SMG 1212.1

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

Effective Date: May 13, 2024

1. Office of Compliance and Biologics Quality (DCBC).

A. Ensures the quality of products regulated by the Center for Biologics Evaluation and Research (CBER) over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach, and compliance.

B. Monitors the quality of CBER-regulated products through surveillance, inspections, and compliance programs; reviews, evaluates and takes appropriate compliance action, pursues enforcement action and supports prosecutions.

C. Reviews, evaluates, and takes appropriate action on manufacturing supplements submitted by manufacturers (except blood and plasma establishments), and leads pre-approval and pre-license inspections supporting Biologics License Application submissions and supplements as part of the CBER managed review process.

D. Advises the Center Director and other Food and Drug Administration (FDA) officials on emerging and significant compliance issues for CBER regulated products and serves as CBER's focal point for surveillance and enforcement policy.

E. Coordinates CBER's participation in the inspection of CBER regulated manufacturing facilities.

F. Develops, with other CBER/FDA components, policies and compliance standards for biological products, including Current Good Manufacturing Practice (CGMP) regulations; ensures the uniform interpretation of standards and evaluates industry's conformance with CGMP in manufacturing biological products.

G. Directs the recall program for CBER-regulated products.

H. Directs CBER's bioresearch monitoring program, and takes appropriate compliance actions, in coordination with other FDA components.

I. Directs CBER's program for Biological Product Deviation reports and reports of complications of blood collection or transfusion confirmed to be fatal.

J. Develops and updates biological product compliance and surveillance programs with Center and FDA's inspection and investigation program input coordinates and directs their implementation and advises other CBER components on these programs.

K. Provides guidance to headquarters and inspections personnel in the development of evidence to support administrative, compliance, and enforcement actions.

L. Coordinates all CBER compliance activities with the Biologics and Bioresearch Monitoring (BIMO) Inspections (the lead Offices for CBER-related inspections activities), including planning and inspections assignments.

M. Determines final classification of all inspections with FDA 483 observations, and issues Field Manual Directive-145 correspondence for such inspections.

N. Coordinates CBER's import and export programs.

O. Coordinates with other CBER components, responsible for lot release of biological products including review of protocols submitted for release by manufacturers.

P. Reviews, evaluates, and takes appropriate compliance action including issuing warning letters and untitled letters and leads regulatory meetings.

Q. Reviews, evaluates, and takes appropriate administrative action including suspension, revocation, denial of license, orders of recall, destruction, and cessation of manufacturing related to Human Cell, Tissue, and Cellular and Tissue-based Products (HCT/Ps), disqualification of clinical investigators, debarment (with the FDA's criminal investigations organization), and other civil and criminal actions, including seizure, injunction, and prosecution based on findings of inspections and investigations.

R. Reviews firm's responses to Form FDA 483 for inspections final classified as OAI and VAI, responses to compliance and administrative actions, regulatory meeting correspondence, and all other correspondence related to compliance actions.

S. Handles matters related to CBER's application integrity policy.

T. Develops, reviews, and analyzes, in coordination with other FDA components, policies that apply to products regulated by CBER, including procedures, instructions, guidance documents, regulations, and other written policy statements.

U. Reviews, evaluates, and takes appropriate compliance actions on advertising and promotional labeling materials for CBER-regulated products to ensure that the information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner and is in compliance with pertinent federal laws and regulations.

V. Evaluates proposed proprietary names to avoid potential medication errors related to look-alike and sound-alike proprietary names and mitigating other factors that contribute to medication errors, such as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design.

W. Plans, develops, and implements, in coordination with other FDA and CBER components, education programs for FDA staff, industry, health professionals, and consumers, concerning products regulated by CBER.

X. Develops and implements, in coordination with other FDA and CBER components, outreach activities for consumers and other stakeholders concerning products regulated by CBER.

Y. Tests biological products submitted for lot release by manufacturers, in cooperation with other Center components, as appropriate.

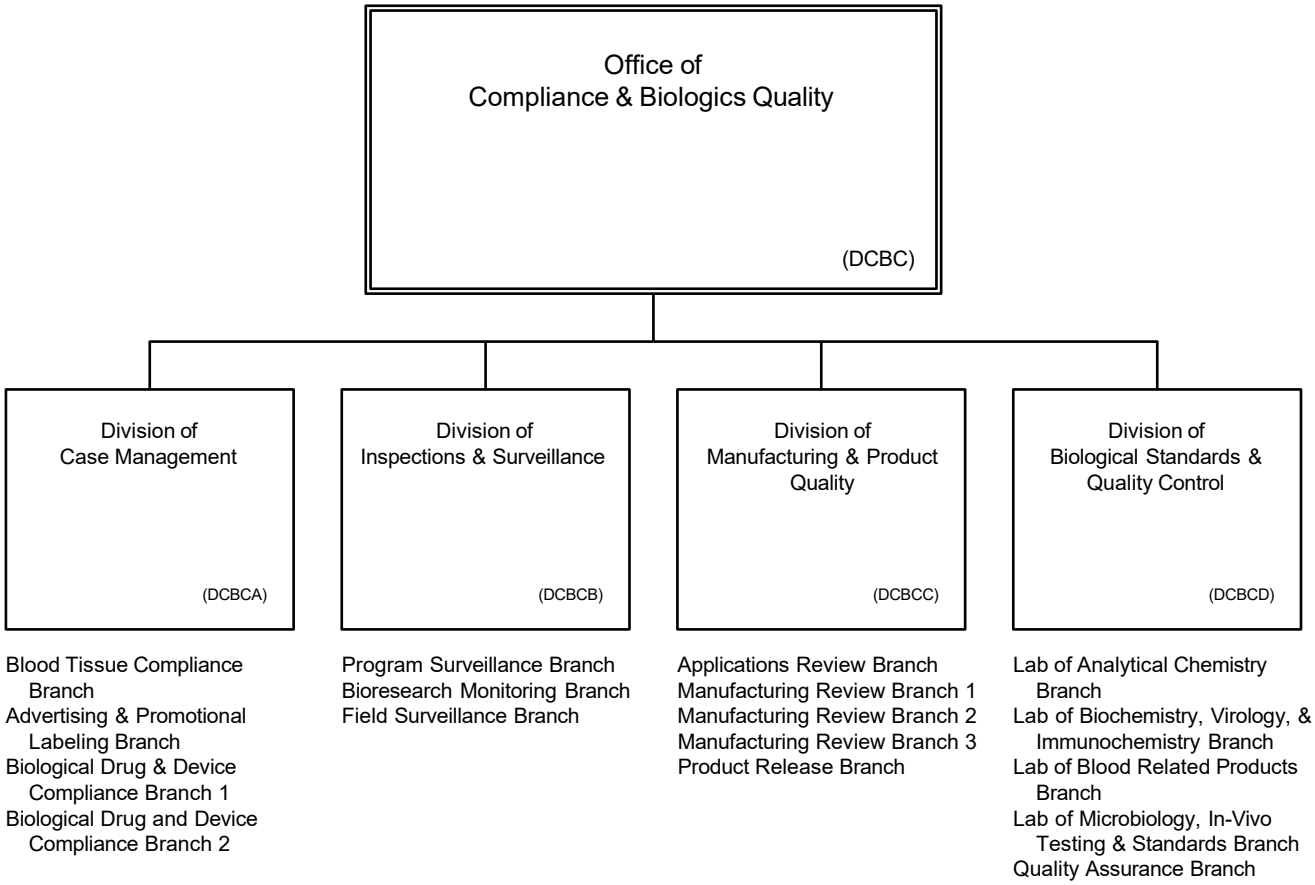
Z. Plans and conducts tests on biological products and conducts research to develop and improve procedures to evaluate safety, efficacy, and purity of biological products.

AA. Develops and maintains scientific programs dealing with the preparation and distribution of official United States (U.S.) reference preparations used in the control testing of biological products in cooperation with other Center components. Collaborates with national and international health agencies on evaluation studies of International Reference Preparations and functions as a World Health Organization/Pan American Health Organization Reference Laboratory.

2. Authority and Effective Date.

The functional statements for the Office of Compliance and Biologics Quality 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



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Compliance and Biologics Quality (DCBC)
Division of Case Management (DCBCA)
Division of Inspections and Surveillance (DCBCB)
Division of Manufacturing and Product Quality (DCBCC)
Division of Biological Standards and Quality Control (DCBCD)

These organizations report to the Division of Case Management (DCBCA):
Advertising and Promotional Labeling Branch
Biological Drug and Device Compliance Branch 1
Blood Tissue Compliance Branch
Biological Drug and Device Compliance Branch 2

These organizations report to the Division of Inspections and Surveillance (DCBCB):
Program Surveillance Branch
Bioresearch Monitoring Branch
Field Surveillance Branch

These organizations report to the Division of Manufacturing and Product Quality (DCBCC):
Applications Review Branch
Manufacturing Review Branch 1
Manufacturing Review Branch 2
Manufacturing Review Branch 3
Product Release Branch

These organizations report to the Division of Biological Standards and Quality Control (DCBCD):
Lab of Analytical Chemistry Branch
Lab of Biochemistry, Virology, and Immunochemistry Branch
Lab of Blood Related Products Branch
Lab of Microbiology, In-Vivo Testing and Standards Branch
Quality Assurance Branch