SMG 1211.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF THE CENTER DIRECTOR

Effective Date: February 20, 2015

1. OFFICE OF THE CENTER DIRECTOR (DKKBA).

A. Coordinates Center activities regarding planning and evaluation of programs, functional activities, and resource utilization.

B. Directs Center financial and budget activities.

C. Coordinates and manages Center extramural programs, including technical and administrative contracts and grant activities.

D. Provides information on biological review process to Center and Agency level management.

E. Coordinates the performance of organization and management studies for the Center and directs implementation of study recommendations.

F. Coordinates Center activities regarding planning, implementation and evaluating programs concerning budget and resource utilization of biotechnology and biomedical issues and the Center's User Fee programs.

G. Coordinates procurement activities with designated Program Managers in each Center/Office.

2. REGULATIONS AND POLICY STAFF (DKKBA5).

A. Prepares notices and proposed and final rules related to the regulation of biological products for publication in the Federal Register.

B. Coordinates for the Center for Biologics Evaluation and Research (CBER) the review of Federal Register documents prepared by other centers or by other agencies; and consolidates the CBER comments and represents Center position to originating office.

C. Provides copies and interpretation of the regulations to persons in the Federal government, the regulated industry and the general public; and maintains historical archives of all Federal Register documents published by the CBER.

D. Advises the CBER staff concerning the administrative procedures for rulemaking, guidelines and other policy documents, hearings and delegations of authority.

E. Prepares advisory opinions and comments in response to requests from other Agency components, industry and trade organizations.

F. Develops policy in response to emerging or existing issues which affect the products and firms regulated by the CBER.

G. Coordinates with the Office of the Chief Counsel on initiation and publication of suspension and revocation actions.

3. RECORDS MANAGEMENT STAFF (DKKBA7).

A. Responsible for receiving, tracking and storing all of CBER's regulatory submissions.

B. Provides Life-cycle Records Management support services for the Center.

4. BIOINFORMATICS SUPPORT STAFF (DKKBA8).

A. Administers and Directs Agency Bioinformatics Initiative within CBER.

B. Formulates Information Technology budget in accordance with OIM initiatives.

C. Represents CBER regarding standards development and Data Standards Committee according to International Standards Organization (ISO).

D. Directs Agency Enterprise Information Technology Initiative implementation within CBER.

5. BUSINESS OPERATIONS STAFF (DKKBA9).

A. Responsible for creating regulations to govern the CBER business processes and the development of work aids for the review cycle.

B. Develops training modules to cover business process aspects and supports reviewer training.

C. Develops and issues letter and review templates to be used by CBER reviewers.

6. EXECUTIVE OPERATIONS STAFF (DKKBA10).

A. Provides administrative management and oversight for CBER/OD activities and resource allocations. Advises the Center Director and senior Center management on administrative services and develop policies and procedures for these services.

B. Plans and directs office operations for financial and personnel management.

7. REGULATORY INFORMATION MANAGEMENT STAFF (DKKBA11).

A. Performs quality control functions to ensure accuracy of review and tracking of application data collected and reported.

B. Monitors the quality assurance and consistency of data collected and reported on CBER review activities.

8. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Deputy Commissioner for Operations and Chief Operating Officer, and effective on February 20, 2015.

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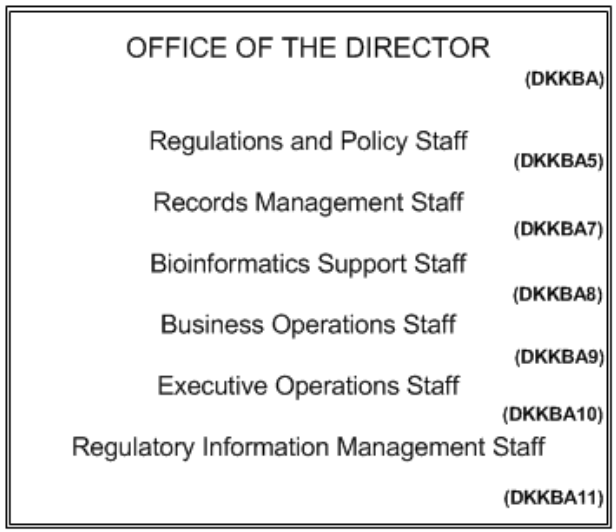

Staff Manual Guide 1211.1
Organizations and Functions
Effective Date: February 20, 2015

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Biologics Evaluation and Research, Office of the Center Director organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKBA):

- Regulations & Policy Staff (DKKBA5)
- Records Management Staff (DKKBA7)
- Bioinformatics Support Staff (DKKBA8)
- Business Operations Staff (DKKBA9)
- Executive Operations Staff (DKKBA10)
- Regulatory Information Management Staff (DKKBA11)