

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 REGULATIONS AND POLICY

Effective Date: 12/07/2017

1. OFFICE OF REGULATIONS AND POLICY (DJJHJ).

- A. Coordinates the development of all Center for Food Safety and Applied Nutrition (CFSAN) regulations and guidance documents, and reviews and clears draft regulations, guidance documents, and Federal Register notices developed by CFSAN, other components of the Food and Drug Administration (FDA), or by other agencies.
- B. Resolves policy issues involving Center-regulated food or cosmetic products in collaboration with the Center Director, the Office of Foods and Veterinary Medicine, and other members of the FDA senior management team.
- C. Provides senior leadership and advice for the Center, the Office of Foods and Veterinary Medicine, and United States (U.S.) government on policies involving sensitive, controversial, and complex food issues, including policies involving food derived from biotechnology.
- D. Provides a centralized monitoring, coordinating, and advisory function for the Center, the Office of Foods and Veterinary Medicine, and U.S. government on development and publication of FVM regulations, Federal Register notices and guidance documents.
- E. Advises Center and Agency officials on regulatory and policy approaches, including legislative positions, and provides leadership in strategic long-and short-term policy development concerning CFSAN's nationwide programs and operational activities in the areas of food and cosmetic safety and nutrition.
- F. Manages the development of periodic plans for the Center's regulation and policy development activities.
- G. Develops legislative proposals related to food and cosmetic safety and defense; provides leadership and advice on draft and pending legislation and advises on

Office of Legislation and Office of Budget requests for information and technical assistance.

- H. Serves as the focal point for the development, implementation, and operation of, and provides support to, CFSAN's Advisory Committees.

2. REGULATIONS DEVELOPMENT STAFF (DJJHJ1).

- A. Advises Center and Office of Foods and Veterinary Medicine staff on the administrative procedures for rulemaking, guidance documents, and other policy documents, hearings and delegations of authority.
- B. Leads the Center's evaluation of existing regulations to determine whether they are efficiently and/or effectively accomplishing their intended purpose.
- C. Drafts, reviews, and edits proposed and final regulations and other Center documents to be published in the Federal Register.
- D. Provides Center-level leadership and coordination regarding briefings with other parts of the Agency or federal government who have clearance responsibility regarding CFSAN regulations and guidance documents, in coordination with Office of Executive Programs (OEP).

3. GOVERNMENT INFORMATION STAFF (DJJHJ2).

- A. Manages the Center's Freedom of Information Act activities, coordinating responses with other Center technical, regulatory, and policy units as well as developing direct responses.
- B. Provides Center-level leadership and coordination with regards CFSAN documents subject to the Paperwork Reduction Act and the Information Quality Act.

4. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of Health and Human Services, and effective December 7, 2017.

FOOD AND DRUG ADMINISTRATION
OFFICE OF FOODS AND VETERINARY MEDICINE
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
OFFICE OF REGULATIONS AND POLICY

OFFICE OF THE DIRECTOR

Regulations Development Staff (DJJHJ1)
Government Information Staff (DJJHJ2)

(DJJHJ)

Staff Manual Guide 1231.19
Organizations and Functions
Effective Date: December 7, 2017

The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy organization structure depicting all the organizational structures in the immediate office reporting to the Director:

These staffs report to the Office of Regulations and Policy (DJJHJ)

- Regulations Development Staff (DJJHJ1)
- Government Information Staff (DJJHJ2)