

SMG 1231.21

**FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF FOODS AND VETERINARY MEDICINE

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

OFFICE OF DIETARY SUPPLEMENT PROGRAMS

Effective Date: December 22, 2015

1. OFFICE OF DIETARY SUPPLEMENT PROGRAMS (DJJHL).

- A. Serves as the Center lead for policy development and strategic management of the dietary supplement program, which includes guidelines, regulations, safety assessments, and compliance strategy.
- B. Provides expert advice throughout the Center, the Agency, other Federal Agencies, United States and foreign government officials including Congress, and external stakeholders including industry, international and domestic organizations on dietary supplement programs and policies.
- C. Communicates and coordinates with other Federal Agencies that have expertise in dietary substances and nutrients.
- D. Conducts chemistry and toxicology research in dietary ingredients.
- E. Enforces the dietary supplement provisions of the Dietary Supplement Health and Education Act (DSHEA) of 1994 and other relevant statutes to ensure the safe marketing and truthful labeling of dietary supplements.
- F. Provides expert scientific testimony and technical review of proposed enforcement actions.
- G. Evaluates risk assessments, adverse events, and other sources of signals related to the safety of dietary ingredients and supplements.
- H. Oversees the implementation of manufacturing and labeling regulations specific to dietary supplements.

2. EVALUATION AND RESEARCH STAFF (DJJHL1).

- A. Provides toxicology, chemistry, and pathology expertise on dietary ingredients and supplement to the Center, develops guidelines and establishes expectations for identity, purity, and safety of dietary ingredients.
- B. Performs, manages, reviews, and coordinates risk assessments and evaluations of dietary ingredients and supplements for policy decisions regarding the safe consumption of dietary supplements.
- C. Provides subject matter expertise for dietary supplement specific guidelines, regulations, position papers, and educational aids.

3. REGULATORY IMPLEMENTATION STAFF (DJJHL2).

- A. Serves as the primary contact between the Office and the Office of Compliance and Food and Drug Administration field organization.
- B. Provides subject matter expertise for dietary supplement specific guidelines, regulations, position papers, and educational aids.
- C. Manages, reviews, and coordinates evaluations of dietary supplement cases for scientific, technical and policy consistency regarding the manufacturing and labeling of dietary supplements.
- D. Provides expert advice for official and other agency 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. Evaluates and promptly responds to applications for Certificates of Free Sale, following Center and Division policies and procedures.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of the Department of Health and Human Services, and effective on December 22, 2015.

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| OFFICE OF THE DIRECTOR | |
| | (DJJHL) |
| Evaluation and Research Staff | (DJJHL1) |
| Regulatory Implementation Staff | (DJJHL2) |

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ORGANIZATION AND FUNCTIONS
EFFECTIVE DATE: December 22, 2015

The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Office of Dietary Supplement Programs organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DJJHL):

- Evaluation and Research Staff (DJJHL1)
- Regulatory Implementation Staff (DJJHL2)