SMG 1212.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY

Effective Date: July 19, 2011

1. OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY (DBBC)

A. Ensures the quality of products regulated by 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 Agency 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 Agency 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/Agency 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 Agency 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. In coordination 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 Agency 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 Agency and CBER components, education programs for Agency staff, industry, health professionals, and consumers, concerning products regulated by CBER

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

V. In cooperation with other Center components, as appropriate, tests biological products submitted for release by manufacturers

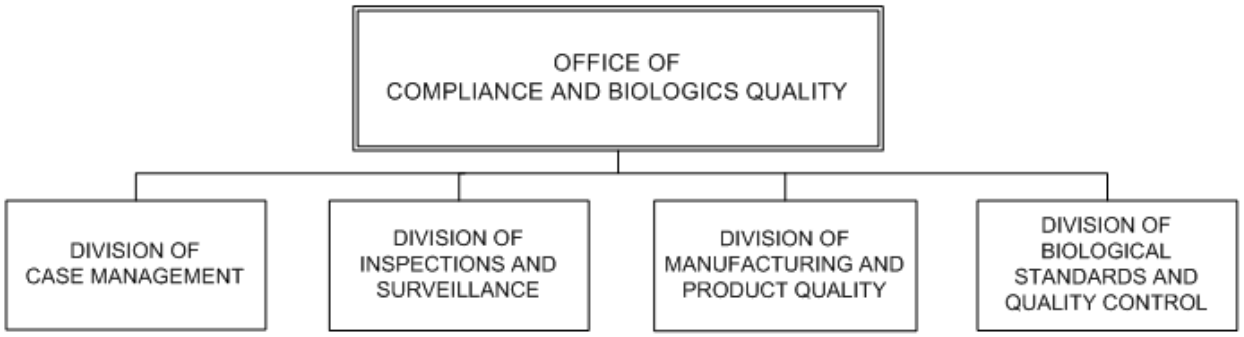
W. Plans and conducts tests on biological products and conducts research to develop and improve procedures to evaluate safety, efficacy and purity of biological products

X. In cooperation with other Center components, 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. 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 (WHO/PAHO) Reference Laboratory

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Director, Center for Biologics Evaluation and Research effective July 19, 2011.

FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY



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The following is the 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 AND BIOLOGICS QUALITY:

- DIVISION OF CASE MANAGEMENT
- DIVISION OF INSPECTION AND SURVEILLANCE
- DIVISION OF MANUFACTURING AND PRODUCT QUALITY
- DIVISION OF BIOLOGICAL STANDARDS AND QUALITY CONTROL