SMG 1290.1a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Generic Drugs

Effective Date: October 9, 2020

1. Office of Generic Drugs (DCDM).

A. Provides oversight, leadership, strategic direction and support for the Office of Generic Drugs (OGD) and its subordinate five offices. Oversees the development and implementation of standards for the safety and effectiveness of generic drugs, the review and assessment activities of Abbreviated New Drug Applications, their amendments and supplements to determine their approvability according to standards consistent with the Food, Drug and Cosmetic Act and relevant sections of the regulations.

B. Collaborates with other Center for Drug Evaluation Research (CDER) Super Offices to address complex and controversial issues surrounding the lifecycle of brand and generic drug products.

C. Leads Food and Drug Administration's (FDA's) fulfillment of Generic Drug User Fee Amendment (GDUFA) review commitments as documented in the GDUFA of 2012 and 2017.

D. Oversees international efforts to harmonize generic drug development and regulation.

E. Implements a knowledge management strategy and methodology to effectively utilize institutional knowledge to identify relevant precedence around regulatory decisions, structure unstructured data, and enable analytics on unstructured data to create reports to create efficiencies and consistencies within the generic drug program.

F. Monitors, documents and supports the development of employees through appropriate skill and knowledge-based training. Ensures that employees are properly equipped for and matched to the type of work for which they are responsible.

2. Program Management and Analysis Staff (DCDM2).

A. Provides leadership and guidance to personnel within OGD on all aspects of administrative operations, budget, and facilities management.

B. Provides service and support for human resource, and personnel operations.

C. Monitors workflow and proposes improvement in program effectiveness to meet goals and objectives.

D. Provides representation for OGD on Center and Agency best practice boards associated with administrative responsibilities.

E. Coordinates, develops, and assesses procedures and best practices related to office administration in OGD.

3. Communications Staff (DCDM3).

A. Reviews and coordinates OGD communications, including publications and presentations, to ensure quality and consistency with CDER and FDA policies for communication.

B. Serves as media liaison responsible for OGD media interactions.

C. Develops and manages communications on generic drug topics, for staff and external stakeholders.

D. Externally communicates accurate information on generic drug topics, in collaboration with CDER's Office of Communications (OCOMM) and FDA's Office of Media Affairs.

E. Serves as the liaison to the CDER OCOMM web team for OGD web content.

4. Quality Management Staff (DCDM4).

A. Develops formal business practices for processes and procedures to ensure efficient and consistent OGD work processes and products.

B. Monitors, reviews and measures OGD performance relative to quality objectives.

C. Formulates and conduct audits to identify non-conformity, gaps and opportunities for quality improvement.

D. Provide reports to OGD senior management on quality data trends and anomalies to identify opportunities for improvement in work processes and product efficiencies.

E. Facilitates, continually, and participates in process improvements and quality planning activities to ensure OGD delivers high quality products, processes and services through quality tools such as lean six sigma.

5. Authority and Effective Date.

The functional statements for the Office of Generic Drugs were approved by the Commissioner of Food and Drugs on September 8, 2020 and effective on October 9, 2020.

Department of Health and Human Services
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Center for Drug Evaluation and Research
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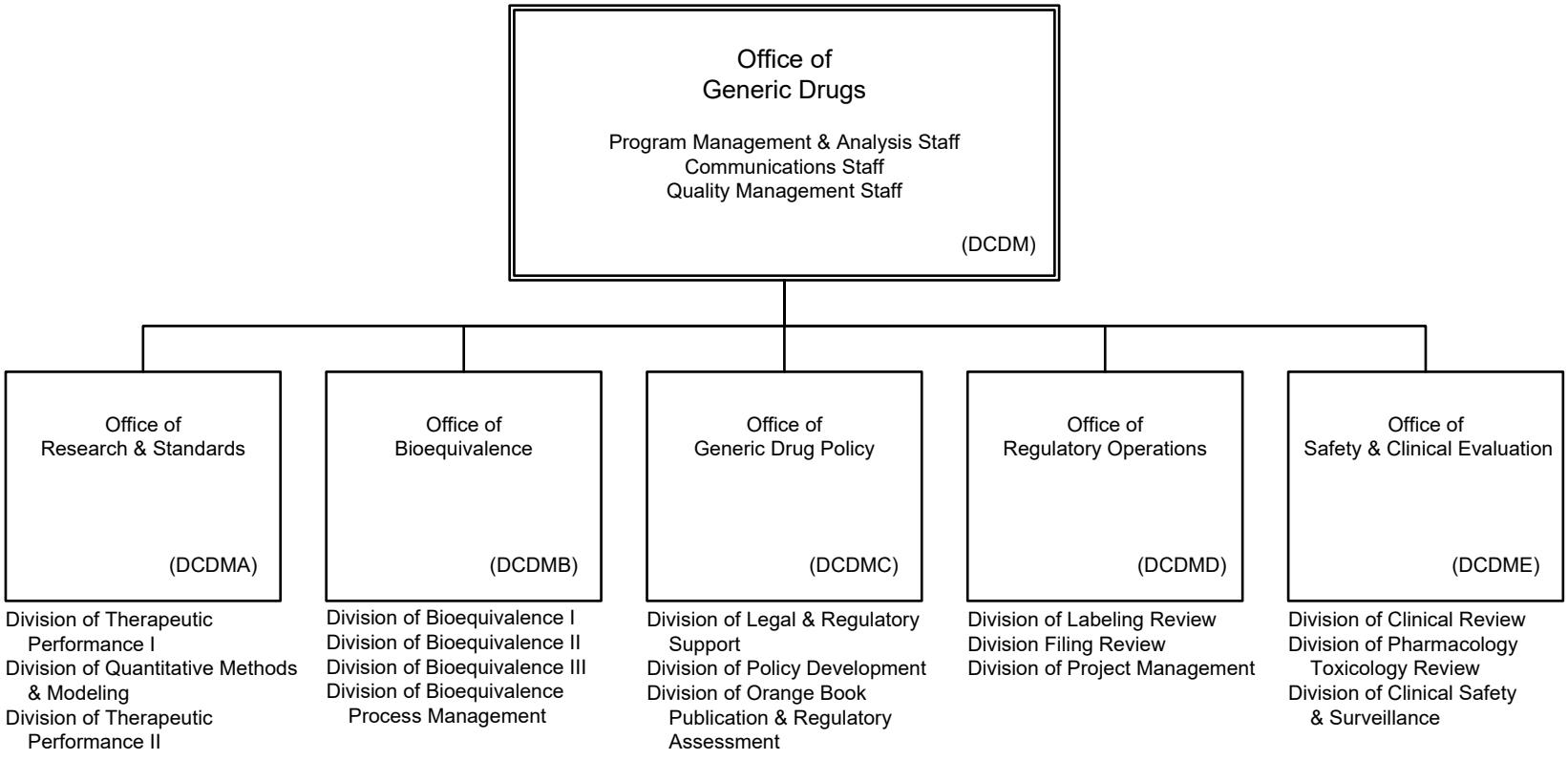

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, organization structure depicting all the organizational structures reporting to the Director:

Office of Generic Drugs (DCDM).

Program Management and Analysis Staff

Communications Staff

Quality Management Staff

Office of Research and Standards (DCDMA)

Office of Bioequivalence (DCDMB)

Office of Generic Drug Policy (DCDMC)

Office of Regulatory Operations (DCDMD)

Office of Safety and Clinical Evaluation (DCDME)

These organizations report to the Office of Research and Standards (DCDMA)

Division of Therapeutic Performance I

Division of Quantitative Methods & Modeling

Division of Therapeutic Performance II

These organizations report to the Office of Bioequivalence (DCDMB)

Division of Bioequivalence I

Division of Bioequivalence II

Division of Bioequivalence III

Division of Bioequivalence Process Management

These organizations report to the Office of Generic Drug Policy (DCDMC)

Division of Legal and Regulatory Support

Division of Policy Development

Division of Orange Book Publication and Regulatory Assessment

These organizations report to the Office of Regulatory Operations (DCDMD)

Division of Labeling Review

Division of Filing Review

Division of Project Management

These organizations report to the Office of Safety and Clinical Evaluation (DCDME)

Division of Clinical Review

Division of Pharmacology Toxicology Review

Division of Clinical Safety and Surveillance