SMG 1211.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of the Center Director

Effective Date: January 6, 2022

1. Office of the Center Director (DCBA).

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. Executive Operations Staff (DCBA1).

A. Provides administrative management and oversight for Center for Biologics Evaluation and Research (CBER)/Office of the Director 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.

3. Regulations and Policy Staff (DCBA3).

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

B. Coordinates for CBER the review of Federal Register documents prepared by other centers or by other agencies; and consolidates the CBER comments and represents Center position in 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.

4. Policy Staff (DCBA7).

A. Leads Center's activities on planning, developing and implementing programs and policies for biological products.

B. Directs policies involving pre- and post-market approval issues, real world evidence, patient engagement, counterterrorism, labeling, manufacturing, communications, human subject protection, emerging infectious diseases, and novel and emerging technologies.

C. Responsible for the review and clearance of regulatory policy programs and strategic initiatives.

D. Directs Center's Regulations and Policy Staff.

E. Advises on senior leadership, program budget and policy.

F. Represents Center Director on signification issues, including pandemic flu, blood safety, clinic trial issues and tissues, cell and gene therapies.

G. Lead Center's development of policy and implementation of provisions of comprehensive legislation (FDASIA) addressing drug shortages, pediatric medicines and expedited pathways.

H. Provides legal and regulatory leadership and advice and support to Center and Agency on blood products, vaccines, cell and gene therapies.

I. Directs CBER's review and clearance of guidance on challenging issues including reference product exclusivity, related policy issues addressing manufacturer's eligibility for exclusivity, and issues related to nonproprietary naming of "related" biological products to describe the process for naming related products.

5. Science Staff (DCBA8).

A. Plans and directs the Center's scientific research programs encompassing a broad spectrum of activities related to the regulatory mission of the FDA.

B. Provides project and program management support to CBER to promote, review, and coordinate all scientific research activities conducted by the center and for assuring their high quality, focus, and scientific and public health outcomes.

C. Supports scientific enterprise through managing and analyzing a variety of data sources, including research program reports, financial information, and infrastructure resources.

D. Provides support on development, revision, and implementation of policies, practices and priorities.

E. Directs and manages the short/long range review of plans and programming documents related to the Center's science program.

F. Provides support and may act to coordinate, and/or respond to request for intra/inter-Center and Agency cooperation on scientific matters.

G. Provides support to a variety of committees related to management of the scientific research enterprise.

6. Authority and Effective Date.

The functional statements for the Office of the Center Director were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

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Food and Drug Administration
Center for Biologics Evaluation and Research
Office of the Center Director

Office of
the Center Director

Executive Operations Staff
Regulations & Policy Staff
Science Staff
Policy Staff

(DCBA)

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of the Center Director organization structure depicting all the organizational structures reporting to the Director:

Office of the Center Director (DCBA)

These organizations report to the Office of the Director:

Executive Operations Staff (DCBA1)

Regulations and Policy Staff (DCBA3)

Policy Staff (DCBA7)

Science Staff (DCBA8)