SMG 1121A.43

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Biologics Inspectorate

Division of Biologics Inspectorate III

Effective Date: May 13, 2024

1. Division of Biologics Inspectorate III (DCSDD).

A. Manages field inspection operations within the associated division for products regulated by the Center for Biologics Evaluation and Research (CBER) and the animal cells, tissues, and cell- and tissue-based products (ACTPs) and intentional genomic alterations (IGA) in animals regulated by the Center for Veterinary Medicine (CVM) in coordination with Centers and Offices.

B. Manages and evaluates resource use in support of the biologics program in coordination with Centers and Offices.

C. Conducts and monitors investigations and inspection activities related to products regulated by CBER and ACTP and IGA products regulated by CVM.

D. Refers inspections with 483 observations for consideration of regulatory and enforcement action and assists in implementing approved action at the directions of the Centers and Offices, including liaising with United States (U.S.) Attorneys and U.S. Marshals and ensuring court-ordered actions are completed on time and in total fulfillment of the Court's order.

E. Manages and evaluates biologics program activities and manages a quality assurance program in coordination with Centers and Offices.

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

G. Advises the Office of Biologics Inspectorate Director of emerging problems, trends, program needs and any local or state issues.

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

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

J. Participates in regulatory meetings on alleged violations.

K. Collaborates with Centers and Offices on the development and updates to Compliance Programs relevant to CBER regulated products and ACTPs and IGA products regulated by CVM.

L. Develops, reviews, and analyzes, in coordination with Centers and Offices, regulations and policies that apply to the inspection of products regulated by CBER and ACTPs and IGA in animals regulated by CVM.

M. Decides whether remote regulatory assessment/alternative tool is appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

N. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

2. Biologics Investigations Branch 1 (DCSDD1).

A. Inspects establishments, collects samples for analysis, performs investigations and field examinations, and prepares reports for CBER regulated products and for ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

B. Refers inspections and investigations with 483 observations to CBER and CVM for consideration of appropriate follow-up.

C. Evaluates and determines effectiveness of corrective actions taken by establishments manufacturing CBER regulated products and ACTPs and IGA products regulated by CVM 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; and performs pre-market activities when requested.

F. Performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to Office of Inspections and Investigations (OII) headquarters, CBER, CVM, and other divisions, as needed.

H. Plans, schedules, and monitors inspectional operations related to CBER regulated products and ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

I. Develops domestic inspectional work plans in collaboration with CBER and CVM.

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

K. Maintains cooperative relationships with State and local counterpart agencies. Collaborates with state and local officials to enable information sharing and to leverage regulatory authorities. Participates as subject matter experts in the design, implementation, and presentation of inspection training programs.

L. Conducts a remote regulatory assessment/alternative tool when appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

M. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

3. Biologics Investigations Branch 2 (DCSDD2).

A. Inspects establishments, collects samples for analysis, performs investigations and field examinations, and prepares reports for CBER regulated products and for ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

B. Refers inspections and investigations with 483 observations to CBER and CVM for consideration of appropriate follow-up.

C. Evaluates and determines effectiveness of corrective actions taken by establishments manufacturing CBER regulated products and ACTPs and IGA products regulated by CVM 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; and performs pre-market activities when requested.

F. Performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to OII headquarters, CBER, CVM, and other divisions, as needed.

H. Plans, schedules, and monitors inspectional operations related to CBER regulated products and ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

I. Develops domestic inspectional work plans in collaboration with CBER and CVM.

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

K. Maintains cooperative relationships with State and local counterpart agencies. Collaborates with state and local officials to enable information sharing and to leverage regulatory authorities. Participates as subject matter experts in the design, implementation, and presentation of inspection training programs.

L. Conducts a remote regulatory assessment/alternative tool when appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

M. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

4. Biologics Investigations Branch 3 (DCSDD3).

A. Inspects establishments, collects samples for analysis, performs investigations and field examinations, and prepares reports for CBER regulated products and for ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

B. Refers inspections and investigations with 483 observations to CBER and CVM for consideration of appropriate follow-up.

C. Evaluates and determines effectiveness of corrective actions taken by establishments manufacturing CBER regulated products and ACTPs and IGA products regulated by CVM 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; and performs pre-market activities when requested.

F. Performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to OII headquarters, CBER, CVM, and other divisions, as needed.

H. Plans, schedules, and monitors inspectional operations related to CBER regulated products and ACTPs and IGA products regulated by CVM in coordination with Centers and Offices.

I. Develops domestic inspectional work plans in collaboration with CBER and CVM.

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

K. Maintains cooperative relationships with State and local counterpart agencies. Collaborates with state and local officials to enable information sharing and to leverage regulatory authorities. Participates as subject matter experts in the design, implementation, and presentation of inspection training programs.

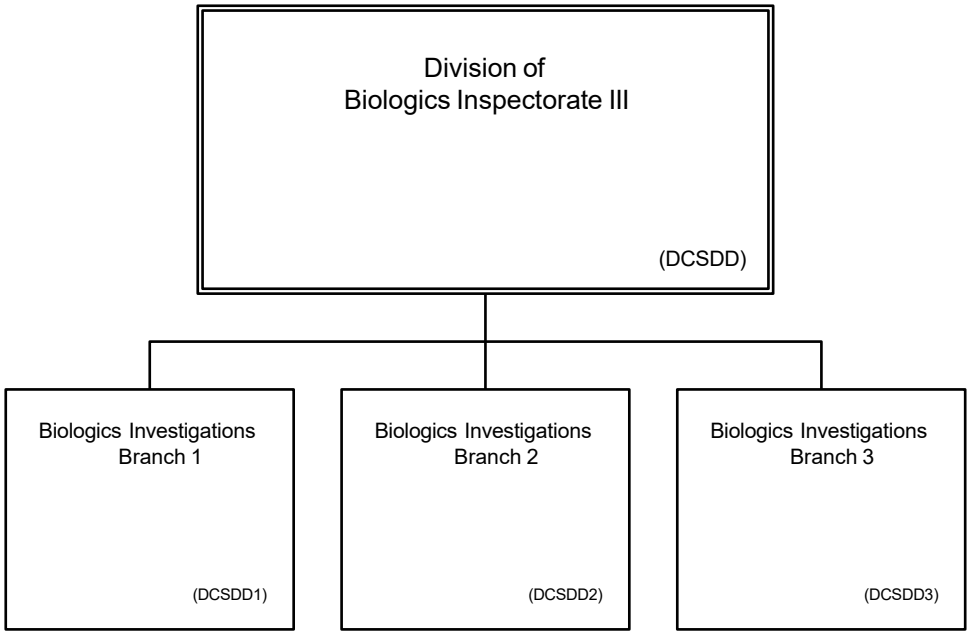
L. Conducts a remote regulatory assessment/alternative tool when appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

M. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

5. Authority and Effective Date.

The functional statements for the Division of Biologics Inspectorate III were approved by the Secretary for Health and Human Services on March 5, 2024, and effective on May 13, 2024.

Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Biologics Inspectorate
Division of Biologics Inspectorate III



Staff Manual Guide 1121A.43
Organizations and Functions
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Biologics Inspectorate, Division of Biologics Inspectorate III organization structure depicting all the organizational structures reporting to the Director:

Biologics Investigations Branch 1 (DCSDD1)
Biologics Investigations Branch 2 (DCSDD2)
Biologics Investigations Branch 3 (DCSDD3)