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: January 6, 2022

1. Division of Inspections and Surveillance (DCBCB).

A. Coordinates and provides support and direction to district offices for investigations and surveillance inspections.

B. Works with the Office of Regulatory Affairs (ORA) to prepare inspection work plans and allocate resources for the Center for Biologics Evaluation and Research (CBER) inspection programs.

C. Develops guidance and other training programs in conjunction with other CBER components, to promote industry compliance and for use in training Food and Drug Administration (FDA) staff, industry, health professionals and consumers concerning products regulated by CBER.

D. Develops and updates CBER compliance programs, coordinates and directs their implementation, and advises other FDA components on these programs.

E. Directs CBER's program for biological product deviation, 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 surveillance assignments in response to reports regarding product defects, adverse events, complaints, biological product deviation reports, and allegations of violative activity. Evaluates the related inspection and investigation reports.

G. Directs CBER's Bioresearch Monitoring program with oversight of clinical investigators, institutional review boards, and sponsors of clinical research for biological products. 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, and the initiating the disqualification of clinical investigators.

H. Coordinates Office follow-up and response to complaints related to investigational products and clinical trials.

I. Works with other FDA components, provides guidance to industry, consumers, and other government officials concerning bioresearch monitoring policies and regulations.

J. Promotes uniformity between CBER and ORA with regard to conducting inspections and the implementation of Current Good Manufacturing Practices policy.

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

L. Supports the CBER pre-approval inspection program.

M. 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. Coordinates CBER information sharing with federal agencies (other than Department of Health and Human Service) consistent with the laws, regulations, and existing memoranda of understanding.

2. Bioresearch Monitoring Branch (DCBCB2).

A. Directs CBER’s Bioresearch Monitoring Program with oversight of clinical investigators, institutional review boards, and sponsors of clinical research for biological products.

B. Plans and directs inspection assignments, evaluates Establishment Inspection Reports, and takes appropriate compliance actions, in coordination with other Agency components, including Untitled Letters, Warning Letters, and the initiation of disqualification of clinical investigators.

3. Program Surveillance Branch (DCBCB1).

A. Coordinates and provides support and direction to district offices for investigations and surveillance inspections.

B. Supports CBER pre-approval inspection program.

C. Plans and directs investigation and surveillance assignments in response to reports regarding product defects, adverse events, complaints, biological product deviation reports, and allegations of violative activity.

D. Evaluates the related inspection and investigation reports.

E. Determines program emphasis and maintains information system for functions such as evaluating fatality reports and biological product deviation reports.

F. Advises and consults with project managers and organizational heads within the center on policy, planning, technical matters and regulatory compliance policy decisions related to subject matters within their jurisdiction.

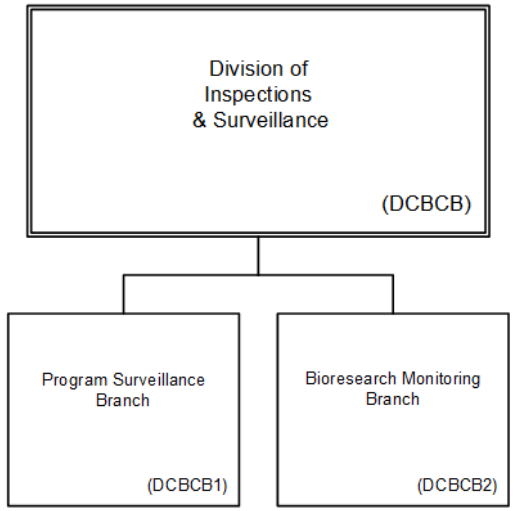
G. Represents the Center in inter-Center and inter-Agency conferences, including conferences with the Agency's chief counsel and members of their staff, concerned with broad policy matters in which biologics are particularly applicable.

H. Speaks for the office in conferences with representatives of the biologic industry concerned with difficult problems of interpreting and applying the law, regulations, compliance policies and inspectional/investigational policies.

4. Authority and Effective Date.

The functional statements for the Division of Inspections and Surveillance were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

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



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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 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)

These organizations report to the Division of Inspections and Surveillance:

Bioresearch Monitoring Branch (DCBCB2)

Program Surveillance Branch (DCBCB1)