SMG 1121.23a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Medical Products and Tobacco Operations

Office of Biological Products Operations

Effective Date: December 14, 2018

1. Office of Biological Products Operations (DCIGC).

A. Provides direction and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Food and Drug Administration (FDA) leaders relative to biological products field operations and emergency response activities, including all biological and biopharmaceutical products regulated by the Center for Biologics Evaluation and Research (CBER).

B. Coordinates, directs and assists with biological product investigative activities.

C. Supports the development of policy and guidance for investigations and compliance for biological products.

D. As needed, participates in systems recognition efforts with other FDA components and national and international governments.

E. Participates as subject matter experts in the design, implementation and presentation of biologics training programs.

F. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.

G. Serves as subject matter expert on field operations relative to external and internal cross-FDA biologics program committees, workgroups and task forces.

H. Creates, reviews, and/or facilitates issuance of field assignments with Centers for biologics programs. Monitors and serves as technical point of contact for these assignments.

I. Develops and maintains cooperative relationships with State, local and other Federal agencies; serves on interagency councils, encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations.

J. Plans and evaluates program activities and manages a Quality Assurance Program.

K. Coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.

L. Conducts investigations and inspections of biological products, and other CBER-regulated commodities.

M. Provides technical assistance regarding biological product investigational operations.

N. Directs and coordinates Office of Regulatory Affairs (ORA) response to reports of adverse events relative to biological products and potential product shortages in collaboration with the Centers.

2. Biological Products Inspection Staff (DCIGC1)

A. Performs inspections of biological drug, device and vaccine products regulated by CBER.

B. Initiates, coordinates and conducts related compliance activities.

C. Participates as subject matter experts in the design, implementation and presentation of biological drug, device and vaccine training programs.

D. Monitors emerging issues and advancement in biological drug, device and vaccine development and manufacturing technology.

E. Plans and evaluates program activities and manages a Quality Assurance Program.

3. Biological Products Operations Staff (DCIGC2)

A. Coordinates, directs, and assists the field and Headquarters with domestic and international investigative activities related to biological and biopharmaceutical products regulated by the Center for Biologics Evaluation and Research (CBER).

B. Provides inspectional and technical assistance to field and foreign offices on biological product inspection and regulatory matters.

C. Creates, clears and/or issues biological products field assignments, including responses to adverse event reports relative to biological products, emergency response activities, and product shortages. Serves as technical point of contact for these assignments and monitors outcomes.

D. Coordinates implementation of user fee programs and collection and analysis of related performance goal data.

E. Implements biological program work plans within the Office. Assists other offices and divisions in interpretation of work plan implementation.

F. Reviews and evaluates implementation of existing procedures and guidance related to biological products.

G. Participates as subject matter experts in the design, implementation and presentation of biologics training programs.

H. Plans and evaluates program activities and manages a Quality Assurance Program.

I. Serves as subject matter expert on field operations relative to the biologics program on external and internal cross-FDA committees, workgroups and task forces.

J. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations, including the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and International Conference on harmonization (ICH), as appropriate.

K. Provides technical and programmatic expertise to the field and Centers through national technical and program experts.

L. Performs biologics inspections, as necessary.

M. Provides biologics program technical assistance and training to other regulatory and public health partners.

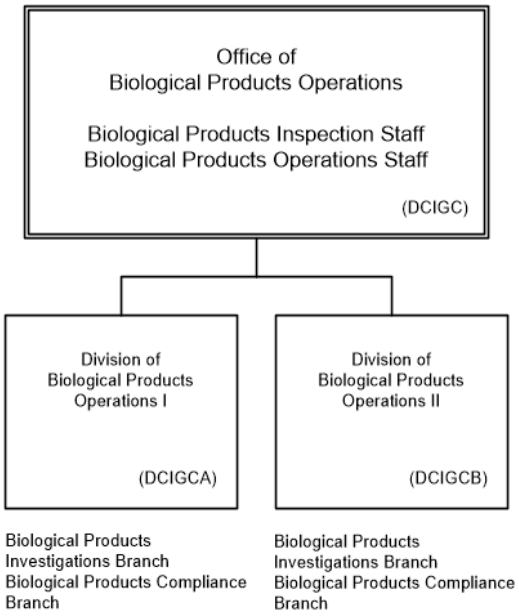
N. Monitors emerging issues and advancements in the biologics program.

O. Assists with responses to adverse event reports relative to biological products.

4. Authority and Effective Date.

The functional statements for the Office of Biological Products Operations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Products and Tobacco Operations
Office of Biological Products Operations



Staff Manual Guide 1121.23a
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Biological Products Operations organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Biological Products Operations (DCIGC):

Biological Products Inspection Staff

Biological Products Operations Staff

Division of Biological Products Operations I (DCIGCA)

Division of Biological Products Operations II (DCIGCB)

These organizations report to the Division of Biological Products Operations I (DCIGCA):

Biological Products Investigations Branch

Biological Products Compliance Branch

These organizations report to the Division of Biological Products Operations II (DCIGCB):

Biological Products Investigations Branch

Biological Products Compliance Branch