

## **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: December 14, 2018

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

- A. Ensures the quality of products regulated by 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 marketed biological products through surveillance, inspections, and compliance programs; reviews, evaluates and takes appropriate compliance action, in coordination with other Food and Drug Administration (FDA) components.
- 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 FDA officials on emerging and significant compliance issues for biological products and serves as CBER's focal point for surveillance and enforcement policy.
- E. Coordinates CBER's participation in the inspection of biological product 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 biological product compliance and surveillance programs, coordinates and directs their field implementation, and advises other CBER components on these programs.
- K. Provides guidance to headquarters and field personnel in the development of evidence to support enforcement actions.
- L. Coordinates all CBER compliance activities with the Office of Regulatory Affairs (the lead Office for all FDA field activities), including planning and field assignments.
- M. Coordinates CBER's import and export programs.
- N. Coordinates with other CBER components, responsible for lot release of biological products including review of protocols submitted for release by manufacturers.
- O. Reviews and evaluates all administrative action recommendations including suspension, revocation, denial of license, disqualification of clinical investigators, and recommended civil and criminal actions, including seizure, injunction, and prosecution based on findings of inspections and investigations.
- P. Coordinates CBER's application integrity policy.
- Q. 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.
- R. 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.
- S. Evaluates proposed proprietary names to avoid potential medication errors related to look-alike and sound-alike proprietary names and mitigating other

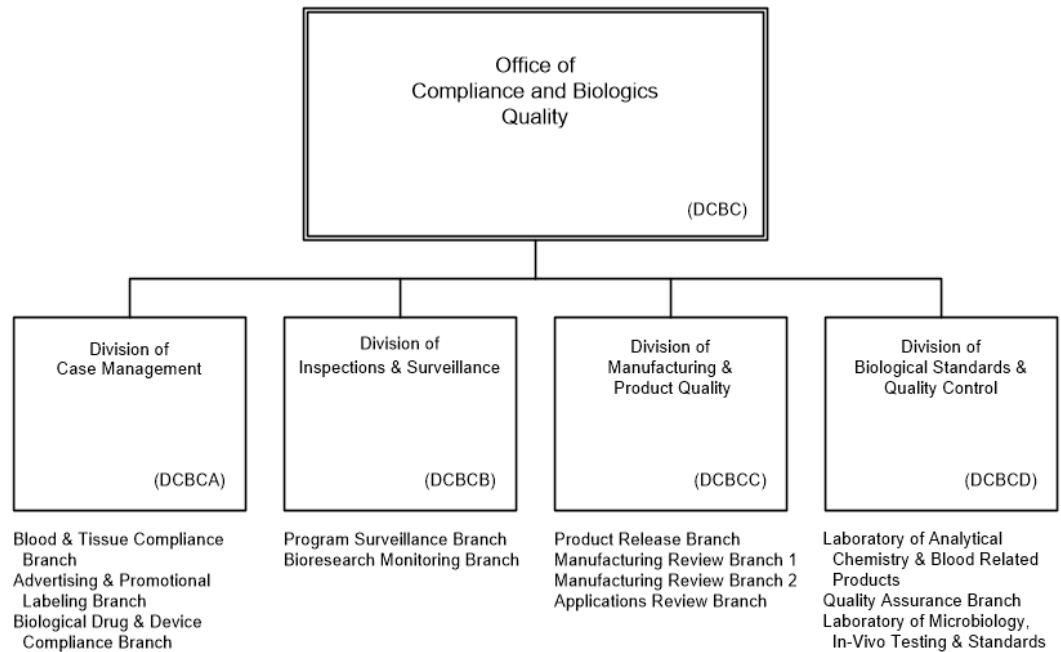
factors that contribute to medication errors, such as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design.

- T. 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.
- U. Develops and implements, in coordination with other FDA and CBER components, outreach activities for consumers and other stakeholders concerning products regulated by CBER.
- V. Tests biological products submitted for release by manufacturers, in cooperation with other Center components, as appropriate.
- W. Plans and conducts tests on biological products and conducts research to develop and improve procedures to evaluate safety, efficacy and purity of biological products.
- X. Develops and maintains scientific programs dealing with the preparation and distribution of official 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 Office of Compliance and Biologics Quality 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  
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 Office Director.

Office of Compliance & Biologics Quality (DCBC):

- Division of Case Management (DCBCA)
- Division of Inspection & Surveillance (DCBCB)
- Division of Manufacturing & Product Quality (DCBCC)
- Division of Biological Standards & Quality Control (DCBCD)