SMG 1210.1

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

Effective Date: December 14, 2018

1. Center for Biologics Evaluation and Research (DCB).

A. Administers regulation of biological products under the biological product control provisions of the Public Health Service Act and applicable provisions of the Federal Food, Drug, and Cosmetic Act.

B. Provides dominant focus in Food and Drug Administration (FDA) for coordination of the Acquired Immune Deficiency Syndrome program.

C. Inspects manufacturers' facilities for compliance with standards, tests products submitted for release, establishes written and physical standards, and approves licensing of manufacturers to produce biological products.

D. Plans and conducts research related to the development, manufacture, testing, and use of both new and old biological products to develop a scientific base for establishing standards designed to ensure the continued safety, purity, potency, and efficacy of biological products.

E. Coordinates with the Center for Drug Evaluation and Research regarding activities for biological drug products. Such activities include research, compliance, and product review and approval.

F. Plans and conducts research on the preparation, preservation, and safety of blood and blood products, the methods of testing safety, purity, potency, and efficacy of such products of therapeutic use, and the immunological problems concerned with products, testing, and use of diagnostic reagents employed in grouping and typing blood.

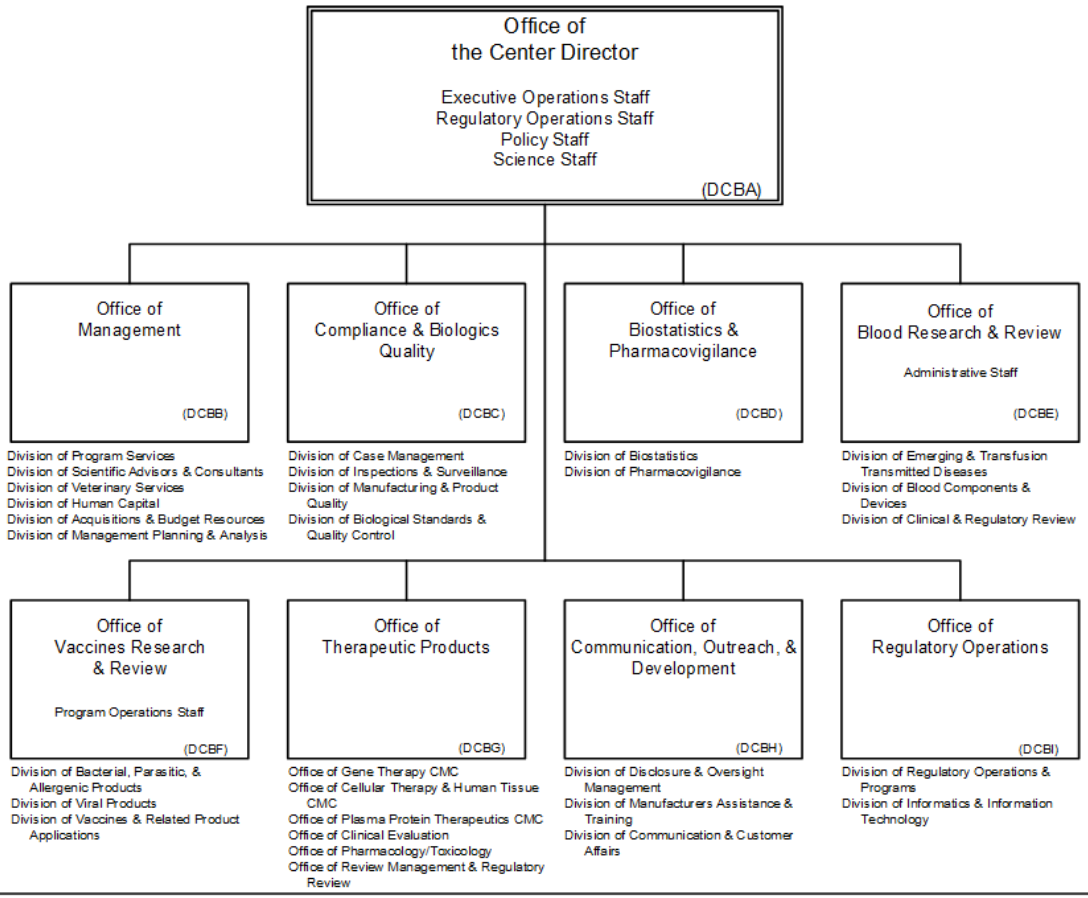
G. Carries out these functions, cooperates with other Agency components of FDA, other Public Health Services organizations, governmental and international

agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of biological products.

2. Authority and Effective Date.

The functional statements for the Center for Biologics Evaluation and Research 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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Effective Date: September 16, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research organization structure depicting all the organizational structures reporting to the Office Director.

Office of the Center Director (DCBA)

Office of Management (DCBB)

Office of Compliance & Biologics Quality (DCBC)

Office of Biostatistics & Pharmacovigilance (DCBD)

Office of Blood Research & Review (DCBE)

Office of Vaccines Research & Review (DCBF)

Office of Therapeutic Products (DCBG)

Office of Communication, Outreach & Development (DCBH)

Office of Regulatory Operations (DCBI)