

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: December 14, 2018

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 reports (including HCT/P deviation reports and medical device reports), 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

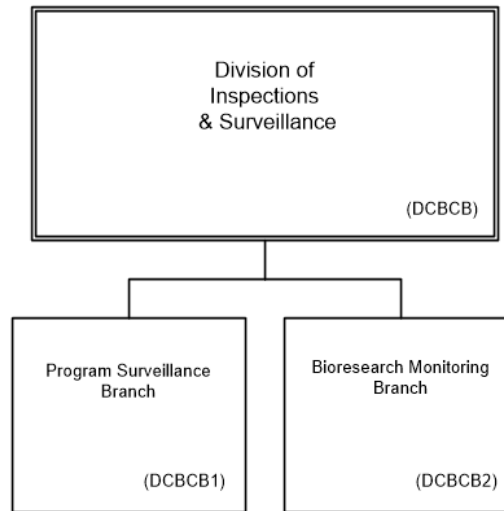
biological products. Plans and directs inspection assignments, evaluates Establishment Inspection Reports, and takes appropriate compliance actions, in coordination with other FDA components, including Untitled Letters, Warning Letters, and the initiating the disqualification of clinical investigators.

- 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 Team Biologics inspections and coordinates participation by qualified product specialists. Serves as CBER's contact for Team Biologics 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. Authority and Effective Date.

The functional statements for the Division of Inspections and Surveillance 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
Center for Biologics Evaluation and Research
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Division of Inspections and Surveillance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Medical Products and Tobacco, 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 Office of the Director.

Division of Inspections & Surveillance (DCBCB):

- Program Surveillance Branch (DCBCB1)
- Bioresearch Monitoring Branch (DCBCB2)