Office leadership team, and subject matter experts.
- C. 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.
- D. Serves as the Office's point of contact for enforcement policy and import and domestic inspectional, investigational, and analytical planning.
- E. 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 enforcement solutions to novel, complex, and precedent-setting regulatory problems.
- F. Responds quickly and accurately to industry, public and others inquires, that are received through phone calls, letters, email, online chat and other media as appropriate.

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

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

**Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Dietary Supplement Programs  
Division of Policy and Regulations Implementation**



**Staff Manual Guide 1231.211**  
**Organizations and Functions**  
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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 Dietary Supplement Programs, Division of Policy and Regulations Implementation organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Policy and Regulations Implementation (DCELB):

Regulations Implementation Branch (DCELB1)

Policy and Communications Branch (DCELB2)