SMG 1121.231

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

Division of Biological Products Operations I

Effective Date: February 9, 2022

1. Division of Biological Products Operations I (DCIGCA).

A. Manages field inspection and compliance operations within the associated division for products regulated by the Center for Biologics Evaluation and Research (CBER).

B. Manages and evaluates resource use in support of the biologics program.

C. Conducts investigations and inspections related to biological products.

D. Recommends legal action and assists in implementing approved action.

E. Manages and evaluates biologics program activities and manages a quality assurance program.

F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.

G. Advises the Office of Biological Products Operations Program Director of emerging problems, trends, program needs and any local or state issues.

H. Manages program and operational activities, including all phases of personnel management, financial management, property and supplies for the Division.

2. Biological Products Investigations Branch (DCIGCA1).

A. Inspects biologics establishments, collects samples for analysis, performs investigations and field examinations, and prepares reports.

B. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.

C. Evaluates corrective actions taken by biologics establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any Food and Drug Administration (FDA)–regulated biological product; and performs pre-market clearance activities of biological products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to Office of Regulatory Affairs (ORA) headquarters, CBER, and other divisions, as needed.

H. Plans, schedules and controls biologics inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides counsel and training regarding inspectional techniques and technical developments to other Federal, State, local agencies and foreign counterpart agencies and to industry, as appropriate.

K. Assists in managing, evaluating and auditing the program aspects of federal-state contracts.

L. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

3. Biological Products Compliance Branch (DCIGCA2).

A. Reviews and evaluates inspectional and analytical findings to assess compliance with FDA-enforced laws and regulations; determines the most suitable course of action and, if appropriate, recommends legal action.

B. Liaises with the United States (U.S.) attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

C. Ensures court-ordered actions are completed on time and in total fulfillment of the Court's order.

D. Conducts administrative meetings on alleged violations and initiates enforcement action.

E. Obtains clearance for administrative and other detentions, prepares related correspondence, and supports detention hearings.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness.

G. Issues untitled and warning letters to regulated industry.

H. Answers inquiries from other Federal agencies, foreign missions and industry regarding interpretations of FDA-enforced laws and regulations, case status and enforcement policies, as appropriate.

I. Works with State and local officials to develop uniform legislation, codes and regulations; advises state and local officials on interpretation of federal laws, regulations and enforcement policies and provides consultation relative to joint regulatory approaches.

J. Plans, organizes and implements comprehensive industry education, training and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other field and Headquarters components.

K. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

4. Biological Products Inspection Staff (DCIGCA3).

A. Performs inspections of biological drug products such as vaccines, cellular and gene therapies, allergenics, and live biotherapeutic agents, and specific medical devices regulated by CBER and prepares reports.

B. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.

C. Evaluates corrective actions taken by biologics establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Plans, schedules and controls biologics inspectional operations.

F. Supports the development and implementation of domestic and foreign inspectional work plans.

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

H. Monitors emerging issues and advancement in biological drug product development and manufacturing technology.

I. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA–regulated biological product; and performs pre-market clearance activities of biological products.

J. Provides inspectional and investigational support to ORA headquarters, CBER, and other divisions, as needed.

K. Provides counsel and training regarding inspectional techniques and technical developments to other Federal, State, local agencies and foreign counterpart agencies and to industry, as appropriate.

5. Authority and Effective Date.

The functional statements for the Division of Biological Products Operations I were approved by the Deputy Secretary for Health and Human Services on December 22, 2021, and effective on February 9, 2022.

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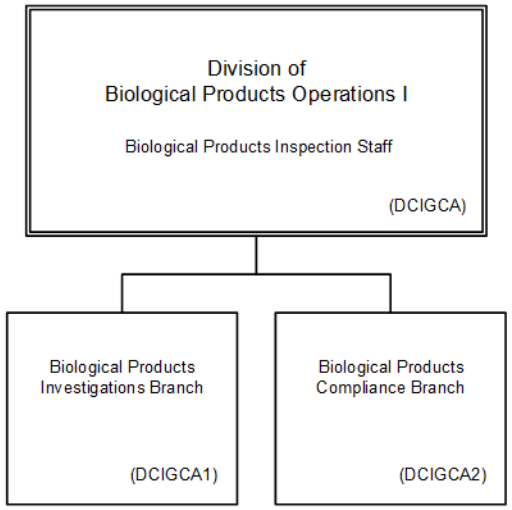

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Biological Product Operations, Division of Biological Product Operations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

These organizations report to the Division of Biological Product Operations I:

Biological Products Investigations Branch (DCIGCA1)

Biological Products Compliance Branch (DCIGCA2)

Biological Products Inspection Staff (DCIGCA3)