SMG 1218A.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 Therapeutic Products

Effective Date: September 16, 2022

1. Office of Therapeutic Products (DCBG).

A. Plans, develops, and directs compliance, enforcement strategies, and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products.

B. Advises the Center Director and other officials on the Food and Drug Administration's (FDA) regulatory and enforcement responsibilities and possible risks associated with cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products.

C. Implements programs and projects to identify, assess, and prioritize the public health significance and patient risk associated with cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products and safety concerns.

D. Leads and oversees the development of cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products enforcement and compliance policy and standards.

E. Develops and guides compliance strategies and enforcement actions and ensures uniform interpretation of standards.

F. Oversees the planning and development of compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products' supply.

G. Executes high-level decisions, monitors performance, and directs strategies and operations of component offices to ensure compliance and enforcement decisions and policies are patient-focused and risk-based.

H. Designs and develops internal procedures and processes to support work quality, provides oversight of implementation, monitoring, and continual improvement of the quality system.

I. Develops, coordinates, and implements post-market risk assessment policies, guidance, and interpretations.

J. Initiates regulation development and enhancement.

K. Coordinates and implements policies and initiatives, including information management initiatives across the FDA.

L. Ensures that Office functions and program activities are aligned to the overall strategy and priorities of the Center for Biologics Evaluation and Research (CBER).

2. Administrative Staff (DCBG1).

A. Provides administrative management and oversight for the Office of Therapeutic Products (OTP) activities and resource allocations. Advises the Office Director on administrative services and develops policies and procedures for these services.

B. Plans and directs office operations for financial and personnel management.

3. Policy and Special Projects Staff (DCBG2).

A. Coordinates with the CBER Office of the Center Director Regulations and Policy Staff on OTP related rulemaking, guidelines, and other policy documents.

B. Serves as the OTP focal point for communications and policies with regard to development of regulations and guidance for OTP's external stakeholders.

C. Participates in the development of policy in response to emerging or existing issues which affect the products and firms regulated by CBER.

D. Identifies and assesses emerging, standing, complex, or precedent setting issues impacting the operational procedures, policies, activities, and resources of OTP.

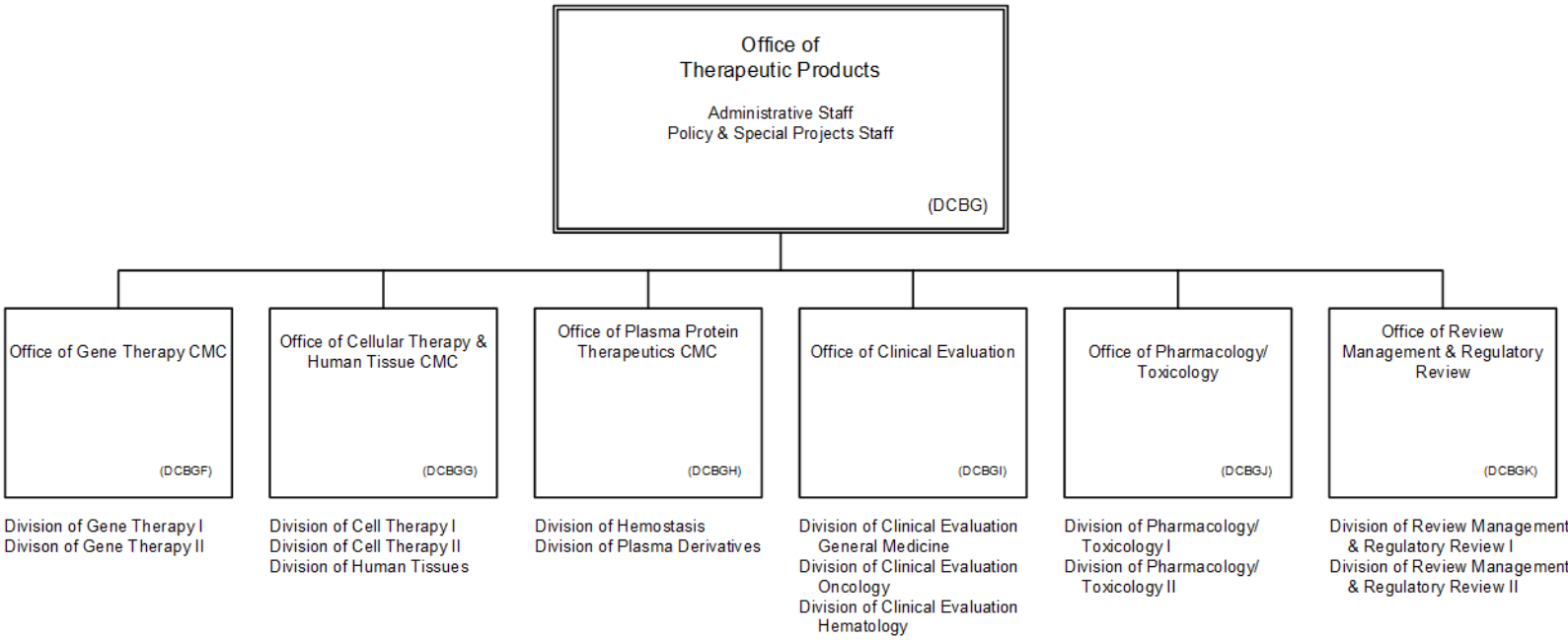
E. Provides authoritative guidance, advice, assistance, interpretations, and recommendations to senior staff officials, program directors, scientific and professional personnel, and others concerning policies, programs, and activities.

F. Engages in strategic problem solving.

4. Authority and Effective Date.

The functional statements for the Immediate Office of the Director, Office of Therapeutic Products were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Therapeutic Products



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

Office of Therapeutic Products (DCBG)

Administrative Staff (DCBG1)

Policy and Special Projects Staff (DCBG2)

Office of Gene Therapy CMC (DCBGF)

Division of Gene Therapy I (DCBGFA)

Gene Therapy Branch 1 (DCBGFA1)

Gene Therapy Branch 2 (DCBGFA2)

Gene Therapy Branch 3 (DCBGFA3)

Division of Gene Therapy II (DCBGFB)

Gene Transfer and Immunogenicity Branch (DCBGFB1)

Gene Therapy Branch 4 (DCBGFB2)

Gene Therapy Branch 5 (DCBGFB3)

Office of Cellular Therapy and Human Tissues CMC (DCBGG)

Division of Cell Therapy I (DCBGGA)

Cell Therapy Branch 1 (DCBGGA1)

Cell Therapy Branch 2 (DCBGGA2)

Cellular and Tissue Therapy Branch (DCBGGA3)

Division of Cell Therapy II (DCBGGB)

Tissue Engineering Branch 1 (DCBGGB1)

Tissue Engineering Branch 2 (DCBGGB2)

Tumor Vaccine and Biotechnology Branch (DCBGGB3)

Division of Human Tissues (DCBGGC)

Human Tissues and Reproduction Staff (DCBGGC1)

Office of Plasma Protein Therapeutics CMC (DCBGH)

Division of Hemostasis (DCBGHA)

Hemostasis Branch 1 (DCBGHA1)

Hemostasis Branch 2 (DCBGHA2)

Division of Plasma Derivatives (DCBGHB)

Plasma Derivatives Branch 1 (DCBGHB1)

Plasma Derivatives Branch 2 (DCBGHB2)

Office of Clinical Evaluation (DCBGI)

Division of Clinical Evaluation General Medicine (DCBGIA)

General Medicine Branch 1 (DCBGIA1)

General Medicine Branch 2 (DCBGIA2)

General Medicine Branch 3 (DCBGIA3)

General Medicine Branch 4 (DCBGIA4)

Division of Clinical Evaluation Oncology (DCBGIB)

Oncology Branch 1 (DCBGIB1)

Oncology Branch 2 (DCBGIB2)

Division of Clinical Evaluation Hematology (DCBGIC)

Benign Hematology Branch (DCBGIC1)

Malignant Hematology Branch (DCBGIC2)

Office of Pharmacology/Toxicology (DCBGJ)

Division of Pharmacology/Toxicology I (DCBGJA)

Pharmacology/Toxicology Branch 1 (DCBGJA1)

Pharmacology/Toxicology Branch 3 (DCBGJA2)

Division of Pharmacology/Toxicology II (DCBGJB)

Pharmacology/Toxicology Branch 2 (DCBGJB1)

Pharmacology/Toxicology Branch 4 (DCBGJB2)

Office of Review Management and Regulatory Review (DCBGK)

Division of Review Management and Regulatory Review I (DCBGKA)

Regulatory Review Branch 1 (DCBGKA1)

Review Management Support Branch 1 (DCBGKA2)

Division of Review Management and Regulatory Review II (DCBGKB)

Regulatory Review Branch 2 (DCBGKB1)

Review Management Support Branch 2 (DCBGKB2)