SMG 1212.4

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 Compliance and Biologics Quality

Division of Inspections and Surveillance

Effective Date: May 13, 2024

1. Division of Inspections and Surveillance (DCBCB).

A. Coordinates and provides support and direction to Biologics and Bioresearch Monitoring (BIMO) Inspections component for investigations and inspections.

B. Maintains detailed risk-based inventory of Center for Biologics Evaluation and Research (CBER) regulated entities eligible for inspection.

C. In collaboration with Food and Drug Administration's (FDA's) inspection and investigation program, plans and directs inspection work and allocates resources for surveillance and directed inspections of CBER regulated products.

D. Develops and updates CBER compliance programs with FDA's regulatory program input, coordinates and directs their implementation, and advises other FDA components on these programs.

E. Directs CBER's program for biological product deviation reporting, and reports of complications of blood collection or transfusion confirmed to be fatal. Coordinates case reviews, as appropriate, by a committee of medical officers.

F. Plans and directs investigation and inspection assignments in response to review of medical device reports, field alert reports, product defects, adverse events, complaints, biological product deviation reports, and allegations of violative activity. Evaluates the related inspection and investigation reports.

G. Plans and directs CBER's BIMO program with oversight of clinical investigators, institutional review boards, good laboratory practices, clinical

trials.gov, and sponsors/monitors/contract research operations of clinical research for biological products.

H. Issues post inspectional correspondence under Field Management Directive (FMD)-145.

I. Promotes uniformity between CBER and the Biologics and BIMO Inspection components with regard to conducting inspections and the implementation of Current Good Manufacturing Practice (CGMP) and Good Clinical Practice (GCP) policy.

J. Provides support for inspections and investigations and coordinates participation by qualified product specialists. Serves as CBER's contact for issues during inspections.

K. Supports the CBER pre-approval inspection program. Issues inspection assignments and manages CBER inspection credentialing program.

L. Serves as the CBER contact for other federal agencies concerning inspection, surveillance, and enforcement matters, and coordinates review of these matters with other FDA components as appropriate.

M. Coordinates CBER information sharing within the Department of Health and Human Services as well as with other Federal and State agencies consistent with the laws, regulations, and existing memoranda of understanding.

N. Supports CBER policy initiatives.

2. Program Surveillance Branch (DCBCB1).

A. Directs CBER’s program for biological product deviation reporting, and reports of complications of blood collection or transfusion confirmed to be fatal. Coordinates case reviews by a committee of medical officers. Processes complaints.

B. Plans and directs investigation and inspection assignments in response to medical device reports, field alert reports, product defects, adverse events, complaints, and allegations of violative activity. Evaluates the related inspection and investigation reports.

C. Plans and directs investigation and inspection assignments for pre-approval, pre-license, and pre-market applications.

D. Supports updates to registration systems.

E. Applies risk-based analysis to evaluate inventories for site selection for the annual inspection priorities.

F. Determines program emphasis and maintains information associated with program report reviews.

G. Advises and consults with project managers and senior management within the Center on policy, planning, and technical matters.

H. Represents the Center in inter-Center and inter-Agency conferences.

I. Speaks for the Office in conferences with representatives of the biologic industry pertaining to regulatory and application as well as compliance and inspectional/investigational policies and inspectional/investigational policies and inspectional/investigational policies.

J. Plans and directs investigation and inspection assignments for pre-approval, pre-license, and pre-market applications.

K. Supports updates to registration systems.

L. Applies risk-based analysis to evaluate inventories for site selection for the annual inspection priorities.

M. Determines program emphasis and maintains information associated with program report reviews.

N. Advises and consults with project managers and senior management within the Center on policy, planning, and technical matters.

O. Represents the Center in inter-Center and inter-Agency conferences.

P. Speaks for the Office in conferences with representatives of the biologic industry pertaining to regulatory and application as well as compliance and inspectional/investigational policies and inspectional/investigational policies and inspectional/investigational policies.

Q. Supports development of training programs in conjunction with CBER components, to promote industry compliance and for use in training FDA staff, industry, health professionals, and consumers concerning products regulated by CBER.

3. Bioresearch Monitoring Branch (DCBCB2).

A. Directs CBER's Bioresearch Monitoring program with oversight of clinical investigators, institutional review boards, good laboratory practices, clinical trials.gov, and sponsors/monitors/contract research operations of clinical research for biological products.

B. Coordinates and provides support to the clinical review of applications submitted to the FDA in support of product development. Reviews INDs,

IDEs, BLAs, and PMAs for Good Clinical Practice, Good Laboratory Practice, and human subject protection compliance.

C. Plans and directs inspection assignments, evaluates Establishment Inspection Reports, and takes appropriate compliance actions, in coordination with other FDA components, including Untitled Letters, Warning Letters, pre notice letters, notice of noncompliance, and initiation of the disqualification of clinical investigators and debarments (in coordination with FDA's criminal investigations and other FDA components). Handles and coordinates Office follow-up and response, as appropriate, to complaints related to investigational products, clinical trials, and IRB operations.

D. Develops guidance and other training programs to promote industry compliance and for use in training FDA staff, industry, health professionals and consumers concerning products regulated by CBER.

E. Represents CBER in Good Laboratory Practice, Good Clinical Practice, IRB, CT.gov working groups and committees.

F. Represents the Center in inter-Center and inter-Agency conferences.

G. Applies risk-based analysis to evaluate specific IND categories to support BIMO annual surveillance programs.

4. Field Programs Branch (DCBCB3).

A. Coordinates and provides support and direction to the Biologics Inspections component within FDA's regulatory program for investigations and inspections.

B. Develops and updates CBER compliance programs with Center and OBPORA input as needed, coordinates, and directs their implementation, and advises other FDA components on these programs.

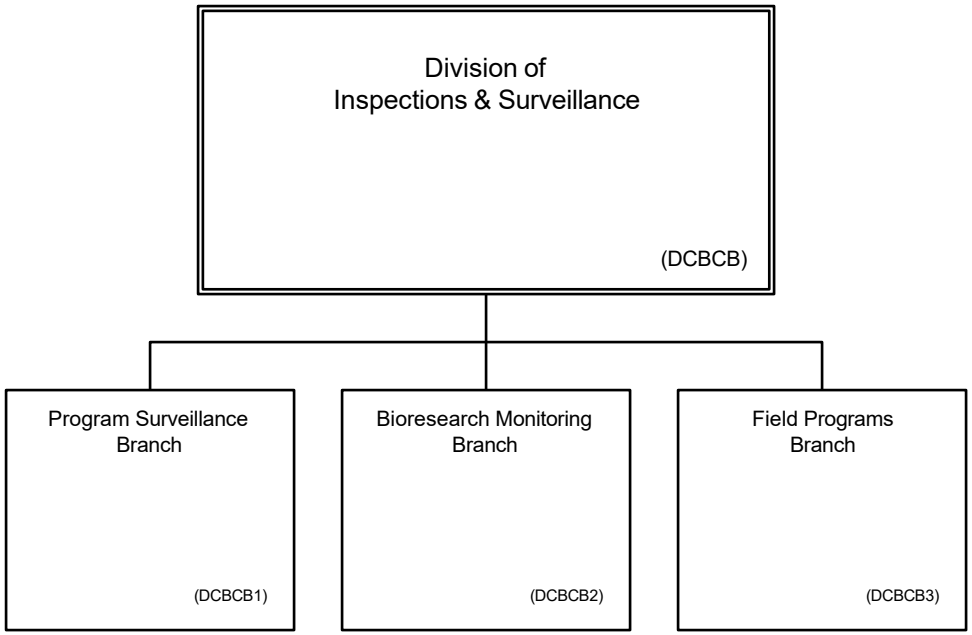
C. Issues FMD-145 Letters.

D. Processes complaints.

5. Authority and Effective Date.

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

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Inspections and Surveillance



Staff Manual Guide 1212.4
Organizations and Functions
Effective Date: May 13, 2024

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

Division of Inspections and Surveillance (DCBCB)
Program Surveillance Branch (DCBCB1)
Bioresearch Monitoring Branch (DCBCB2)
Field Programs Branch (DCBCB3)